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)

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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)*: 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; 10.00; 02-20-18

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

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)*

Blood and Marrow Transplant Clinical Trials Network

Conditioning Regimen Form - 1204 (CR5)

Web Version: 1.0; 1.02; 10-16-15

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

1. Record the patient's weight used to calculate dose:*(CR5WGHT)* _____ *(xxx.x)* kg
2. Record the date the patient's weight was obtained:*(CR5WTDT)* _____ *(mm/dd/yyyy)*
3. Record the patient's Body Surface Area (BSA) used to calculate dose:*(CR5BSA)* _____ *(x.xx)* m^2
4. Record the date the patient's BSA was obtained:*(CR5BSADT)* _____ *(mm/dd/yyyy)*

Alemtuzumab

5. Did the patient experience an adverse reaction to the test dose of Alemtuzumab?*(CR5ALAE)* ☐ 1 - Yes ☐ 2 - No

An Adverse Event Form must be completed for all unexpected, grade 3-5 adverse events.

6. What type of reaction did the patient experience?*(CR5ARXTP)* ☐ 1 - Local ☐ 2 - Systemic ☐ 3 - Both
7. Was an intervention required?*(CR5ALINT)* ☐ 1 - Yes ☐ 2 - No

Indicate the intervention(s) given:

		If "Yes", specify (drug/dose):
8. Antihistamines:	*(CR5ANTH)* ☐ 1 - Yes ☐ 2 - No	*(CR5ANTHS)*
9. Steroids:	*(CR5STER)* ☐ 1 - Yes ☐ 2 - No	*(CR5STERS)*
10. Fluid:	*(CR5FLD)* ☐ 1 - Yes ☐ 2 - No	*(CR5FLDS)*
11. Resuscitation:	*(CR5RES)* ☐ 1 - Yes ☐ 2 - No	*(CR5RESS)*
12. Anti-pyretic:	*(CR5ANTP)* ☐ 1 - Yes ☐ 2 - No	*(CR5ANTPS)*
13. Pressors:	*(CR5PRES)* ☐ 1 - Yes ☐ 2 - No	*(CR5PRESS)*
14. Intubation:	*(CR5INTU)* ☐ 1 - Yes ☐ 2 - No	*(CR5INTUS)*
15. Other:	*(CR5OTH)* ☐ 1 - Yes ☐ 2 - No	*(CR5OTHS)*

Record the doses, times and dates of Alemtuzumab administration:

	Dose	Time Given	Date Given	Was the full dose given?	If "No", what partial dose was given?
16. Alemtuzumab - 1st Dose:	*(CR5A1DOS)* *(xx.xx)* mg	*(CR5A1T)* *(hh:mm)*	*(CR5A1DT)* *(mm/dd/yyyy)*	*(CR5A1PAR)* ☐ 1 - Yes ☐ 2 - No	*(CR5A1PDA)* *(xx.xx)* mg
17. Alemtuzumab - 2nd Dose:	*(CR5A2DOS)* *(xx.xx)* mg	*(CR5A2T)* *(hh:mm)*	*(CR5A2DT)* *(mm/dd/yyyy)*	*(CR5A2PAR)* ☐ 1 - Yes ☐ 2 - No	*(CR5A2PDA)* *(xx.xx)* mg
18. Alemtuzumab - 3rd Dose:	*(CR5A3DOS)* *(xx.xx)* mg	*(CR5A3T)* *(hh:mm)*	*(CR5A3DT)* *(mm/dd/yyyy)*	*(CR5A3PAR)* ☐ 1 - Yes ☐ 2 - No	*(CR5A3PDA)* *(xx.xx)* mg
19. Alemtuzumab - 4th Dose:	*(CR5A4DOS)* *(xx.xx)* mg	*(CR5A4T)* *(hh:mm)*	*(CR5A4DT)* *(mm/dd/yyyy)*	*(CR5A4PAR)* ☐ 1 - Yes ☐ 2 - No	*(CR5A4PDA)* *(xx.xx)* mg
20. Alemtuzumab - 5th Dose:	*(CR5A5DOS)* *(xx.xx)* mg	*(CR5A5T)* *(hh:mm)*	*(CR5A5DT)* *(mm/dd/yyyy)*	*(CR5A5PAR)* ☐ 1 - Yes ☐ 2 - No	*(CR5A5PDA)* *(xx.xx)* mg

Fludarabine

Record the doses and dates of Fludarabine administration:

	Dose	Date Given
21. Fludarabine - 1st Dose:	*(CR5F1DOS)* *(xx.xx)* mg	*(CR5F1DT)* *(mm/dd/yyyy)*
22. Fludarabine - 2nd Dose:	*(CR5F2DOS)* *(xx.xx)* mg	*(CR5F2DT)* *(mm/dd/yyyy)*
23. Fludarabine - 3rd Dose:	*(CR5F3DOS)* *(xx.xx)* mg	*(CR5F3DT)* *(mm/dd/yyyy)*
24. Fludarabine - 4th Dose:	*(CR5F4DOS)* *(xx.xx)* mg	*(CR5F4DT)* *(mm/dd/yyyy)*
25. Fludarabine - 5th Dose:	*(CR5F5DOS)* *(xx.xx)* mg	*(CR5F5DT)* *(mm/dd/yyyy)*

Melphalan

Record the dose and date of Melphalan administration:

	Dose	Date Given
26. Melphalan:	*(CR5MLDOS)* *(xxx.xx)* mg	*(CR5MLDT)* *(mm/dd/yyyy)*

Comments:*(CR5COMM)*

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

Disease-Specific Studies Form - 1204 (DSS)

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

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

For HLH patients:
For CAEBV patients:

1. NK cell function:*(DSSNKFNC)*
   1 - Present - Normal
   2 - Present - Decreased
   3 - Absent
   4 - Sample Uninterpretable
2. Percentage of NK cells:*(DSSNKPCT)* *(xxx.x)* %
3. Date sample obtained:*(DSSNKDT)* *(mm/dd/yyyy)*
4. Type of EBV test:*(DSSEBVTP)* ☐ 1 - Whole Blood ☐ 2 - Plasma
5. Result of EBV test:*(DSSEBVRS)*
   1 - Positive
   2 - Negative
6. If "Positive", was the result quantifiable?*(DSSEBVQT)*
   1 - Yes
   2 - No, not quantifiable
   3 - No, below level of detection
7. EBV viral load:*(DSSEBVVL)* *(xxxxxxxx)* copies/mL
8. Lower limit of detection:*(DSSEBVLL)* *(xxxxxx)* copies/mL
9. Date sample obtained:*(DSSEBVDT)* *(mm/dd/yyyy)*
10. Does the patient have the PRF1 mutation?*(DSSPRFMU)* ☐ 1 - Yes ☐ 2 - No
11. Perforin expression:*(DSSPRFEX)*
    1 - Present - Normal
    2 - Present - Decreased
    3 - Absent
    4 - Sample Uninterpretable
12. Date sample obtained:*(DSSPRFDT)* *(mm/dd/yyyy)*
13. Does the patient have the XLP mutation?*(DSSXLPMU)* ☐ 1 - Yes ☐ 2 - No
14. SAP expression:*(DSSSAPEX)*
    1 - Present - Normal
    2 - Present - Decreased
    3 - Absent
    4 - Sample Uninterpretable
15. Date sample obtained:*(DSSXLPDT)* *(mm/dd/yyyy)*

For CGD patients:

16. DHR assay results:*(DSSDHRAS)*
    1 - Present - Normal
    2 - Present - Decreased
    3 - Absent
    4 - Sample Uninterpretable
17. Date sample obtained:*(DSSDHRDT)* *(mm/dd/yyyy)*

For HIGM1 patients:

18. CD40L expression on activated CD4+ T cells by flow cytometry:*(DSSCD40L)*

1 - Present - Normal
2 - Present - Decreased
3 - Absent
4 - Sample Uninterpretable

19. Date sample obtained:*(DSSC40DT)* *(mm/dd/yyyy)*

For IPEX patients:

20. Quantitative Treg analysis by flow cytometry:*(DSSTREG)* *(xxx.x)* %

21. Date sample obtained:*(DSSTRGDT)* *(mm/dd/yyyy)*

For LAD-I patients:

22. CD18 expression on granulocytes by flow cytometry:*(DSSCD18E)*

1 - Present - Normal
2 - Present - Decreased
3 - Absent
4 - Sample Uninterpretable

23. CD18 percentage:*(DSSCD18P)* *(xxx.x)* %

24. Date sample obtained:*(DSSC18DT)* *(mm/dd/yyyy)*

Comments:*(DSSCOMM)*

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

EBV/CMV Surveillance Form (ECV)

Web Version: 1.0; 1.01; 01-17-17

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

1. Has the patient received Rituxan prior to conditioning?*(ECPRIRTX)* ☐ 1 - Yes ☐ 2 - No
2. If "Yes", record date of last Rituxan dose:*(ECLRTXDT)* _____ *(mm/dd/yyyy)*
3. Has the patient received Alemtuzumab (Campath) prior to conditioning? *(ECPRIALM)* ☐ 1 - Yes ☐ 2 - No
4. If "Yes", record date of last Alemtuzumab (Campath) dose:*(ECLALMDT)* _____ *(mm/dd/yyyy)*
5. Was a peripheral blood sample drawn for EBV testing during this assessment period?*(ECEBVSAM)* ☐ 1 - Yes ☐ 2 - No
6. If "Yes", record the date the peripheral blood sample for EBV testing was obtained:*(ECEBVODT)* _____ *(mm/dd/yyyy)*
7. Type of EBV test:*(ECEBVTYP)* ☐ 1 - Whole Blood ☐ 2 - Plasma
8. Result of EBV test:*(ECEBVRES)*
   1 - Positive
   2 - Negative
9. If "Positive", was the result quantifiable?*(ECEBVQNT)*
   1 - Yes
   2 - No, not quantifiable
   3 - No, below level of detection
10. EBV viral load:*(ECEBVVLD)* _____ *(xxxxxxxx)* copies/mL
11. Lower limit of detection:*(ECEBVLIM)* _____ *(xxxxxx)* copies/mL
12. Was a peripheral blood sample drawn for CMV testing during this assessment period?*(ECCMVSAM)* ☐ 1 - Yes ☐ 2 - No
13. If "Yes", record the date the peripheral blood sample for CMV testing was obtained:*(ECCMVODT)* _____ *(mm/dd/yyyy)*
14. Type of CMV test:*(ECCMVTYP)* ☐ 1 - Whole Blood ☐ 2 - Plasma
15. Result of CMV test:*(ECCMVRES)*
    1 - Positive
    2 - Negative
16. If "Positive", was the result quantifiable?*(ECCMVQNT)*
    1 - Yes
    2 - No, not quantifiable
    3 - No, below level of detection
17. CMV viral load:*(ECCMVVLD)* _____ *(xxxxxxxx)* copies/mL
18. Lower limit of detection:*(ECCMVLIM)* _____ *(xxxxxx)* copies/mL

Comments:*(ECVCOMM)*

Blood and Marrow Transplant Clinical Trials Network

1204A (ENR)

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

HLH & Related Disorders Enrollment Form - Segment A

1. Record the proposed start date of the conditioning regimen: *(HIPCONDT)* _____ *(mm/dd/yyyy)*

Inclusion Criteria

2. Patient diagnosis:*(HIDIAGNO)*

- 1 - Hemophagocytic lymphohistiocytosis (HLH) or related disorder
- 2 - Chronic active Epstein-Barr virus (CAEBV)
- 3 - Chronic granulomatous disease (CGD)
- 4 - Hyperimmunoglobulin M syndrome (HIGM1)
- 5 - Immune dysregulation, polyendocrinopathy, enteropathy, and X-linked inheritance (IPEX)
- *Additional Options Listed Below

If HLH or related disorder, does the patient have <u>at least one</u> of the following?

3. Inherited gene mutation associated with HLH: PRF1, UNC13D (MUNC13-2), STXBP2 (MUNC18-2), STX11, RAB27A (Griscelli syndrome, type 2), SH2D1A (XLP1), XIAP (XLP2), LYST (Chediak-Higashi syndrome)?*(HI1HLH)* ☐ 1 - Yes ☐ 2 - No
4. Meets clinical criteria for HLH, refractory to therapy according to HLH-94 or HLH-2004 (dexamethasone/etoposide), or recurrent episodes of hyperinflammation?*(HI2HLH)* ☐ 1 - Yes ☐ 2 - No
5. Meets clinical criteria for HLH, without identified gene defects, with affected sibling OR decreased or absent NK cell function at the last evaluation OR a history of CNS inflammation as evidenced by pleocytosis in CSF or MRI evidence of hyper-inflammation in the CNS?*(HI3HLH)* ☐ 1 - Yes ☐ 2 - No

If CAEBV, does the patient have <u>all</u> of the following?

6. Severe progressive illness, usually with fever, lymphadenopathy and splenomegaly that either began as primary EBV infection or was associated with markedly elevated antibody titers to EBV viral capsid antibody (> 1:5120) or early antigen (> 1:640) or markedly elevated EBV DNA in the blood?*(HI1CAEBV)* ☐ 1 - Yes ☐ 2 - No
7. Infiltration of tissues (e.g. lymph nodes, liver, lungs, CNS, bone marrow, eye, skin) with lymphocytes?*(HI2CAEBV)* ☐ 1 - Yes ☐ 2 - No
8. Elevated EBV DNA, RNA or proteins in affected tissues? *(HI3CAEBV)* ☐ 1 - Yes ☐ 2 - No
9. Absence of HIV or post-transplant lymphoproliferative disorder? *(HI4CAEBV)* ☐ 1 - Yes ☐ 2 - No

If CGD, does the patient have <u>all</u> of the following?

10. Oxidative burst < 10% normal with dihydrorhodamine (DHR) assay?*(HI1CGD)* ☐ 1 - Yes ☐ 2 - No
11. Documented CGD mutation(s) in $gp91^{phox}$, $p47^{phox}$, $p67^{phox}$, $p22^{phox}$ or $p40^{phox}$?*(HI2CGD)* ☐ 1 - Yes ☐ 2 - No

    Severe disease as evidenced by <u>one or more</u> of the following?

    12. History of one or more potentially life-threatening infections?*(HI3ACGD)* ☐ 1 - Yes ☐ 2 - No
    13. Inflammatory bowel disease?*(HI3BCGD)* ☐ 1 - Yes ☐ 2 - No
    14. Failure to thrive with height <10% for age (unless parent(s) height <10%)?*(HI3CCGD)* ☐ 1 - Yes ☐ 2 - No
    15. Autoimmune complication felt to be linked to CGD?*(HI3DCGD)* ☐ 1 - Yes ☐ 2 - No

If HIGM1, does the patient have <u>both</u> of the following?

16. Decreased serum IgG (> 2 standard deviations below normal for age)?*(HI1HIGM1)* ☐ 1 - Yes ☐ 2 - No
17. Mutation in CD40LG OR family history of maternally related males with HIGM1?*(HI2HIGM1)* ☐ 1 - Yes ☐ 2 - No

If IPEX syndrome, does the patient have <u>both</u> of the following?

18. Absent FOXP3+ CD4+ T cells OR abnormal function of FOXP3+ CD4+ T cells?*(HI1IPEX)* ☐ 1 - Yes ☐ 2 - No
19. Disease-associated mutation in FoxP3 (bi-allelic in females) OR family history of maternally related males with clinical diagnosis of IPEX?*(HI2IPEX)* ☐ 1 - Yes ☐ 2 - No

If LAD-I, does the patient have <u>both</u> of the following?

20. Decreased CD18 expression on neutrophils (<5% normal for age)?*(HI1LAD1)* ☐ 1 - Yes ☐ 2 - No
21. Mutation of ITGB2 OR absence of ITGB2 mRNA in leukocytes? *(HI2LAD1)* ☐ 1 - Yes ☐ 2 - No

22. Performance status scale used to evaluate patient (Lansky for patients < 16 years old; Karnofsky for patients ≥ 16):*(HIPSCALE)* ☐ 1 - Karnofsky ☐ 2 - Lansky
23. Record patient's performance status:*(HIPSTATS)*

    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

24. Record type of fraction test performed:*(HIEFTYPE)*

    1 - Left Ventricular Ejection Fraction (LVEF)
    2 - Shortening Fraction

25. Left ventricular ejection fraction:*(HILVEJFR)* _____ *(xx)* % Date ejection fraction performed:*(HILVEFDT)* _____ *(mm/dd/yyyy)*
26. Shortening fraction:*(HISHORFR)* _____ *(xx)* % Date shortening fraction performed:*(HISHFRDT)* _____ *(mm/dd/yyyy)*
27. Has the patient been asymptomatic (no clinical concerns by medical team for new cardiac issues) since the time of the fraction test?*(HIASYMCD)* ☐ 1 - Yes ☐ 2 - No

28. Does the patient have hyperbilirubinemia due to Gilbert's syndrome or as a result of liver inflammation in the setting of persistent, active HLH?*(HIHYBIRU)* ☐ 1 - Yes ☐ 2 - No
29. Does the patient have elevated transaminase levels as a result of liver inflammation in the setting of persistent, active HLH?*(HIELTRAN)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value	ULN for your institution	Date Sample Obtained
30. GFR (mL/min/1.73m^2):	*(HIGFRVAL)* _____ *(xxx)*		*(HIGFRDT)* _____ *(mm/dd/yyyy)*
31. Direct bilirubin (mg/dL):	*(HIBILVAL)* _____ *(x.x)*	*(HIBILULN)* _____ *(xx.x)*	*(HIBILDT)* _____ *(mm/dd/yyyy)*
32. ALT (units/L):	*(HIALTVAL)* _____ *(xxx)*	*(HIALTULN)* _____ *(xxx)*	*(HIALTDT)* _____ *(mm/dd/yyyy)*
33. AST (units/L):	*(HIASTVAL)* _____ *(xxx)*	*(HIASTULN)* _____ *(xxx)*	*(HIASTDT)* _____ *(mm/dd/yyyy)*

34. Is the patient on mechanical ventilation support?*(HIMNVENT)* ☐ 1 - Yes ☐ 2 - No
35. Does the patient have a progressive pulmonary infection? *(HIPULMIN)* ☐ 1 - Yes ☐ 2 - No
36. Is the patient able to undergo pulmonary function tests (PFTs)? *(HIPFTEST)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value	Date of Assessment
37. FEV1 (%):	*(HIFEVVAL)* _____ *(xxx)*	*(HIFEVDT)* _____ *(mm/dd/yyyy)*

38. DLCO corrected for hemoglobin (%):	*(HIDLCOVL)*	*(xxx)*	*(HIDLCODT)*	*(mm/dd/yyyy)*
39. SaO2 on a max of 2L/min supplemental O2 (%):	*(HISO2VAL)*	*(xxx)*	*(HISO2DT)*	*(mm/dd/yyyy)*

40. Has the patient been asymptomatic (no clinical concerns by medical team for new pulmonary issues) since the time of the FEV1 and DLCO tests?*(HIASYMPF)* ☐ 1 - Yes ☐ 2 - No

Exclusion Criteria

41. Has the patient had a hematopoietic stem cell transplant within 6 months of enrollment?*(HIRECHCT)* ☐ 1 - Yes ☐ 2 - No
42. Does the patient have a current uncontrolled bacterial, viral, or fungal infection (currently taking medication with evidence of progression of clinical symptoms or radiological findings)? *(HIBVFINF)* ☐ 1 - Yes ☐ 2 - No
43. Does the patient have ongoing EBV viremia?*(HIEBVVIR)* ☐ 1 - Yes ☐ 2 - No
44. Is the patient pregnant (positive β-HCG) or breastfeeding? *(HIPREGBF)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
45. Is the patient pregnant (positive β-HCG) or breastfeeding? *(HIPREGBF)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
46. Is the patient sero-positive for human immunodeficiency virus (HIV)?*(HIPATHIV)* ☐ 1 - Yes ☐ 2 - No
47. Has the patient received alemtuzumab within 2 weeks of enrollment?*(HIALEMTU)* ☐ 1 - Yes ☐ 2 - No
48. Does the patient have a current or prior malignancy, except EBV-associated lymphomas related to immune deficiency or lymphomas associated with X-linked LPD in a good remission, or resected basal cell carcinoma or treated cervical carcinoma in situ?*(HIPRIMAL)* ☐ 1 - Yes ☐ 2 - No

Donor Inclusion Criteria

49. Is the donor willing and able to donate bone marrow stem cells? *(HIDONRBM)* ☐ 1 - Yes ☐ 2 - No
50. Patient's donor type:*(HIDNRREL)*

1 - Related Sibling Donor
2 - Related Non-Sibling Donor
3 - Unrelated Donor

For related donors of patients with HLH or related disorders:

51. Does the patient have a known HLH-associated gene mutation?*(HIHLHGM)* ☐ 1 - Yes ☐ 2 - No
52. Does the donor harbor the same gene mutation causing HLH in the recipient?*(HIHLHGLM)* ☐ 1 - Yes ☐ 2 - No
53. Is the donor a sibling with a heterozygous mutation of an autosomal recessive HLH-associated gene?*(HISIBAUT)* ☐ 1 - Yes ☐ 2 - No
54. Is the donor a female relative who is a carrier of an X-linked HLH-associated gene mutation?*(HISISXLI)* ☐ 1 - Yes ☐ 2 - No
55. Does the donor have a medical history concerning for HLH?*(HIHLHHIS)* ☐ 1 - Yes ☐ 2 - No
56. Does the donor have laboratory values suggestive of significant immune dysfunction (for example, highly elevated ferritin or absent NK cell function)? *(HIHLHLAB)* ☐ 1 - Yes ☐ 2 - No

For sibling donors of patients with CGD, HIGM1, IPEX, and LAD-I:

57. Does the donor meet diagnostic criteria for the immune deficiency for which the patient is receiving HCT?*(HISAMEPI)* ☐ 1 - Yes ☐ 2 - No

Donor Exclusion Criteria

58. Is the donor pregnant (positive β-HCG) or uninterruptedly breastfeeding?*(HIDNRPRG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
59. Is the donor sero-positive for human immunodeficiency virus (HIV)? *(HIDNRHIV)* ☐ 1 - Yes ☐ 2 - No
60. Is the donor currently receiving experimental therapy or investigational agents?*(HIDNREXP)*

1 - Yes
2 - Yes, Approved by Study Chair or Protocol Officer
3 - No

61. Date approved by study chair or protocol officer:*(HIEXPDT)* *(mm/dd/yyyy)*

Consent for Use of Biological Samples for Research

62. Did the patient give consent to provide blood for future research purposes?*(HIRSCHIC)* ☐ 1 - Yes ☐ 2 - No

Comments:*(HICOMM)*

Additional Selection Options for ENR

Patient diagnosis:
6 - Leukocyte adhesion deficiency (LAD-1)

Record patient's performance status:
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 - 1204 (F14)

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

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

1. Date of last contact:*(F14LSCTD)* *(mm/dd/yyyy)*

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

2. Has the patient died?*(F14PTDTH)* ☐ 1 - Yes ☐ 2 - No
   If Yes, a Death Form must be submitted.
   3. Date of patient death:*(F14DTHDT)* *(mm/dd/yyyy)*
4. Has the patient experienced HLH reactivation?*(F14PTHLH)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
   If Yes, a HLH Reactivation Form must be submitted.
   5. Date of HLH Reactivation:*(F14HLHDT)* *(mm/dd/yyyy)*
6. Is the patient taking any immunosuppressive agents (including PUVA) to treat or prevent GVHD?*(F14WDIMM)* ☐ 1 - Yes ☐ 2 - No
   7. If no, was the final date the patient received any immunosuppressant to treat or prevent GVHD previously reported?*(F14IMRPT)* ☐ 1 - Yes ☐ 2 - No
   8. Date final immunosuppressant agent to treat or prevent GVHD received: *(F14IMMDT)* *(mm/dd/yyyy)*
9. Has the patient received a donor leukocyte infusion (DLI)?*(F14DLI)* ☐ 1 - Yes ☐ 2 - No
   10. Date of DLI:*(F14DLIDT)* *(mm/dd/yyyy)*
11. Has the patient received a second transplant?*(F142NTXP)* ☐ 1 - Yes ☐ 2 - No
    12. Date of second transplant:*(F14TXPDT)* *(mm/dd/yyyy)*
13. Has the patient experienced secondary graft failure?*(F14PTSGF)* ☐ 1 - Yes ☐ 2 - No
    If Yes, a Secondary Graft Failure Form must be submitted.
    14. Date of secondary graft failure:*(F14SGFDT)* *(mm/dd/yyyy)*
15. Has the patient experienced any new grade 2-3 infections?*(F14PTINF)* ☐ 1 - Yes ☐ 2 - No
    If Yes, an Infection Form must be submitted.
    16. Date of infection:*(F14INFDT)* *(mm/dd/yyyy)*
17. Has the patient been hospitalized (other than for transplant)?*(F14PTHOS)* ☐ 1 - Yes ☐ 2 - No
18. Has the patient been hospitalized?*(F14PTHOS)* ☐ 1 - Yes ☐ 2 - No
    If Yes, a Re-Admission Form must be submitted.
    19. Date of hospitalization:*(F14HSPDT)* *(mm/dd/yyyy)*
20. Has the patient experienced any Unexpected, Grade 3-5 Adverse Events? *(F14PTSAE)* ☐ 1 - Yes ☐ 2 - No
    If Yes, an Unexpected, Grade 3 - 5 Adverse Event Form must be submitted.
    21. Date of onset of Unexpected, Grade 3-5 Adverse Event:*(F14SAEDT)* *(mm/dd/yyyy)*

Comments:*(F14COMM)*

Blood and Marrow Transplant Clinical Trials Network

Follow Up/Chronic GVHD Form (FGV)

Web Version: 1.0; 2.03; 08-15-17

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

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

Acute GVHD

3. Maximum overall grade of acute GVHD during this assessment period:*(FGGRAGVH)*
   - 0 - No Symptoms of Acute GVHD
   - 1 - I
   - 2 - II
   - 3 - III
   - 4 - IV

4. Did new clinical signs and/or symptoms of acute GVHD develop during this assessment period?*(FGAGVDVL)* ☐ 1 - Yes ☐ 2 - No

   Only report new clinical signs and/or symptoms of acute GVHD that developed during the assessment period at the top of the form.

5. Date of diagnosis of acute GVHD:*(FGAGDGDT)* _____ *(mm/dd/yyyy)*

   If the date is out of range because the diagnosis occurred before this assessment period, question 4 should be answered '2-No'.

Record the highest severity for the following organ systems at the time of maximum overall grade of acute GVHD.

6. Skin abnormalities:*(FGASKNAB)*
   - 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

7. Upper GI abnormalities:*(FGAUGIAB)*
   - 0 - No Protracted Nausea and Vomiting
   - 1 - Persistent Nausea, Vomiting or Anorexia

8. Lower GI abnormalities:*(FGALGIAB)*
   - 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

9. Liver abnormalities:*(FGALVRAB)*
   - 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

10. Was prophylaxis for GVHD given during this assessment period?*(FGPROPIM)*
    - 1 - Yes
    - 2 - No
    - 3 - Discontinued During This Assessment Period

11. If yes or discontinued during assessment period, specify all immunosuppressants used for GVHD prophylaxis:
    - a. ATG:*(FGPRATG)* ☐ 1 - Yes ☐ 2 - No
    - b. Bortezomib:*(FGPRBORT)* ☐ 1 - Yes ☐ 2 - No
    - c. Campath:*(FGPRCAMP)* ☐ 1 - Yes ☐ 2 - No
    - d. Cyclophosphamide:*(FGPRCYPH)* ☐ 1 - Yes ☐ 2 - No
    - e. Cyclosporine:*(FGPRCYCL)* ☐ 1 - Yes ☐ 2 - No
    - f. MMF:*(FGPRMMF)* ☐ 1 - Yes ☐ 2 - No

g. Maraviroc:*(FGPRMRVR)* ☐ 1 - Yes ☐ 2 - No

h. Methotrexate:*(FGPRMTRX)* ☐ 1 - Yes ☐ 2 - No

i. Prednisone:*(FGPRPRED)* ☐ 1 - Yes ☐ 2 - No

j. Sirolimus:*(FGPRSIR)* ☐ 1 - Yes ☐ 2 - No

k. Tacrolimus:*(FGPRTAC)* ☐ 1 - Yes ☐ 2 - No

l. Other:*(FGPROTHR)* ☐ 1 - Yes ☐ 2 - No

Specify other agent used:*(FGPROTSP)*

12. If GVHD prophylaxis was discontinued during this assessment, record the date:*(FGPRDCDT)* *(mm/dd/yyyy)*

Chronic GVHD

13. Maximum overall severity of chronic GVHD during this assessment period:*(FGSVCGVH)*
    - 0 - No Chronic GVHD
    - 1 - Mild
    - 2 - Moderate
    - 3 - Severe

14. Did new clinical signs and/or symptoms of chronic GVHD develop during this assessment period?*(FGCGVDVL)* ☐ 1 - Yes ☐ 2 - No ?

Only initial diagnosis or onset of chronic GVHD should be reported.

15. Date of initial diagnosis/onset of chronic GVHD:*(FGCGDGDT)* *(mm/dd/yyyy)* ?

16. Minimum Karnofsky/Lansky Score at time of diagnosis: *(FGDGKNLN)*
    - 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

17. Minimum platelet count at time of diagnosis:*(FGDGPLT)* *(xxxxxx)* /mm^3

18. Alkaline phosphatase at time of diagnosis:*(FGDGALKP)* *(xxxx)* Units/L

19. Weight at time of diagnosis:*(FGDGWGT)* *(xxx.x)* kg

20. Total bilirubin at time of diagnosis:*(FGDGBILI)* *(xx.x)* mg/dL

21. Did the patient have an erythematous or maculopapular rash at the time of diagnosis?*(FGRSDIAG)* ☐ 1 - Yes ☐ 2 - No

22. Was diarrhea, nausea, vomiting or liver function abnormalities present at the time of diagnosis? *(FGDRDIAG)* ☐ 1 - Yes ☐ 2 - No

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

Skin/Hair

23. Extent of skin involvement:*(FGSKNINV)*
    - 0 - No Symptoms
    - 1 - <18% BSA with disease signs but NO sclerotic features
    - 2 - 19-50% BSA OR involvement with superficial sclerotic features not hidebound (able to pinch)
    - 3 - >50% BSA OR deep sclerotic features hidebound OR impaired mobility, ulceration, severe pruritis

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

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

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

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

d. Other:*(FGRSOTHR)* ☐ 1 - Yes ☐ 2 - No

Specify other rash:*(FGRSOTSP)*

Ocular

24. Xerophthalmia:*(FGXEROPH)*
    - 0 - No Symptoms
    - 1 - Dry Eyes but Not Requiring Therapy
    - 2 - Dryness of Eyes or Inflammation Requiring Therapy

Oral

25. Mucositis/ulcers (functional):*(FGMUCOS)*

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

26. Bronchiolitis obliterans:*(FGBRNCH)*

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

27. FEV1:*(FGFEV1VL)* *(xxx)* %

Record the lowest value during this assessment period.

28. Date FEV1 obtained:*(FGFEV1DT)* *(mm/dd/yyyy)*

29. FVC:*(FGFVCVL)* *(xxx)* %

Record the value at the time of the lowest FEV1 measurement.

30. DLCO:*(FGDLCOVL)* *(xxx)* %

Record the value at the time of the lowest FEV1 measurement.

Gastrointestinal

31. Esophagus:*(FGESOPH)*

0 - No Symptoms
1 - Symptoms, Confirmed with Diagnostic Procedure

32. Nausea and vomiting:*(FGNAUSVM)*

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

33. Diarrhea:*(FGDIARH)*

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

Hepatic

Record the highest value during this assessment period for the following:

	Highest Value	Date Sample Obtained
34. Bilirubin:	*(FGBILI)* *(xx.x)* mg/dL	*(FGBILIDT)* *(mm/dd/yyyy)*
35. ALT:	*(FGALT)* *(xxxx)* Units/L	*(FGALTDT)* *(mm/dd/yyyy)*
36. AST:	*(FGAST)* *(xxxx)* Units/L	*(FGASTDT)* *(mm/dd/yyyy)*
37. Alkaline Phosphatase:	*(FGALKPH)* *(xxxx)* Units/L	*(FGAKPHDT)* *(mm/dd/yyyy)*

Genitourinary

38. Non-infective vaginitis:*(FGVAGNIT)*

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

Musculoskeletal

39. Contractures:*(FGCONTRC)*

0 - No Symptoms/Undefined
1 - Mild Joint Contractures
2 - Moderate Joint Contractures
3 - Severe Joint Contractures

40. Myositis:*(FGMYOSIT)*

☐ 1 - Yes ☐ 2 - No

Hematologic

41. Eosinophilia:*(FGEOSINP)* ☐ 1 - Yes ☐ 2 - No

Other

42. Serositis:*(FGSEROS)* ☐ 1 - Yes ☐ 2 - No

43. Fascitis:*(FGFASCIT)* ☐ 1 - Yes ☐ 2 - No

44. Was there any other organ involvement?*(FGOTORGN)* ☐ 1 - Yes ☐ 2 - No

Specify other organ involvement:*(FGOTORSP)*

Biopsies Performed During this Assessment Period

45. Were any biopsies performed during this assessment period for suspected GVHD?*(FGBIOPSY)* ☐ 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:
46. *(FGBIO1TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO1SP)*	*(FGBIO1DT)* *(mm/dd/yyyy)*	*(FGBIO1RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
47. *(FGBIO2TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO2SP)*	*(FGBIO2DT)* *(mm/dd/yyyy)*	*(FGBIO2RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
48. *(FGBIO3TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO3SP)*	*(FGBIO3DT)* *(mm/dd/yyyy)*	*(FGBIO3RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
49. *(FGBIO4TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO4SP)*	*(FGBIO4DT)* *(mm/dd/yyyy)*	*(FGBIO4RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
50. *(FGBIO5TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO5SP)*	*(FGBIO5DT)* *(mm/dd/yyyy)*	*(FGBIO5RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
51. *(FGBIO6TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO6SP)*	*(FGBIO6DT)* *(mm/dd/yyyy)*	*(FGBIO6RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal

GVHD Therapy

52. Was a specific therapy used to **treat** chronic GVHD during this assessment period?*(FGCHRTRT)*

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

Therapies used for GVHD prophylaxis should not be recorded here. Only report therapies that were initiated during this assessment period.

Treatment is defined as increasing the dose of an ongoing agent or addition of a new agent. Adjusting a drug taper does not qualify as treatment.

53. Date chronic GVHD treatment initiated:*(FGCTRTDT)* *(mm/dd/yyyy)*

If the date is out of range because the therapy was initiated during a previous assessment period, it should be entered on the previous form.

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

a. ALS, ALG, ATS, ATG:*(FGTHATG)* 1 - Yes 2 - No

b. Azathioprine:*(FGTHAZAT)* 1 - Yes 2 - No

c. Cyclosporine:*(FGTHCYCL)* 1 - Yes 2 - No

d. Systemic Corticosteroids:*(FGTHSYCO)* 1 - Yes 2 - No

e. Topical Corticosteroids:*(FGTHTPCO)* 1 - Yes 2 - No

f. Thalidomide:*(FGTHTHAL)* 1 - Yes 2 - No

g. Tacrolimus (FK 506, Prograf):*(FGTHTAC)* 1 - Yes 2 - No

h. Mycophenolate Mofetil (MMF, Cellcept):*(FGTHMMF)* 1 - Yes 2 - No

i. PUVA (Psoralen and UVA):*(FGTHPUVA)* 1 - Yes 2 - No

j. ECP (Extra-corporeal Photopheresis):*(FGTHECP)* 1 - Yes 2 - No

k. Sirolimus (Rapamycin):*(FGTHSIR)* 1 - Yes 2 - No

l. Etretinate:*(FGTHETR)* 1 - Yes 2 - No

m. Lamprene:*(FGTHLAMP)* 1 - Yes 2 - No

n. Etanercept:*(FGTHETAN)* 1 - Yes 2 - No

o. Zenapax (Daclizumab):*(FGTHZENA)* 1 - Yes 2 - No

p. Chloroquine Phosphate:*(FGTHCHPH)* 1 - Yes 2 - No

q. In Vivo Anti T-lymphocyte Monoclonal Antibody:*(FGTHMAB)* 1 - Yes 2 - No

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

r. In Vivo Immunotoxin:*(FGTHIMM)* 1 - Yes 2 - No

Specify in vivo immunotoxin used:*(FGTHIMSP)*

s. Other:*(FGTHOTHR)* 1 - Yes 2 - No

Specify other agent used:*(FGTHOTSP)*

Comments:*(FGVCOMM)*

Additional Selection Options for FGV

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

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 (Severly Disabled/Needs Assistance for Quiet Play)
09 - 20 (Very Sick/Limited to Very Passive Activity)
10 - 10 (Moribund; Completely Disabled)
11 - 0 (Dead)

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

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 - 1204 (HF3)

Web Version: 1.0; 2.00; 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

Per protocol, if prior chimerism results are equivocal (donor chimerism < 20%), a chimerism assay must be performed at the Day 42 visit.

6. Was a chimerism assay performed during this assessment period?*(CHIMPERF)* ☐ 1 - Yes ☐ 2 - No
7. Are prior chimerism results equivocal (donor chimerism < 20%)?*(RESEQUIV)* ☐ 1 - Yes ☐ 2 - No

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

Unfractionated:

8. Was a chimerism assay performed on an unfractionated sample during this assessment period?*(MRWCHIM)* ☐ 1 - Yes ☐ 2 - No
   9. Record date specimen collected:*(MRWCHIDT)* *(mm/dd/yyyy)*
   10. 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
      11. Specify other method of evaluation:*(MRWMTHSP)*
   12. Record the type of unfractionated sample:*(UNFTYP)* ☐ 1 - Blood ☐ 2 - Marrow
   13. Record unfractionated assay results:*(MRWRSLT)*
       - 1 - All Host Cells
       - 2 - All Donor Cells
       - 3 - Host and Donor
   14. Record % donor:*(MRWPCTD)* *(xx)* %

T Cell (CD3+):

15. Was a chimerism assay performed on a T cell sample during this assessment period?*(TCLCHIM)* ☐ 1 - Yes ☐ 2 - No
   16. Record date specimen collected:*(TCLCHIDT)* *(mm/dd/yyyy)*

17. 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

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

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

☐ 1 - Blood ☐ 2 - Marrow

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

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

21. Record % donor:*(TCLPCTD)*

(xx) %

Comments:*(HTPCOMM)*

Additional Selection Options for HF3

Record method of evaluation:
9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

HLH Reactivation Form - 1204 (HLR)

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

Segment *(PROTSEG)*: A

HLH Reactivation Date *(HLHRCTDT)*:

1. Type of HLH reactivation:*(HLRSYSCN)*
   1 - Systemic
   2 - CNS
   3 - Both
2. Patient's CSF white blood cell count:*(HLRWBCCT)* _____ *(xx)* /mm^3
3. Has the radiologist determined that there were MRI changes suggestive of HLH?*(HLRMRICH)*
   1 - Yes
   2 - No
   3 - Uncertain
   4 - Not Evaluated

Indicate patient HLH reactivation criteria:

4. Fever ≥ 38.3°C:*(HLRFEVER)* ☐ 1 - Yes ☐ 2 - No
5. Splenomegaly:*(HLRSPMEG)* ☐ 1 - Yes ☐ 2 - No

Cytopenias affecting the following lineages in the peripheral blood:

6. Hemoglobin < 9 g/dL:*(HLRHEM)* ☐ 1 - Yes ☐ 2 - No
7. Platelets < 100x10^3/mL:*(HLRPLATE)* ☐ 1 - Yes ☐ 2 - No
8. Neutrophils < 1x10^3/mL:*(HLRNEUT)* ☐ 1 - Yes ☐ 2 - No
9. Hypertriglyceridemia (fasting, ≥ 265 mg/dL): *(HLRHTG)* ☐ 1 - Yes ☐ 2 - No
10. Hypofibrinogenemia ≤ 150 mg/dL:*(HLRHFG)* ☐ 1 - Yes ☐ 2 - No

Hemophagocytosis in the following:

11. Bone marrow:*(HLRBM)* ☐ 1 - Yes ☐ 2 - No
12. Spleen:*(HLRSPLN)* ☐ 1 - Yes ☐ 2 - No
13. Lymph nodes:*(HLRLYMPH)* ☐ 1 - Yes ☐ 2 - No
14. Liver:*(HLRLIVER)* ☐ 1 - Yes ☐ 2 - No
15. Low or absent NK-cell activity:*(HLRNKACT)* ☐ 1 - Yes ☐ 2 - No
16. Ferritin > 500 ng/mL:*(HLRFERR)* ☐ 1 - Yes ☐ 2 - No
17. Elevated soluble CD25:*(HLRCD25)* ☐ 1 - Yes ☐ 2 - No
18. Are there other potential contributing causes? *(HLROTCAU)* ☐ 1 - Yes ☐ 2 - No
19. If 'Yes,' specify other causes:*(HLROTCSP)* _____
20. Record absolute neutrophil count:*(HLRANC)* _____ *(xxxxx)* /mm^3 Date obtained:*(HLRANCDT)* _____ *(mm/dd/yyyy)*
21. Record platelet count:*(HLRPLAT)* _____ *(xxxxxx)* /mm^3 Date obtained:*(HLRPLTDT)* _____ *(mm/dd/yyyy)*

Chimerism Assay Data

Unfractionated:

22. Was a chimerism assay performed on an unfractionated sample?*(HLRTOPRF)* ☐ 1 - Yes ☐ 2 - No
23. Record date specimen collected:*(HLRTCHDT)* _____ *(mm/dd/yyyy)*

24. Record method of evaluation:*(HLRTOMTH)*

- 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

25. Specify other method of evaluation: *(HLRTOMSP)*

26. Record the type of unfractionated sample: *(HLRTOCTP)* ☐ 1 - Blood ☐ 2 - Marrow

27. Record unfractionated assay results: *(HLRTOCRS)*

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

28. Record % donor:*(HLRTOCPT)* *(xx)* %

T Cell (CD3+):

29. Was a chimerism assay performed on a T cell sample?*(HLRTCPRF)* ☐ 1 - Yes ☐ 2 - No

30. Record date specimen collected:*(HLRTCCDT)* *(mm/dd/yyyy)*

31. Record method of evaluation:*(HLRTCMTH)*

- 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

32. Specify other method of evaluation: *(HLRTCMSP)*

33. Record the type of T cell sample:*(HLRTCCTP)* ☐ 1 - Blood ☐ 2 - Marrow

34. Record T cell assay results:*(HLRTCCRS)*

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

35. Record % donor:*(HLRTCCPT)* *(xx)* %

Comments:*(HLRCOMM)*

Additional Selection Options for HLR

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

Immune Reconstitution (IR1)

Web Version: 1.0; 2.00; 10-16-15

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

Immune and Hematologic Function

Flow Cytometry

1. Date flow cytometry was performed:*(FLOWCYDT)* _____ *(mm/dd/yyyy)*
2. CD3 absolute count:*(CD3AB)* _____ *(xxxx)* cells/uL
3. CD4 absolute count:*(CD4AB)* _____ *(xxxx)* cells/uL
4. CD8 absolute count:*(CD8AB)* _____ *(xxxx)* cells/uL
5. CD19 absolute count:*(CD19AB)* _____ *(xxxx)* cells/uL
6. CD16+/56 absolute count:*(CD1656AB)* _____ *(xxxx)* cells/uL

Quantitative Immunoglobulins

7. Date sample for quantitative immunoglobulins assay was collected:*(QIMGSDT)* _____ *(mm/dd/yyyy)*
8. IgA:*(QIGA)* _____ *(xxx)* mg/dL
9. IgG:*(QIGG)* _____ *(xxxx)* mg/dL
10. IgM:*(QIGM)* _____ *(xxx)* mg/dL

11. Were immunoglobulin products administered during this assessment period? *(IVIGADMN)* ☐ 1 - Yes ☐ 2 - No
12. Record date of last administration:*(IVIGLSDT)* _____ *(mm/dd/yyyy)*

Comments:*(IR1COMM)*

Blood and Marrow Transplant Clinical Trials Network

Chronic GVHD Provider Survey (PCG)

Web Version: 1.0; 1.04; 06-16-16

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

Instructions:

Please score a symptom only if you know or suspect it to be *related to chronic GVHD*. Subjective symptoms are acceptable. For example, joint tightness can be scored based on subjective findings despite the absence of objective limitations.

Please score symptoms present in the *last week*. Even if they may have resolved with treatment in the past week, if they were present recently and may possibly return, please score them.

1. Date of visit:*(PCGDATE)* _____ *(mm/dd/yyyy)*

	0	1	2	3
Skin Score	*(PCGSKIN)* ☐ No Symptoms	☐ <18% BSA with disease signs but NO sclerotic features	☐ 19-50% BSA OR involvement with superficial sclerotic features not hidebound (able to pinch)	☐ >50% BSA OR deep sclerotic feats. hidebound OR impaired mobility, ulceration or severe pruritis
Mouth Score	*(PCGMOUTH)* ☐ No Symptoms	☐ Mild symptoms with disease signs but not limiting oral intake significantly	☐ Moderate symptoms with signs with **partial** limitation of oral intake	☐ Severe symptoms with disease signs on examination with **major** limitation of oral intake
GI Tract Score	*(PCGGITRC)* ☐ No symptoms	☐ Symptoms: dysphagia, anorexia, nausea, vomiting, abdominal pain or diarrhea with weight loss (<5%)	☐ Symptoms associated with mild to moderate weight loss (5-15%)	☐ Symptoms with significant weight loss >15%, requires nutritional supplements OR esophageal dilation
Eye Score	*(PCGEYE)* ☐ No symptoms	☐ Mild dry eye not affecting ADL OR asymptomatic signs of kerato-conjunctivitis sicca	☐ Moderate dry eye partially affecting ADL WITHOUT vision impairment	☐ Severe dry eye symptoms significantly affecting ADL OR unable to work OR loss of vision
Joint and Fascia Score	*(PCGJOINT)* ☐ No symptoms	☐ Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting ADL	☐ Tightness of arms or legs OR joint contractures, erythema due to fasciitis, moderate decrease in ROM	☐ Contracture WITH significant decrease of ROM AND significant limitation of ADL
Genital Tract Score (score even if no GYN exam; score required for men, too)*(PCGNOEXM)* ☐ **No GYN Exam**	*(PCGGNITL)* ☐ No symptoms	☐ Symptomatic, mild distinct signs on exam and no effect on coitus, minimal discomfort w/ GYN exam	☐ Symptomatic, distinct signs on exam and mild dyspareunia or discomfort w/ GYN exam	☐ Symptomatic, advanced signs, severe pain with coitus or inability to insert vaginal spectrum
Lung Score	*(PCGLUNG)* ☐ No symptoms	☐ Mild symptoms (shortness of breath after climbing one flight of steps)	☐ Moderate symptoms (shortness of breath after walking on flat ground)	☐ Severe symptoms (shortness of breath at rest; requiring oxygen)

Please rate the severity of this person's chronic GVHD

on this scale	*(PCGSEV1)* ☐ 1 - None	☐ 2 - Mild	☐ 3 - Moderate	☐ 4 - Severe

and on this scale	*(PCGSEV2)* ☐ 0 - cGVHD symptoms are not at all severe	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 - cGVHD symptoms are most severe possible

Is an erythematous or maculopapular rash present?*(PCGRASH)* ☐ 1 - Yes ☐ 2 - No

Does the patient have nausea, vomiting or diarrhea?*(PCGVOMIT)* ☐ 1 - Yes ☐ 2 - No

Liver score to be completed using most recent LFTs from within +/- 2 weeks of the assessment

	0	1	2	3
Liver Score	*(PCGLIVER)* ☐ Normal LFTs	☐ Elevated bilirubin, alkaline phosphatase, AST or ALT < 2x ULN	☐ Bilirubin > 3 mg/dl or bilirubin, AST or ALT 2-5x ULN	☐ Bilirubin, AST or ALT > 5x ULN

Date LFT sample obtained:*(PCGLFTDT)* _____ *(mm/dd/yyyy)*

PFT values from within one month of the assessment

% FEV1*(PCGFEV1)* _____ *(xxx)* %	Date of FEV1*(PCGFEVDT)* _____ *(mm/dd/yyyy)*	*(PCGFEVND)* ☐ Not Done
% DLCOc*(PCGDLCO)* _____ *(xxx)* %	Date of DLCOc*(PCGDLCDT)* _____ *(mm/dd/yyyy)*	*(PCGDLCND)* ☐ Not Done

Comments:*(PCGCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Specimen Acquisition Form - 1204 (S10)

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

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

Patient Samples for Future Testing - Whole Blood

1. Was a whole blood sample collected for future research?*(S10BLD)* ☐ 1 - Yes ☐ 2 - No
2. Date whole blood sample was collected:*(S10BLDDT)* _____ *(mm/dd/yyyy)*

IMPORTANT: Remember to enter the sample into the GlobalTrace Specimen Tracking System the same day it is collected.

Comments:*(S10COMM)*

Blood and Marrow Transplant Clinical Trials Network

Secondary Graft Failure (SGR)

Web Version: 1.0; 4.01; 01-04-17

Segment *(PROTSEG)*: A

Secondary Graft Fail Date *(SGFDATE)*:

1. Was there a decline in neutrophil counts to <500/mm^3 for three consecutive measurements on different days after initial neutrophil engraftment?*(DECLANC)* ☐ 1 - Yes ☐ 2 - No

2. Record the first three consecutive neutrophil counts and specimen collection dates:

Day 1:	*(DAY1ANC)*		*(xxx)* /mm^3	*(SG1ANCDT)*	*(mm/dd/yyyy)*
Day 2:	*(DAY2ANC)*		*(xxx)* /mm^3	*(SG2ANCDT)*	*(mm/dd/yyyy)*
Day 3:	*(DAY3ANC)*		*(xxx)* /mm^3	*(SG3ANCDT)*	*(mm/dd/yyyy)*

3. Was growth factor administered following the decline in neutrophil counts? *(GIVEGF)* ☐ 1 - Yes ☐ 2 - No

4. Has the percent of donor chimerism decreased to <5% donor?*(DONDEC)* ☐ 1 - Yes ☐ 2 - No

5. Record percent donor cell:*(PERDONOR)* *(x)* %

6. Record date of collection of the sample indicating secondary graft failure: *(TCCHIMDT)* *(mm/dd/yyyy)*

Comments:*(SGRCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 1204 (T22)

Web Version: 1.0; 1.01; 12-08-15

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

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

The Day 0000 Toxicity Form is intended to capture conditioning and infusion-related toxicities. Record the highest grade of toxicity diagnosed. The toxicity grades are based on the NCI CTCAE Version 4.02.

Record the highest grade of toxicity diagnosed since the previous evaluation. The toxicity grades are based on the NCI CTCAE Version 4.02.

General Disorders

2. Fever:*(TXFEVER)*
   - 0 - Grades 0-2
   - 3 - >40.0 degrees C (>104.0 degrees F) for < = 24 hours
   - 4 - >40 degrees C (>104.0 degrees F) for >24 hours
   - 5 - Death

Immune System Disorders:

3. Allergic reaction:*(ALRGCRXN)*
   - 0 - Grades 0-2
   - 3 - Prolonged; recurrence of symptoms following initial improvement; hospitalization indicated
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

4. Anaphylaxis:*(ANAPHYLX)*
   - 0 - No event
   - 3 - Symptomatic bronchospasm; parenteral intervention indicated; allergy-related edema/angioedema
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

GI Disorders

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

6. Nausea:*(TXNAUSEA)*
   - 0 - Grades 0-2
   - 3 - Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated

7. Vomiting:*(VOMIT)*
   - 0 - Grades 0-2
   - 3 - >=6 episodes [separated by 5 minutes] in 24 hrs; tube feeding, TPN or hospitalization indicated
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

8. Diarrhea:*(DIARRHEA)*
   - 0 - Grades 0-2
   - 3 - Increase of >=7 stools per day; incontinence; severe increase in ostomy; limiting self care ADL
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

Renal Disorders

9. 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

10. 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

11. 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

12. Did the patient receive dialysis?*(RCVDIALY)*

☐ 1 - Yes ☐ 2 - No

13. If yes, were laboratory values corrected?*(LBVALCOR)*

☐ 1 - Yes ☐ 2 - No

Hemorrhagic Disorders

14. Hemorrhage:*(HEMORRHG)*

0 - Grades 0-2
3 - Transfusion, radiologic, endoscopic, or elective operative intervention indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

15. 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

16. Hypotension:*(HYPOTEN)*

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

17. 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

18. 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

19. Specify arrhythmia:*(CRDARRSP)*

20. Myocardial infarction:*(MYOCDINF)*

0 - Grades 0-2
3 - Severe symptoms; hemodynamically stable; ECG changes consistent with infarction
4 - Life-threatening consequences; hemodynamically unstable
5 - Death

21. 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

22. Pericardial effusion:*(PERCRDEF)*

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

23. Restrictive cardiomyopathy:*(RSTCDMYP)*

0 - No event
3 - Symptomatic heart failure or other cardiac symptoms, responsive to intervention
4 - Refractory heart failure or other poorly controlled cardiac symptoms
5 - Death

Nervous System Disorders

24. Somnolence:*(SOMNOLN)*

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

25. Seizure:*(TXSEIZR)*

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

26. Neuropathy:*(NEURPTHY)*

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

27. Specify neuropathy type:*(NEURTYSP)*

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

28. Did the patient experience reversible posterior leukoencephalopathy syndrome (RPLS) or posterior reversible encephalopathy syndrome (PRES)?*(T22PRES)*

☐ 1 - Yes ☐ 2 - No

Blood and Lymphatic Disorders

29. 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

30. Capillary leak syndrome:*(CAPLKSYN)*

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

31. Thromboembolic event:*(THROMBEV)*

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

Musculoskeletal and Connective Tissue Disorders

32. Avascular necrosis:*(AVASCNEC)*

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

33. Osteoporosis:*(OSTEOPOR)*

0 - Grades 0-1
2 - BMD t-score <-2.5; loss of height <2 cm; limiting instrumental ADL
3 - Loss of height >/= 2cm; hospitalization indicated; limiting self care ADL

Respiratory, Thoracic and Mediastinal Disorders

34. 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

35. 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

36. 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

37. 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

38. 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

39. ALT:*(TXALT)*

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

40. AST:*(TXAST)*

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

41. Bilirubin:*(TXBILIRB)*

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

42. Alkaline Phosphatase:*(TXALKPH)*

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

Indicate all clinical signs/symptoms of abnormal liver functioning present during this assessment period:

43. Jaundice:*(TXJAUND)* ☐ 1 - Yes ☐ 2 - No
44. Hepatomegaly:*(HEPTMGLY)* ☐ 1 - Yes ☐ 2 - No
45. Right upper quadrant pain:*(RTQUADPN)* ☐ 1 - Yes ☐ 2 - No
46. Weight gain (>5%) from baseline:*(TXWGHTGN)* ☐ 1 - Yes ☐ 2 - No

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
47. 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
48. 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
49. 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
50. 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

51. Unknown:	(UNKETIOL) 1 - Yes 2 - No	N/A	N/A

Specify other etiology:*(OTHETSP)*

Stem Cell Infusional Toxicity (Within 24 Hours of Infusion)

52. Allergic reaction/hypersensitivity:*(T22ALRGY)*
0 - Grades 0-2
3 - Symptomatic Bronchospasm, with or without Urticaria; Parenteral Med(s) Indicated
4 - Anaphylaxis
5 - Death

53. Cardiac arrhythmia:*(T22CARDC)*
0 - Grades 0-2
3 - Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
4 - Life-Threatening; Disabling (e.g., Arrhythmia Associated with CHF, Syncope, Shock)
5 - Death

54. Hypertension:*(T22HYPRT)*
0 - Grades 0-2
3 - Requiring More than One Drug or More Intensive Therapy than Previously
4 - Life-Threatening Consequences (e.g., Hypertensive Crisis)
5 - Death

55. Hypotension:*(T22HYPOT)*
0 - Grades 0-2
3 - Sustained (>/=24 hrs) Therapy, Resolves w/o Persisting Physiologic Consequences
4 - Shock (e.g., Acidemia; Impairment of Vital Organ Function)
5 - Death

56. Fever:*(T22FEVER)*
0 - Grades 0-1
2 - >39.0-40.0C (102.3-104.0F)
3 - >40C (>104.0F) for <24 hrs
4 - >40C (>104.0F) for >24 hrs
5 - Death

57. Rigors, chills:*(T22RIGOR)*
0 - Grades 0-2
3 - Severe or Prolonged, not Responsive to Narcotics

58. Vomiting:*(T22VOMIT)*
0 - Grades 0-1
2 - 2-5 Episodes in 24 hrs; IV Fluids Indicated <24 hrs
3 - >/=6 Episodes in 24 hrs; IV Fluids, or TPN Indicated >/=24 hrs
4 - Life-Threatening Consequences
5 - Death

59. Hypoxia:*(T22HYPOX)*
0 - Grades 0-2
3 - Decreased Oxygen Saturation at Rest; Continuous Oxygen Indicated
4 - Life-Threatening; Intubation or Ventilation Indicated
5 - Death

Comments:*(T22COMM)*

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 patient weight on day of transplant:*(PTWGTTB)* _____ *(xxx.x)* kg
4. Record the total nucleated cell (TNC) count of the infused product:*(TNCCTINF)* _____ *(xxx.xx)* x 10^8
5. Record the $CD34^+$ cell count of the infused product:*(CDCNTINF)* _____ *(xxxx.xx)* x 10^6
6. Record the patient's pre-transplant CMV antibody (IgG) status:*(CMVSTAT)* ☐ 1 - Positive ☐ 2 - Negative

Comments:*(COMMTXP1)* _____

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

12040 (ENR)

Web Version: 1.0; 1.02; 10-16-15

HLH & Related Disorders Enrollment Form - Segment 0

Please verify this patient is to be enrolled on the BMT CTN 1204 trial prior to completing the form below.

1. Patient's date of birth:*(HIBRTHDT)* 04/03/1978 *(mm/dd/yyyy)*

2. Date BMT CTN 1204 informed consent form signed:*(HICNSTDT)* *(mm/dd/yyyy)*

3. Patient's donor type:*(HIDNRTYP)*

1 - Related Sibling Donor
2 - Related Non-Sibling Donor
3 - Unrelated Donor

4. If related, is the donor an identical twin of the recipient?*(HIDNTWIN)* ☐ 1 - Yes ☐ 2 - No

Comments:*(HICOMM)*

Blood and Marrow Transplant Clinical Trials Network

HLH HLA Form - Page 1 (HI1)

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

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

HLA Typing

Donor type:*(HLARLTD)*

1 - Related Sibling Donor
2 - Related Non-Sibling Donor
3 - 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

Recipient HLA Typing

Upload HLA-typing source documents. Be sure to remove patient identifiers prior to uploading.

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:*(HI1COMM)*

Additional Selection Options for HI1

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

HLH HLA Form - Page 2 (HI2)

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

Donor HLA Typing

Upload HLA-typing source documents. Be sure to remove patient identifiers prior to uploading.

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)* /

Indicate your institution's HLA Match Score for Recipient-to-Donor:*(HT2SISC)*

0/6
1/6
2/6
3/6
4/6
*Additional Options Listed Below

Comments:*(HI2COMM)*

Additional Selection Options for HI2

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

Indicate your institution's HLA Match Score for Recipient-to-Donor:
5/6
6/6
0/8
1/8
2/8
3/8
4/8
5/8
6/8
7/8
8/8