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)*:

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	*(A9C1ACT)*
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	*(A9C2ACT)*
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	*(A9C3ACT)*
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	*(A9C4ACT)*
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	*(A9C5ACT)*
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	*(A9C6ACT)*
Communication #7*(A9C7RPT)* Report	*(A9C7STS)* Pending / Resolved	*(A9C7DT)* *(mm/dd/yyyy)*	*(A9C7TYP)* 1 - Email; 2 - Telephone; 3 - Fax; 4 - In Person; 5 - Updated AdvantageEDC	*(A9C7NME)*	*(A9C7RLE)* 1 - Tx Center Coordinator; 2 - Medical Monitor; 3 - Tx Center PI/Investigator; 4 - NHLBI PO; 5 - EMMES PI/PD; *Additional Options Listed Below	*(A9C7ACT)*
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	*(A9C8ACT)*
Communication #9*(A9C9RPT)* Report	*(A9C9STS)* Pending / Resolved	*(A9C9DT)* *(mm/dd/yyyy)*	*(A9C9TYP)*	*(A9C9NME)*	*(A9C9RLE)*	*(A9C9ACT)*

			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 #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	*(A9C10ACT)*
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	*(A9C11ACT)*
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	*(A9C12ACT)*
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	*(A9C13ACT)*
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	*(A9C14ACT)*
Communication #15*(A9C15RPT)* Report	*(A9C15STS)* Pending Resolved	*(A9C15DT)* *(mm/dd/yyyy)*	*(A9C15TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C15NME)*	*(A9C15RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C15ACT)*
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	*(A9C16ACT)*
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	*(A9C17ACT)*
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	*(A9C18ACT)*
Communication #19*(A9C19RPT)* Report	*(A9C19STS)* Pending Resolved	*(A9C19DT)* *(mm/dd/yyyy)*	*(A9C19TYP)*	*(A9C19NME)*	*(A9C19RLE)*	*(A9C19ACT)*

			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 #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	*(A9C20ACT)*
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	*(A9C21ACT)*
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	*(A9C22ACT)*

Additional Selection Options for A9C

COM 1 Contact Role
6 - Pharma Rep
99 - Other

Blood and Marrow Transplant Clinical Trials Network

Ann Arbor Results Form - 1501 (AAR)

Web Version: 1.0; 2.00; 06-07-17

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

Ann Arbor Panel Scoring

1. GlobalTrace specimen number:*(AARGTNUM)*
2. Date blood sample was tested:*(AARBLDDT)* *(mm/dd/yyyy)* Time started:*(AARBLDTM)* *(hh:mm)* *(AARBAMPM)* (AM / PM)
3. Ann Arbor result using 3 biomarkers:*(AARSCORE)*
   - 1 - AA1
   - 2 - AA2
   - 3 - AA3
   - 4 - Missing
4. Ann Arbor result using 2 biomarkers:*(AAR2SCOR)*
   - 1 - AA1
   - 2 - AA2
   - 3 - AA3
   - 4 - Missing
5. Reason result is missing:*(AARMISS)*
   - 1 - Sample Not Received
   - 2 - Sample Destroyed/Unusable
   - 3 - Poor Sample Quality
   - 4 - Assay Error
   - 5 - Other

   Specify other:*(AARMISSP)*
6. TNFR1:*(AAR1TNFR)* *(xxxxx)* pg/mL
7. REG3a:*(AARREG3A)* *(xxxx)* ng/mL
8. ST2:*(AAR2ST)* *(xxxxxx)* pg/mL
9. Algorithm output using 3 biomarkers:*(AARALGM)* *(x.xx)*
10. Algorithm output using 2 biomarkers:*(AARALG2M)* *(x.xx)*
11. Was the paper Biomarker Test Requisition Form included with the specimen?*(AARBMTRF)* ☐ 1 - Yes ☐ 2 - No
12. Was the first attempt to contact the site successful?*(AAR1CONT)* ☐ 1 - Yes ☐ 2 - No
13. Was the second attempt to contact the site successful?*(AAR2CONT)* ☐ 1 - Yes ☐ 2 - No

Comments:*(AARCOMM)*

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 serious adverse event?*(AMDETERU)* ☐ 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)*

Acute GVHD Form II (AGV)

Web Version: 1.0; 4.00; 11-02-16

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

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

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

1. Date of most recent GVHD staging:*(AGSTGDT)* *(mm/dd/yyyy)*
2. Date of most recent GVHD staging:*(AGSTGDT)* *(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.

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

3. Skin abnormalities:*(AGVSKINA)*

0 - No Active (Erythematous) GVHD Rash
1 - Maculopapular Rash <25% BSA
2 - Maculopapular Rash 25-50% BSA
3 - Maculopapular Rash >50% BSA
4 - Generalized Erythroderma (>50% BSA) Plus Bullous Formation and Desquamation >5% BSA

4. Skin etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(AGVSKINE) ☐ 1 - Yes ☐ 2 - No	*(AGVSKNET)* ☐ 1 - Yes ☐ 2 - No	*(AGVSKCRT)* ☐ 1 - Yes ☐ 2 - No
Infection	**Other**	
(AGVSKINF) ☐ 1 - Yes ☐ 2 - No	*(AGVSKOT)* ☐ 1 - Yes ☐ 2 - No	

Specify other skin etiologies:*(AGVSKNSP)*

5. Skin biopsy for GVHD:*(AGVSKINB)*

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

6. Upper GI abnormalities:*(AGVUPGIA)*

0 - No or Intermittent Nausea, Vomiting, or Anorexia
1 - Persistent Nausea, Vomiting, or Anorexia

7. Upper intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(AGVUPGI) ☐ 1 - Yes ☐ 2 - No	*(AGBUGDRG)* ☐ 1 - Yes ☐ 2 - No	*(AGVETCON)* ☐ 1 - Yes ☐ 2 - No
TPN	**Infection**	**Other**
(AGVUGTPN) ☐ 1 - Yes ☐ 2 - No	*(AGVUGINF)* ☐ 1 - Yes ☐ 2 - No	*(AGVUGIOT)* ☐ 1 - Yes ☐ 2 - No

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

8. Upper intestinal tract biopsy for GVHD:*(AGVUGIBI)*

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

9. Lower GI abnormalities (stool volume):*(AGVLGIVM)*

0 - No Diarrhea
1 - Diarrhea-Adult: <500 mL/day; Child: <10 mL/Kg/day
2 - Diarrhea-Adult: 500-999 mL/day; Child: 10-19.9 mL/Kg/day
3 - Diarrhea-Adult: 1000-1500 mL/day; Child: 20-30 mL/Kg/day
4 - Diarrhea-Adult: >1500 mL/day; Child: >30 mL/Kg/day
*Additional Options Listed Below

10. Lower GI abnormalities (number of episodes/day):*(AGVLGIEP)*

1 - Diarrhea-Adult: <3 Episodes/day; Child: <4 Episodes/day
2 - Diarrhea-Adult: 3-4 Episodes/day; Child: 4-6 Episodes/day
3 - Diarrhea-Adult: 5-7 Episodes/day; Child: 7-10 Episodes/day
4 - Diarrhea-Adult: >7 Episodes/day; Child: >10 Episodes/day
5 - Diarrhea-Severe Abdominal Pain With or Without Ileus or Grossly Bloody Stool
*Additional Options Listed Below

The lower GI stage displayed below reflects the lower GI stage to be used for risk stratification. Staging is based on stool volume, if available. If volume is not available, number of stool episodes/day will be used.

11. Lower GI abnormalities:*(AGVLGIAB)*

0 - No Diarrhea
1 - Diarrhea - Adult: <500 mL/day, <3 Episodes/day; Child: <10 mL/kg/day, <4 Episodes/day
2 - Diarrhea - Adult: 500-999 mL/day, 3-4 Episodes/day; Child: 10-19.9 mL/kg/day, 4-6 Episodes/day
3 - Diarrhea - Adult: 1000-1500 mL/day, 5-7 Episodes/day; Child: 20-30 mL/kg/day, 7-10 Episodes/day
4 - Diarrhea - Adult: >1500 mL/day, >7 Episodes/day; Child: >30 mL/kg/day, >10 Episodes/day
*Additional Options Listed Below

12. Lower intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(AGVLGIET) ☐ 1 - Yes ☐ 2 - No	*(AGVLGIDR)* ☐ 1 - Yes ☐ 2 - No	*(AGVLGICO)* ☐ 1 - Yes ☐ 2 - No
TPN	**Infection**	**Other**
(AGVLGETP) ☐ 1 - Yes ☐ 2 - No	*(AGVLGIIN)* ☐ 1 - Yes ☐ 2 - No	*(AGVLGETO)* ☐ 1 - Yes ☐ 2 - No

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

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

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

14. Liver abnormalities:*(AGVLIVAB)*

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
(AGVLIVET) ☐ 1 - Yes ☐ 2 - No	*(AGVLIVDR)* ☐ 1 - Yes ☐ 2 - No	*(AGVLVCON)* ☐ 1 - Yes ☐ 2 - No	*(AGVLVTPN)* ☐ 1 - Yes ☐ 2 - No
Infection	**VOD**	**Other**	
(AGVLVINF) ☐ 1 - Yes ☐ 2 - No	*(AGVLIVOD)* ☐ 1 - Yes ☐ 2 - No	*(AGVLVETO)* ☐ 1 - Yes ☐ 2 - No	

Specify other liver etiologies:*(AGVLIVES)*

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

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

Comments:*(AGVCOMM)*

Additional Selection Options for AGV

Lower GI abnormalities (stool volume):
5 - Diarrhea-Severe Abdominal Pain With or Without Ileus or Grossly Bloody Stool
9 - Not Available

Lower GI abnormalities (number of episodes/day):
9 - Not Available

Lower GI abnormalities:
5 - Severe Abdominal Pain With or Without Ileus or Grossly Bloody Stool (Regardless of Volume)

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)* *(xxxxxxxxx)*

Comments:*(CIDCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

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

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

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

   Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

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

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

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

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

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

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

Specify other:*(DTHSPEC1)*

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

Specify other:*(DTHSPEC2)*

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

Specify other:*(DTHSPEC3)*

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

Specify other:*(DTHSPEC4)*

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

Specify other:*(DTHSPEC5)*

Comments:*(DTCMMNTS)*

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

Additional Selection Options for DTH

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

Blood and Marrow Transplant Clinical Trials Network

Endpoint Review Form - 1501 (E14)

Web Version: 1.0; 1.00; 03-05-18

Case ID *(CASEID)*:

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

Patient ID:*(EXXPATID)*

1. Review Date:*(REVIEWDT)* *(mm/dd/yyyy)*
2. Primary Reviewer Name:*(REVNAME)*
3. Case Status:*(CASESTAT)*
   - 1- Complete (C)
   - 2- Query (Q)
   - 3- Ready for Review (R)
4. Review Committee Comments:*(REVCOMM)*
5. Emmes Comments:*(EMMCOMM)*

Reviewer Adjudicated Fields

6. Response at Day 28:*(AGVRES28)*
   - 1 - Complete
   - 2 - Partial
   - 3 - Mixed
   - 4 - No response
   - 5 - Progression
7. Was systemic steroid therapy used to treat acute GVHD?*(STERGVHD)* ☐ 1 - Yes ☐ 2 - No
8. Was the steroid dose 0.25 mg/kg or less at Day 28 (prednisone or equivalent)?*(STERDOSE)* ☐ 1 - Yes ☐ 2 - No
9. Was additional systemic immunosuppression therapy given for the treatment of acute GVHD? *(ADDISTRT)* ☐ 1 - Yes ☐ 2 - No
10. Additional systemic immunosuppression therapy start date:*(ADDISTDT)* *(mm/dd/yyyy)*
11. Did the patient develop chronic GVHD?*(CGVHD)* ☐ 1 - Yes ☐ 2 - No
12. Chronic GVHD onset date:*(CGVHDT)* *(mm/dd/yyyy)*
13. Exclude patient from the primary analysis population?*(EXCLUDE)* ☐ 1 - Yes ☐ 2 - No
14. Specify reason for exclusion:*(EXCLUDSP)*
15. Was the patient eligible?*(ELIGIBLE)* ☐ 1 - Yes ☐ 2 - No
16. Specify reason for ineligibility:*(ELIGIBSP)*
17. Number of Queries:*(QUERYNUM)*
    - 00- Its A Miracle!
    - 01
    - 02
    - 03
    - 04
    - *Additional Options Listed Below

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

Comments:*(EXXCOMM)*

Additional Selection Options for E14

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

1501A (ENR)

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

BMT CTN 1501 SR aGVHD Enrollment Form

1. Patient's date of birth:*(SVPBTHDT)* *(mm/dd/yyyy)*

Inclusion Criteria

2. Date informed consent form signed:*(SVPCONDT)* *(mm/dd/yyyy)*
3. Was the patient diagnosed with previously untreated, standard-risk acute GVHD according to the refined Minnesota Criteria?*(SVPDIAG)* 1 - Yes 2 - No
4. Has the patient received an allogeneic hematopoietic cell transplant?*(SVPAHCT)* 1 - Yes 2 - No
5. Has the patient received systemic immune suppressive therapy for treatment of active GVHD (except for topical skin or GI corticosteroids)?*(SVPRECTR)* 1 - Yes 2 - No
6. Has the patient received topical skin or GI corticosteroids for treatment of GVHD?*(SVPRECTP)* 1 - Yes 2 - No
7. Can the patient tolerate orally or enterically administered medications?*(SVPTOLME)* 1 - Yes 2 - No
8. Patient's Absolute Neutrophil Count (ANC):*(SVPANC)* *(xxxxx)* /µL ANC Date:*(SVPANCDT)* *(mm/dd/yyyy)*
9. Date Ann Arbor scoring blood sample collected:*(SVPAADT)* *(mm/dd/yyyy)*

Organ Involvement

Biopsy of involved organs with acute graft-versus-host disease (GVHD) is encouraged, but not required for study entry.

Skin

10. Skin abnormalities:*(SVPSKAB)*
    - 0 - No Active (Erythematous) GVHD Rash
    - 1 - Maculopapular Rash <25% BSA
    - 2 - Maculopapular Rash 25-50% BSA
    - 3 - Maculopapular Rash >50% BSA
    - 4 - Generalized Erythroderma (>50% BSA) Plus Bullous Formation and Desquamation >5% BSA
11. Skin Etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SVPSKGV) 1 - Yes 2 - No	*(SVPSKDR)* 1 - Yes 2 - No	*(SVPSKCON)* 1 - Yes 2 - No
Infection	**Other**	
(SVPSKINF) 1 - Yes 2 - No	*(SVPSKOTH)* 1 - Yes 2 - No	

Specify other skin etiologies:*(SVPSKNSP)*

12. Skin biopsy for GVHD:*(SVPSKBIO)*
    - 1 - Positive
    - 2 - Negative
    - 3 - Equivocal
    - 4 - Pending
    - 5 - Not Done

Upper Intestinal Tract

13. Upper GI abnormalities:*(SVPUGAB)*
    - 0 - No or Intermittent Nausea, Vomiting, or Anorexia
    - 1 - Persistent Nausea, Vomiting, or Anorexia
14. Upper GI etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SVPUGGV) 1 - Yes 2 - No	*(SVPUGDR)* 1 - Yes 2 - No	*(SVPUGCON)* 1 - Yes 2 - No
TPN	**Infection**	**Other**
(SVPUGTPN) 1 - Yes 2 - No	*(SVPUGINF)* 1 - Yes 2 - No	*(SVPUGOTH)* 1 - Yes 2 - No

Specify other upper GI etiologies:*(SVPUGSP)*

15. Upper GI biopsy for GVHD:*(SVPUGBIO)*
    - 1 - Positive
    - 2 - Negative
    - 3 - Equivocal
    - 4 - Pending
    - 5 - Not Done

Lower Intestinal Tract

16. Lower GI abnormalities (stool volume):*(SVPLGIVM)*

0 - No Diarrhea
1 - Diarrhea-Adult: <500 mL/day; Child: <10 mL/Kg/day
2 - Diarrhea-Adult: 500-999 mL/day; Child: 10-19.9 mL/Kg/day
3 - Diarrhea-Adult: 1000-1500 mL/day; Child: 20-30 mL/Kg/day
4 - Diarrhea-Adult: >1500 mL/day; Child: >30 mL/Kg/day
*Additional Options Listed Below

17. Lower GI abnormalities (number of episodes/day):*(SVPLGIEP)*

1 - Diarrhea-Adult: <3 Episodes/day; Child: <4 Episodes/day
2 - Diarrhea-Adult: 3-4 Episodes/day; Child: 4-6 Episodes/day
3 - Diarrhea-Adult: 5-7 Episodes/day; Child: 7-10 Episodes/day
4 - Diarrhea-Adult: >7 Episodes/day; Child: >10 Episodes/day
5 - Diarrhea-Severe Abdominal Pain With or Without Ileus or Grossly Bloody Stool
*Additional Options Listed Below

The lower GI stage displayed below reflects the lower GI stage to be used for risk stratification. Staging is based on stool volume, if available. If volume is not available, number of stool episodes/day will be used.

18. Lower GI abnormalities:*(SVPLGAB)*

0 - No Diarrhea
1 - Diarrhea - Adult: <500 mL/day, <3 Episodes/day; Child: <10 mL/kg/day, <4 Episodes/day
2 - Diarrhea - Adult: 500-999 mL/day, 3-4 Episodes/day; Child: 10-19.9 mL/kg/day, 4-6 Episodes/day
3 - Diarrhea - Adult: 1000-1500 mL/day, 5-7 Episodes/day; Child: 20-30 mL/kg/day, 7-10 Episodes/day
4 - Diarrhea - Adult: >1500 mL/day, >7 Episodes/day; Child: >30 mL/kg/day, >10 Episodes/day
*Additional Options Listed Below

19. Lower GI etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SVPLGGV) ☐ 1 - Yes ☐ 2 - No	*(SVPLGDR)* ☐ 1 - Yes ☐ 2 - No	*(SVPLGCON)* ☐ 1 - Yes ☐ 2 - No
TPN	**Infection**	**Other**
(SVPLGTPN) ☐ 1 - Yes ☐ 2 - No	*(SVPLGINF)* ☐ 1 - Yes ☐ 2 - No	*(SVPLGOTH)* ☐ 1 - Yes ☐ 2 - No

Specify other lower GI etiologies:*(SVPLGSP)*

20. Lower GI biopsy for GVHD:*(SVPLGBIO)*

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

Liver

21. Liver abnormalities:*(SVPLVAB)*

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

22. Liver etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity	TPN
(SVPLVGV) ☐ 1 - Yes ☐ 2 - No	*(SVPLVDR)* ☐ 1 - Yes ☐ 2 - No	*(SVPLVCON)* ☐ 1 - Yes ☐ 2 - No	*(SVPLVTPN)* ☐ 1 - Yes ☐ 2 - No
Infection	**VOD**	**Other**	
(SVPLVINF) ☐ 1 - Yes ☐ 2 - No	*(SVPLVVOD)* ☐ 1 - Yes ☐ 2 - No	*(SVPLVOTH)* ☐ 1 - Yes ☐ 2 - No	

Specify other liver etiologies:*(SVPLVSP)*

23. Liver biopsy for GVHD:*(SVPLVBIO)*

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

Exclusion Criteria

24. Has the patient received sirolimus (for any indication including GVHD prophylaxis) within 14 days of screening for enrollment?*(SVPSIRO)* ☐ 1 - Yes ☐ 2 - No
25. Has the patient relapsed, progressed or had a persistent malignancy requiring withdrawal of systemic immune suppression?*(SVPRELAP)* ☐ 1 - Yes ☐ 2 - No
26. Did the patient develop acute GVHD after a donor lymphocyte infusion?*(SVPLYMPH)* ☐ 1 - Yes ☐ 2 - No
27. Does the patient have an active or recent (within 7 days) episode of transplant associated microangiopathy?*(SVPMICAN)* ☐ 1 - Yes ☐ 2 - No
28. Does the patient have an uncontrolled infection?*(SVPINFEC)* ☐ 1 - Yes ☐ 2 - No

Infections are considered controlled if appropriate therapy has been instituted and, at the time of enrollment, no signs of progression are present. Progression of infection is defined as hemodynamic instability attributable to sepsis, new symptoms, worsening physical signs or radiographic findings attributable to infection. Persisting fever without other signs or symptoms will not be interpreted as progressing infection.

29. Is the patient unlikely to be available for evaluation at the transplant center on Day 28 and 56 of therapy?*(SVP2856D)* ☐ 1 - Yes ☐ 2 - No
30. Does the patient have a clinical presentation resembling de novo chronic GVHD or overlap syndrome (as defined in the protocol, Appendix D) that developed before or is present at the time of enrollment?*(SVPCHGVH)* ☐ 1 - Yes ☐ 2 - No
31. Did the patient receive systemic corticosteroids for any indication within 7 days before the onset of acute GVHD, except for the following: Stable replacement doses of corticosteroids for adrenal insufficiency (e.g. hydrocortisone total dose of 10-12 mg/m^2/day or prednisone 5-7.5mg daily or equivalent) or corticosteroids administered as premedication before transfusion of blood products or before intravenous medications to prevent infusion reactions?*(SVPSTROD)* ☐ 1 - Yes ☐ 2 - No
32. Is the patient pregnant or breastfeeding?*(SVPPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
33. Is the patient pregnant or breastfeeding?*(SVPPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
34. Is the patient a female of childbearing potential (FCBP) or a man who has sexual contact with a ☐ 1 - Yes ☐ 2 - No

FCBP?*(SVPFCBP)*

35. If yes, is the patient willing to use effective birth control during the length of the study? *(SVPBIRCO)* ☐ 1 - Yes ☐ 2 - No

36. Is the patient on dialysis?*(SVPDIAL)* ☐ 1 - Yes ☐ 2 - No

37. Is the patient on mechanical ventilation?*(SVPVENT)* ☐ 1 - Yes ☐ 2 - No

38. Does the patient have severe hepatic sinusoidal obstruction syndrome?*(SVPHEPAT)* ☐ 1 - Yes ☐ 2 - No

39. If yes, is the patient expected to have normalized bilirubin by Day 56 after enrollment? *(SVPBILI)* ☐ 1 - Yes ☐ 2 - No

40. Does the patient have a history of hypersensitivity to sirolimus or any component of the formulation?*(SVPSENSR)* ☐ 1 - Yes ☐ 2 - No

Consent for Use of Biological Samples for Optional Future Research

41. Did the patient give consent to provide blood samples for optional future research?*(SVPCONSA)* ☐ 1 - Yes ☐ 2 - No

42. Date patient consented to optional future research samples:*(SVPFCNDT)* _____ *(mm/dd/yyyy)*

Comments:*(SVPCOMM)*

Additional Selection Options for ENR

Lower GI abnormalities (stool volume):
5 - Diarrhea-Severe Abdominal Pain With or Without Ileus or Grossly Bloody Stool
9 - Not Available

Lower GI abnormalities (number of episodes/day):
9 - Not Available

Lower GI abnormalities:
5 - Severe Abdominal Pain With or Without Ileus or Grossly Bloody Stool (Regardless of Volume)

Blood and Marrow Transplant Clinical Trials Network

Follow Up Status Form - 1501 (F20)

Web Version: 1.0; 1.00; 04-08-16

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

1. Date of last contact:*(F20LSCDT)* *(mm/dd/yyyy)*

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

2. Has the patient died?*(F20PTDTH)* ☐ 1 - Yes ☐ 2 - No
   If Yes, a Death Form must be submitted.
   3. Date of patient death:*(F20DTHDT)* *(mm/dd/yyyy)*
4. Has the patient's underlying disease (e.g., malignancy) progressed or relapsed?*(F20PTRLP)* ☐ 1 - Yes ☐ 2 - No
   5. Date of relapse or disease progression:*(F20RLPDT)* *(mm/dd/yyyy)*
   6. Has the patient's underlying disease (e.g., malignancy) been treated for progression or relapse? *(F20TRRLP)* ☐ 1 - Yes ☐ 2 - No
      7. Date treatment administered:*(F20TRADT)* *(mm/dd/yyyy)*
8. Has the patient received an additional transplant?*(F20TXADD)* ☐ 1 - Yes ☐ 2 - No
   9. Date of transplant:*(F20TX2DT)* *(mm/dd/yyyy)*
10. Has the patient developed any EBV-associated lymphoproliferative disorder or EBV reactivation requiring therapy?*(F20PTEBV)* ☐ 1 - Yes ☐ 2 - No
    11. Date of EBV development or reactivation:*(F20EBVDT)* *(mm/dd/yyyy)*
    12. Has the patient received treatment for EBV?*(F20EBVTR)* ☐ 1 - Yes ☐ 2 - No
        13. Date of EBV treatment:*(F20EBTDT)* *(mm/dd/yyyy)*
14. Has the patient experienced CMV reactivation requiring therapy?*(F20PTCMV)* ☐ 1 - Yes ☐ 2 - No
    15. Date of CMV reactivation:*(F20CMVDT)* *(mm/dd/yyyy)*
    16. Has the patient received treatment for CMV reactivation?*(F20CMVTR)* ☐ 1 - Yes ☐ 2 - No
        17. Date of CMV treatment:*(F20CMTDT)* *(mm/dd/yyyy)*
18. Has the patient experienced secondary graft failure?*(F20PTSGF)* ☐ 1 - Yes ☐ 2 - No
    19. Date of secondary graft failure:*(F20SGFDT)* *(mm/dd/yyyy)*
20. Has the patient experienced any new Grade 2-3 infections?*(F20PTINF)* ☐ 1 - Yes ☐ 2 - No
    If Yes, an Infection Form must be submitted.
    21. Date of infection:*(F20INFDT)* *(mm/dd/yyyy)*
22. Has the patient been hospitalized?*(F20PTHSP)* ☐ 1 - Yes ☐ 2 - No
    If Yes, a Re-Admission Form must be submitted.
    23. Date of hospitalization:*(F20HSPDT)* *(mm/dd/yyyy)*
24. Has the patient experienced any Unexpected, Grade 3-5 Adverse Events?*(F20PTSAE)* ☐ 1 - Yes ☐ 2 - No
    If Yes, an Unexpected, Grade 3-5 Adverse Event Form must be submitted.
    25. Date of onset of Unexpected, Grade 3-5 Adverse Event:*(F20SAEDT)* *(mm/dd/yyyy)*

Comments:*(F20COMM)*

Blood and Marrow Transplant Clinical Trials Network

FACT-BMT (Version 4) (FCT)

Web Version: 1.0; 3.05; 10-16-15

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

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer each question by selecting the best choice. If you are unsure about how to answer a questions, please give the best answer you can.

Date of Evaluation:*(FACTDATE)* _____ *(mm/dd/yyyy)*

Physical Well-Being

1. I have a lack of energy*(LCKENRG)*
2. I have nausea*(NAUSEA)*
3. Because of my physical condition, I have trouble meeting the needs of my family*(FMLYNEED)*
4. I have pain*(PAIN)*
5. I am bothered by the side effects of treatment*(SIDEFFCT)*
6. I feel ill*(FEELILL)*
7. I am forced to spend time in bed*(TIMINBED)*

Each of the above items has the same response options:

- 0 - Not at all
- 1 - A little bit
- 2 - Somewhat
- 3 - Quite a bit
- 4 - Very much
- *Additional Options Listed Below

Social/Family Well-Being

8. I feel close to my friends*(CLSFRNDS)*
9. I get emotional support from my family*(FAMSPPRT)*
10. I get support from my friends*(FRNDSPRT)*

Each of the above items has the same response options:

- 0 - Not at all
- 1 - A little bit
- 2 - Somewhat
- 3 - Quite a bit
- 4 - Very much
- *Additional Options Listed Below

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

11. My family has accepted my illness*(ACPTILNS)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

12. I am satisfied with family communication about my illness*(SFAMCOMN)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

13. I feel close to my partner (or the person who is my main support)*(PRTNRSPT)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

Did the patient answer the following question?(CHECKBOX)

☐ 1 - Yes ☐ 2 - No

14. I am satisfied with my sex life*(SEXLIFE)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

Emotional Well-Being

15. I feel sad*(FEELSAD)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

16. I am satisfied with how I am coping with my illness*(COPING)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

17. I am losing hope in the fight against my illness*(LOSEHOPE)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

18. I feel nervous*(NERVOUS)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

19. I worry about dying*(WORRYDIE)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

20. I worry that my condition will get worse*(WORSEN)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

Functional Well-Being

21. I am able to work (include work at home)*(WORK)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

22. My work (include work at home) is fulfilling*(FULFILL)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

23. I am able to enjoy life*(ENJYLIFE)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

24. I have accepted my illness*(ACCEPTED)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

25. I am sleeping well*(SLEEPWEL)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

26. I am enjoying the things I usually do for fun*(FUN)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

27. I am content with the quality of my life right now*(QOL)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

Additional Concerns

28. I am concerned about keeping my job (include work at home)*(JOB)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

29. I feel distant from other people*(DISTANT)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

30. I worry that the transplant will not work*(TRNSPWRY)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

31. The effects of treatment are worse than I had imagined*(TXEFFX)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

32. I have a good appetite*(APPETITE)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

33. I like the appearance of my body*(BDYAPRNC)*

34. I am able to get around myself*(GETARND)*

35. I get tired easily*(GETTIRED)*

36. I am interested in sex*(SEXINTRS)*

37. I have concerns about my ability to have children*(FERTILTY)*

38. I have confidence in my nurse(s)*(NURSE)*

39. I regret having the bone marrow transplant*(BMTREGRT)*

40. I can remember things*(MEMORY)*

41. I am able to concentrate (e.g., reading)*(CNCTRATE)*

42. I have frequent colds/infections*(COLDS)*

43. My eyesight is blurry*(EYESIGHT)*

44. I am bothered by a change in the way food tastes*(GUSTATOR)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

45. I have tremors*(TREMORS)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

46. I have been short of breath*(SHRTBRTH)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

47. I am bothered by skin problems (e.g., rash, itching)*(SKINPROB)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

48. I have problems with my bowels*(BOWELS)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

49. My illness is a personal hardship for my close family members*(HARDSHIP)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

50. The cost of my treatment is a burden on me or my family*(COSTOFTX)*

0 - Not at all
1 - A little bit
2 - Somewhat
3 - Quite a bit
4 - Very much
*Additional Options Listed Below

English (Universal)

16 November 2007

Additional Selection Options for FCT

I have a lack of energy
9 - Subject did not complete

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

Chronic GVHD

10. Maximum overall severity of chronic GVHD during this assessment period:*(FGSVCGVH)*
    - 0 - No Chronic GVHD
    - 1 - Mild
    - 2 - Moderate
    - 3 - Severe
11. 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.
12. Date of initial diagnosis/onset of chronic GVHD:*(FGCGDGDT)* _____ *(mm/dd/yyyy)*
13. 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
14. Minimum platelet count at time of diagnosis:*(FGDGPLT)* _____ *(xxxxxx)* /mm^3
15. Alkaline phosphatase at time of diagnosis:*(FGDGALKP)* _____ *(xxxx)* Units/L
16. Weight at time of diagnosis:*(FGDGWGT)* _____ *(xxx.x)* kg
17. Total bilirubin at time of diagnosis:*(FGDGBILI)* _____ *(xx.x)* mg/dL
18. Did the patient have an erythematous or maculopapular rash at the time of diagnosis? *(FGRSDIAG)* ☐ 1 - Yes ☐ 2 - No
19. 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

20. 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

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

Oral

22. 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

23. Bronchiolitis obliterans:*(FGBRNCH)*
    - 1 - Yes, Histologic diagnosis
    - 2 - Yes, Clinical diagnosis
    - 3 - No
    - 4 - Unknown

24. FEV1:*(FGFEV1VL)* _____ *(xxx)* %

Record the lowest value during this assessment period.

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

26. FVC:*(FGFVCVL)* _____ *(xxx)* %

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

27. DLCO:*(FGDLCOVL)* _____ *(xxx)* %

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

Gastrointestinal

28. Esophagus:*(FGESOPH)*
    - 0 - No Symptoms
    - 1 - Symptoms, Confirmed with Diagnostic Procedure

29. Nausea and vomiting:*(FGNAUSVM)*
    - 0 - No Protracted Nausea and Vomiting
    - 1 - Persistent Nausea, Vomiting or Anorexia

30. 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
31. Bilirubin:	*(FGBILI)* _____ *(xx.x)* mg/dL	*(FGBILIDT)* _____ *(mm/dd/yyyy)*
32. ALT:	*(FGALT)* _____ *(xxxx)* Units/L	*(FGALTDT)* _____ *(mm/dd/yyyy)*
33. AST:	*(FGAST)* _____ *(xxxx)* Units/L	*(FGASTDT)* _____ *(mm/dd/yyyy)*
34. Alkaline Phosphatase:	*(FGALKPH)* _____ *(xxxx)* Units/L	*(FGAKPHDT)* _____ *(mm/dd/yyyy)*

Genitourinary

35. 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

36. Contractures:*(FGCONTRC)*

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

37. Myositis:*(FGMYOSIT)* ☐ 1 - Yes ☐ 2 - No

Hematologic

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

Other

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

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

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

Specify other organ involvement:*(FGOTORSP)*

Biopsies Performed During this Assessment Period

42. 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:
43. *(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
44. *(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
45. *(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
46. *(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
47. *(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
48. *(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

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

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

Medication Form - 1501 (M10)

Web Version: 1.0; 4.01; 02-20-18

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

Start of the assessment period:*(M10STDT)* *(mm/dd/yyyy)*

End of the assessment period:*(M10ENDDT)* *(mm/dd/yyyy)*

1. Record weight used to determine initiation of study therapy:*(M10WTKG)* *(xxx.x)* kg

Sirolimus

2. Did the patient receive sirolimus during this assessment period?*(M10SRREC)* 1 - Yes 2 - No
3. Date the patient first used sirolimus:*(M10SRIDT)* *(mm/dd/yyyy)*
4. Time the patient first used sirolimus:*(M10SRITM)* *(hh:mm)*
5. Is the patient currently receiving sirolimus?*(M10SRCUR)* 1 - Yes 2 - No
6. Did the patient stop receiving sirolimus during this assessment period?*(M10SRSTP)* 1 - Yes 2 - No
7. Date sirolimus stopped:*(M10SRSDT)* *(mm/dd/yyyy)*
8. Reason sirolimus stopped:*(M10SRREA)*
   - 01 - Toxicity
   - 02 - Acute GVHD Progression/Flare
   - 03 - Chronic GVHD
   - 04 - Insufficient Response
   - 05 - Taper Completed
   - *Additional Options Listed Below
9. If physician decision or other specify:*(M10SRRSP)*
10. Did the patient restart sirolimus during this assessment period?*(M10SRRES)* 1 - Yes 2 - No
11. Date sirolimus restarted:*(M10SRRDT)* *(mm/dd/yyyy)*
12. Record most recent trough level:*(M10SRTRL)* *(xx.xx)* ng/mL
13. Date of trough level:*(M10SRTDT)* *(mm/dd/yyyy)*

Prednisone or Equivalent

14. Did the patient receive prednisone or equivalent during this assessment period?*(M10PRREC)* 1 - Yes 2 - No
15. Date the patient first used prednisone or equivalent:*(M10PRIDT)* *(mm/dd/yyyy)*
16. Time the patient first used prednisone or equivalent:*(M10PRITM)* *(hh:mm)*
17. Is the patient currently receiving prednisone or equivalent?*(M10PRCUR)* 1 - Yes 2 - No
18. Did the patient stop receiving prednisone or equivalent during this assessment period?*(M10PRSTP)* 1 - Yes 2 - No
19. Date prednisone or equivalent stopped:*(M10PRSDT)* *(mm/dd/yyyy)*
20. Reason prednisone or equivalent stopped:*(M10PRREA)*
    - 01 - Toxicity
    - 02 - Acute GVHD Progression/Flare
    - 03 - Chronic GVHD
    - 04 - Insufficient Response
    - 05 - Taper Completed
    - *Additional Options Listed Below
21. If physician decision or other specify:*(M10PRRSP)*
22. Did the patient restart prednisone or equivalent during this assessment period?*(M10PRRES)* 1 - Yes 2 - No
23. Date prednisone or equivalent restarted:*(M10PRRDT)* *(mm/dd/yyyy)*

24. Prednisone or equivalent dosing:

	Minimum Dose During Assessment Period	Maximum Dose During Assessment Period	Current Dose
Steroid	*(M10PRMNM)* 1 - Prednisone; 2 - Methylprednisolone; 3 - Prednisolone	*(M10PRMXM)* 1 - Prednisone; 2 - Methylprednisolone; 3 - Prednisolone	*(M10PRCUM)* 1 - Prednisone; 2 - Methylprednisolone; 3 - Prednisolone
Dose Schedule	*(M10PRMNS)* 1 - Daily; 2 - Alternating Days	*(M10PRMXS)* 1 - Daily; 2 - Alternating Days	*(M10PRCUS)* 1 - Daily; 2 - Alternating Days
Dose 1	*(M10PRN1S)* *(xx.xx)* mg/kg/day	*(M10PRX1S)* *(xx.xx)* mg/kg/day	*(M10PRC1S)* *(xx.xx)* mg/kg/day
Dose 1 Date	*(M10PN1DT)* *(mm/dd/yyyy)*	*(M10PX1DT)* *(mm/dd/yyyy)*	*(M10PC1DT)* *(mm/dd/yyyy)*
Dose 2	*(M10PRN2S)* *(xx.xx)* mg/kg/day	*(M10PRX2S)* *(xx.xx)* mg/kg/day	*(M10PRC2S)* *(xx.xx)* mg/kg/day
Dose 2 Date	*(M10PN2DT)* *(mm/dd/yyyy)*	*(M10PX2DT)* *(mm/dd/yyyy)*	*(M10PC2DT)* *(mm/dd/yyyy)*

Additional Systemic Immunosuppression Therapy

25. Did the patient receive additional systemic immunosuppression therapy during this assessment period? *(M10ADDTH)* ☐ 1 - Yes ☐ 2 - No

26. How many systemic immunosuppression therapy medications has the patient taken during this assessment period? *(M10ADDNM)* _____ *(x)*

Include all agents given even if stopped during the assessment period.

If there are more than 9 additional therapies, please enter them in the Comments section.

27. Additional Systemic Immunosuppression:

Medication Name	If Other, Specify	Reason	Started	Date Started	Stopped During This Assessment Period	Date Stopped
(M10MD1OT) 01 - MMF 02 - Cyclosporine 03 - Tacrolimus 04 - Methotrexate 05 - ATG *Additional Options Listed Below	*(M10MD1SP)*	*(M10M1RSN)* GVHD Prophylaxis Acute GVHD Treatment Chronic GVHD Treatment Overlap Syndrome Other	*(M10MD1S)* ☐ Continued From Prior Assessment ☐ Started This Assessment Period	*(M10M1SDT)* *(mm/dd/yyyy)*	*(M10MD1E)* ☐ 1 - Yes ☐ 2 - No	*(M10M1EDT)* *(mm/dd/yyyy)*
(M10MD2OT) 01 - MMF 02 - Cyclosporine 03 - Tacrolimus 04 - Methotrexate 05 - ATG *Additional Options Listed Below	*(M10MD2SP)*	*(M10M2RSN)* GVHD Prophylaxis Acute GVHD Treatment Chronic GVHD Treatment Overlap Syndrome Other	*(M10MD2S)* ☐ Continued From Prior Assessment ☐ Started This Assessment Period	*(M10M2SDT)* *(mm/dd/yyyy)*	*(M10MD2E)* ☐ 1 - Yes ☐ 2 - No	*(M10M2EDT)* *(mm/dd/yyyy)*
(M10MD3OT) 01 - MMF 02 - Cyclosporine 03 - Tacrolimus 04 - Methotrexate 05 - ATG *Additional Options Listed Below	*(M10MD3SP)*	*(M10M3RSN)* GVHD Prophylaxis Acute GVHD Treatment Chronic GVHD Treatment Overlap Syndrome Other	*(M10MD3S)* ☐ Continued From Prior Assessment ☐ Started This Assessment Period	*(M10M3SDT)* *(mm/dd/yyyy)*	*(M10MD3E)* ☐ 1 - Yes ☐ 2 - No	*(M10M3EDT)* *(mm/dd/yyyy)*
(M10MD4OT) 01 - MMF 02 - Cyclosporine 03 - Tacrolimus 04 - Methotrexate 05 - ATG *Additional Options Listed Below	*(M10MD4SP)*	*(M10M4RSN)* GVHD Prophylaxis Acute GVHD Treatment Chronic GVHD Treatment Overlap Syndrome Other	*(M10MD4S)* ☐ Continued From Prior Assessment ☐ Started This Assessment Period	*(M10M4SDT)* *(mm/dd/yyyy)*	*(M10MD4E)* ☐ 1 - Yes ☐ 2 - No	*(M10M4EDT)* *(mm/dd/yyyy)*
(M10MD5OT) 01 - MMF 02 - Cyclosporine 03 - Tacrolimus 04 - Methotrexate 05 - ATG *Additional Options Listed Below	*(M10MD5SP)*	*(M10M5RSN)* GVHD Prophylaxis Acute GVHD Treatment Chronic GVHD Treatment Overlap Syndrome Other	*(M10MD5S)* ☐ Continued From Prior Assessment ☐ Started This Assessment Period	*(M10M5SDT)* *(mm/dd/yyyy)*	*(M10MD5E)* ☐ 1 - Yes ☐ 2 - No	*(M10M5EDT)* *(mm/dd/yyyy)*
(M10MD6OT) 01 - MMF 02 - Cyclosporine 03 - Tacrolimus 04 - Methotrexate 05 - ATG *Additional Options Listed Below	*(M10MD6SP)*	*(M10M6RSN)* GVHD Prophylaxis Acute GVHD Treatment Chronic GVHD Treatment Overlap Syndrome Other	*(M10MD6S)* ☐ Continued From Prior Assessment ☐ Started This Assessment Period	*(M10M6SDT)* *(mm/dd/yyyy)*	*(M10MD6E)* ☐ 1 - Yes ☐ 2 - No	*(M10M6EDT)* *(mm/dd/yyyy)*
(M10MD7OT) 01 - MMF 02 - Cyclosporine 03 - Tacrolimus 04 - Methotrexate 05 - ATG *Additional Options Listed Below	*(M10MD7SP)*	*(M10M7RSN)* GVHD Prophylaxis Acute GVHD Treatment Chronic GVHD Treatment Overlap Syndrome Other	*(M10MD7S)* ☐ Continued From Prior Assessment ☐ Started This Assessment Period	*(M10M7SDT)* *(mm/dd/yyyy)*	*(M10MD7E)* ☐ 1 - Yes ☐ 2 - No	*(M10M7EDT)* *(mm/dd/yyyy)*
(M10MD8OT) 01 - MMF 02 - Cyclosporine 03 - Tacrolimus 04 - Methotrexate 05 - ATG *Additional Options Listed Below	*(M10MD8SP)*	*(M10M8RSN)* GVHD Prophylaxis Acute GVHD Treatment Chronic GVHD Treatment Overlap Syndrome Other	*(M10MD8S)* ☐ Continued From Prior Assessment ☐ Started This Assessment Period	*(M10M8SDT)* *(mm/dd/yyyy)*	*(M10MD8E)* ☐ 1 - Yes ☐ 2 - No	*(M10M8EDT)* *(mm/dd/yyyy)*
(M10MD9OT)	*(M10MD9SP)*	*(M10M9RSN)* GVHD Prophylaxis Acute GVHD Treatment Chronic GVHD Treatment Overlap Syndrome Other	*(M10MD9S)* ☐ Continued From Prior Assessment ☐ Started This Assessment Period	*(M10M9SDT)* *(mm/dd/yyyy)*	*(M10MD9E)* ☐ 1 - Yes ☐ 2 - No	*(M10M9EDT)* *(mm/dd/yyyy)*

01 - MMF 02 - Cyclosporine 03 - Tacrolimus 04 - Methotrexate 05 - ATG *Additional Options Listed Below						

28. Did the patient use topical steroids during this assessment period?*(M10TOPST)*

1 - Yes, Started This Assessment Period
2 - Yes, Started Prior to This Assessment Period
3 - No

29. Date the patient first used topical steroids:*(M10TOPDT)*

(mm/dd/yyyy)

30. Did the patient use non-absorbed oral steroids (budesonide, entocort, decadron mouthwash) during this assessment period? *(M10ORLST)*

1 - Yes, Started This Assessment Period
2 - Yes, Started Prior to This Assessment Period
3 - No

31. Date the patient first used non-absorbed oral steroids:*(M10ORLDT)*

(mm/dd/yyyy)

Comments:*(M10COMM)*

Additional Selection Options for M10

Reason sirolimus stopped:
06 - Underlying Malignancy Progression/Relapse
07 - Infection
08 - Patient Refused
09 - Physician Decision
99 - Other

Other Medication Taken 1
06 - Rituximab
07 - Infliximab
08 - Etanercept
09 - Azathioprine
10 - Ontak
11 - ECP
12 - PUVA
99 - Other

M.D. Anderson Symptom Inventory (MDA)

Web Version: 1.0; 3.04; 10-16-15

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

Date M.D. Anderson Symptom Inventory was completed by the patient:*(MDACOMDT)* *(mm/dd/yyyy)*

Date M.D. Anderson Symptom Inventory was completed by the patient:*(MDACOMDT)* *(mm/dd/yyyy)*

Is the patient ≥ 18 years old?*(MDA18OLD)* ☐ 1 - Yes ☐ 2 - No

If no, please indicate if the form was completed by the patient or the patient's guardian: *(MDAPAREN)* ☐ 1 - Patient ☐ 2 - Guardian

Part I. How severe are the reported symptoms?

Complete the following questions regarding the patient's symptoms within 24 hours. Please rate the symptoms on a scale of 0 (not present) to 10 (as bad as imaginable).

1. Pain at its worst?*(MDAPAIN)*
2. Fatigue at its worst?*(MDAFATIG)*
3. Nausea at its worst?*(MDANAUSE)*
4. Disturbed sleep at its worst?*(MDASLEEP)*
5. Feelings of being distressed at its worst?*(MDADISTR)*
6. Shortness of breath at its worst?*(MDASOB)*
7. Problem with remembering things at its worst?*(MDAREMEM)*
8. Problem with lack of appetite at its worst?*(MDAAPPET)*
9. Feeling drowsy at its worst?*(MDADROWS)*

0
1
2
3
4
*Additional Options Listed Below

10. Having a dry mouth at its worst?*(MDADRYM)*

11. Feeling sad at its worst?*(MDASAD)*

12. Vomiting at its worst?*(MDAVOMIT)*

13. Numbness or tingling at its worst?*(MDANUMB)*

0
1
2
3
4
*Additional Options Listed Below

Part II. How have symptoms interfered with the patient's life?

Complete the following questions regarding the frequency of interference in the patient's life within 24 hours. Please rate the level of interference on a scale of 0 (did not interfere) to 10 (interfered completely).

14. General activity?*(MDAGENAC)*

15. Mood?*(MDAMOOD)*

16. Work (including work around the house)?*(MDAWORK)*

17. Relations with other people?*(MDARELA)*

18. Walking?*(MDAWALK)*

19. Enjoyment of life?*(MDAENJOY)*

0
1
2
3
4
*Additional Options Listed Below

Additional Selection Options for MDA

Pain at its worst?
5
6
7
8
9
10

General activity?
5
6
7
8
9
10

Blood and Marrow Transplant Clinical Trials Network

Functional Myopathy Form (MYP)

Web Version: 1.0; 2.00; 10-25-16

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

A. Adult Myopathy Assessment Tool (AMAT, abbreviated test)

1. Record the date of the Functional Myopathy Test:*(MYPTSTDT)* _____ *(mm/dd/yyyy)*

2. Arm Raise Test:*(MYPART)*
   - 0 - Unable to raise arms above shoulder level (acromioclavicular joint)
   - 1 - Hands raised between shoulder level (acromioclavicular joint) and top of head
   - 2 - Hands raised above top of the head with elbows bent
   - 3 - Hands raised above top of head with elbows straight (extended)

3. Arm Raise Endurance:*(MYPARMEN)*
   - 0 - Unable to do or < 5 seconds
   - 1 - 5-30 seconds
   - 2 - 31-60 seconds
   - 3 - 61-90 seconds
   - 4 - >90 seconds

4. Sit to Stand:*(MYPSTSTN)*
   - 0 - Unable to do
   - 1 - Completes transfer with two or more extremities in contact with the exam table or thigh
   - 2 - Completes transfer with one extremity in contact with the exam table or thigh
   - 3 - Completes transfer without contact of any extremity with the exam table or thigh

5. Hip Flexion Endurance:*(MYPHPFLX)*
   - 0 - Unable to do or < 5 seconds
   - 1 - 5-30 seconds
   - 2 - 31-60 seconds
   - 3 - 61-90 seconds
   - 4 - >90 seconds

6. Knee Extension Endurance:*(MYPKNEX)*
   - 0 - Unable to do or < 5 seconds
   - 1 - 5-30 seconds
   - 2 - 31-60 seconds
   - 3 - 61-90 seconds
   - 4 - >90 seconds

7. Total AMAT Score: Summation of the 5 above components (out of a possible 18):*(MYPAMSCR)* _____ *(xx)*

B. Hip Flexor and Quadriceps Strength via Handheld Dynamometer (HHD)

8. Hip Flexion Score:

	Right HF	Left HF
Measurement #1	*(MYPRTHF1)* _____ *(xx)*	*(MYPLTHF1)* _____ *(xx)*
Measurement #2	*(MYPRTHF2)* _____ *(xx)*	*(MYPLTHF2)* _____ *(xx)*
Average ((#1 + #2)/2)	*(MYPRTHFA)* _____ *(xx.x)*	*(MYPLTHFA)* _____ *(xx.x)*

9. Knee Extension Score:

	Right KE	Left KE
Measurement #1	*(MYPRTKE1)* _____ *(xx)*	*(MYPLTKE1)* _____ *(xx)*
Measurement #2	*(MYPRTKE2)* _____ *(xx)*	*(MYPLTKE2)* _____ *(xx)*
Average ((#1 + #2)/2)	*(MYPRTKEA)* _____ *(xx.x)*	*(MYPLTKEA)* _____ *(xx.x)*

C. Two Minute Walk Test

10. Was the patient able to complete this test?*(MYPWKTST)* ☐ 1 - Yes ☐ 2 - No

11. Specify reason:*(MYPWKSP)*
    - 1 - Age
    - 2 - Fatigued
    - 3 - Dizzy
    - 4 - Pain
    - 5 - Immobile
    - *Additional Options Listed Below

Specify other:*(MYPWOSP)* _____

12. Did the patient use a mobility aid?*(MYPWKAID)* ☐ 1 - Yes ☐ 2 - No

13. Specify mobility aid:*(MYPAIDSP)*

1 - Walker
2 - Cane
3 - IV Pole
4 - Wheelchair/Scooter
9 - Other, Specify

Specify other:*(MYPADOSP)*

14. Dyspnea rating prior to walk:*(MYPDYSRT)*

0 - Nothing at all
0.5 - Very, very slight (just noticeable)
1 - Very slight
2 - Slight (light)
3 - Moderate
*Additional Options Listed Below

15. Fatigue rating prior to walk:*(MYPFATG)*

0 - Nothing at all
0.5 - Very, very slight (just noticeable)
1 - Very slight
2 - Slight (light)
3 - Moderate
*Additional Options Listed Below

16. Distance walked:*(MYPDSTWK)* *(xxx)* m

17. Dyspnea rating post walk:*(MYPDYSPW)*

0 - Nothing at all
0.5 - Very, very slight (just noticeable)
1 - Very slight
2 - Slight (light)
3 - Moderate
*Additional Options Listed Below

18. Fatigue rating post walk:*(MYPFTGPW)*

0 - Nothing at all
0.5 - Very, very slight (just noticeable)
1 - Very slight
2 - Slight (light)
3 - Moderate
*Additional Options Listed Below

D. 5X Sit to Stand Test

19. Was the patient able to complete this test?*(MYPSSTST)* 1 - Yes 2 - No

20. Specify reason:*(MYPSSTSP)*

1 - Age
2 - Fatigued
3 - Dizzy
4 - Pain
5 - Immobile
*Additional Options Listed Below

Specify other:*(MYPSSOSP)*

21. Sit to stand time:*(MYPSSTM)* *(xxx)* sec

Comments:*(MYPCOMM)*

Additional Selection Options for MYP

Specify reason:
9 - Other, Specify

Dyspnea rating prior to walk:
4 - Somewhat severe
5 - Severe (heavy)
6 -
7 - Very severe
8 -
9 -
10 - Very, very severe (maximal)

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

Protocol Deviation/Violation Review Form (PDR)

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

Segment *(PROTSEG)*: A
Deviation/Violation Date *(PDDATE)*:
Deviation/Violation Num *(PDSEQNUM)*:

1. Date event reviewed:*(PDREVDT)* _____ *(mm/dd/yyyy)*
2. Event summary:*(PDREVSUM)*
3. Does the event qualify as a reportable protocol deviation/violation?*(PDRQUAL)* ☐ 1 - Yes ☐ 2 - No
4. Confirm deviation/violation category:*(PDRCATEG)*

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

   Specify other:*(PDRCATSP)*
5. Confirm reason for deviation/violation:*(PDRREASN)*

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

   Specify other:*(PDRRSNSP)*
6. Is this event reportable to the DSMB?*(PDRDSMB)* ☐ 1 - Yes ☐ 2 - No
7. Date to be reported to the DSMB:*(PDRDSMSF)* ☐ Spring ☐ Fall Year:*(PDRDSMYR)* _____ *(xxxx)*
8. Will this event be included in the Core Consortia Center Performance Report?*(PDRCCCPR)* ☐ 1 - Yes ☐ 2 - No
9. Does this event require additional site re-training or a CAPA?*(PDRCAPA)* ☐ 1 - Yes ☐ 2 - No

   If yes, specify:*(PDRCAPSP)*
10. Review complete?*(PDRRECOM)* ☐ 1 - Yes ☐ 2 - No
11. BMT CTN Project Director reviewed?*(PDRPDREV)* ☐ 1 - Yes ☐ 2 - No

Comments:*(PDRCOMM)*

Additional Selection Options for PDR

Deviation/Violation Num *(PDSEQNUM)* (key field):
01 - 1st Deviation/Violation of the Day
02 - 2nd Deviation/Violation of the Day
03 - 3rd Deviation/Violation of the Day
04 - 4th Deviation/Violation of the Day
05 - 5th Deviation/Violation of the Day
06 - 6th Deviation/Violation of the Day
07 - 7th Deviation/Violation of the Day
08 - 8th Deviation/Violation of the Day
09 - 9th Deviation/Violation of the Day
10 - 10th Deviation/Violation of the Day

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

Confirm reason for deviation/violation:
99 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Protocol Deviation/Violation Form (PDV)

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

Segment *(PROTSEG)*: A
Deviation/Violation Date *(PDDATE)*:
Deviation/Violation Num *(PDSEQNUM)*:

1. Date deviation/violation identified:*(PDVIDTDT)* *(mm/dd/yyyy)*
2. Record deviation/violation category:*(PDVCATEG)*
   - 01 - Treatment Assignment
   - 02 - Treatment Administration
   - 03 - Unblinding
   - 04 - Eligibility
   - 05 - Consent Related
   - *Additional Options Listed Below

   Specify other:*(PDVCATSP)*
3. Record reason for deviation/violation:*(PDVREASO)*
   - 01 - Clinic Error
   - 02 - Pharmacy Error
   - 03 - Physician or PI Decision
   - 04 - Subject Refusal
   - 05 - Subject Compliance Error
   - *Additional Options Listed Below

   Specify other:*(PDVREASP)*
4. Deviation/violation description:*(PDVDESCR)*
5. Did the deviation/violation result in the discontinuation of study therapy?*(PDVSTDIS)* ☐ 1 - Yes ☐ 2 - No

   Note: The patient must still be followed for all endpoints regardless of whether the patient continues to receive study therapy.
6. Does the deviation/violation meet IRB of record reporting requirements?*(PDVIRBRE)* ☐ 1 - Yes ☐ 2 - No
   7. Specify type of notification to the IRB per institutional policy:*(PDVIRBOU)*
      - 1 - Expedited Reporting
      - 2 - Reportable at Time of Annual Review

   8. Expedited reporting date:*(PDVIRBDT)* *(mm/dd/yyyy)*
9. Was any corrective action taken?*(PDVCORRC)* ☐ 1 - Yes ☐ 2 - No
   10. Record corrective action:*(PDVCORSP)*

   Comments:*(PDVCOMM)*

Additional Selection Options for PDV

Deviation/Violation Num *(PDSEQNUM)* (key field):
01 - 1st Deviation/Violation of the Day
02 - 2nd Deviation/Violation of the Day
03 - 3rd Deviation/Violation of the Day
04 - 4th Deviation/Violation of the Day
05 - 5th Deviation/Violation of the Day
06 - 6th Deviation/Violation of the Day
07 - 7th Deviation/Violation of the Day
08 - 8th Deviation/Violation of the Day
09 - 9th Deviation/Violation of the Day
10 - 10th Deviation/Violation of the Day

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

Record reason for deviation/violation:
99 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

PedsQL Pediatric Quality of Life Survey (PQL)

Web Version: 1.0; 1.00; 03-16-16

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

1. Date of assessment:*(PQLDT)* _____ *(mm/dd/yyyy)*
2. Age of patient at time of survey completion:*(PQLPTAGE)* ☐ 1 - Ages 8-12 ☐ 2 - Ages 13-18

In the past **ONE month,** how much of a **problem** has this been for you…

Pain and Hurt (problems with...)	Never	Almost Never	Some-times	Often	Almost Always	
1. I ache or hurt in my muscles and/or joints:	*(PQLACHE)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
2. I ache or hurt:	*(PQLHURT)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered

I ache or hurt...
(please indicate where you ache or hurt): *(PQLHURSP)* _____

Fatigue and Sleep (problems with...)	Never	Almost Never	Some-times	Often	Almost Always	
1. I feel tired:	*(PQLTIRED)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
2. I feel physically weak:	*(PQLWEAK)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
3. It is hard for me to sleep through the night:	*(PQLHDSLP)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
4. I have to sleep a lot:	*(PQLSLLOT)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
5. I feel too tired to do things that I like to do:	*(PQLLIKE)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered

Nausea (problems with...)	Never	Almost Never	Some-times	Often	Almost Always	
1. I become sick to my stomach when I have medical treatments:	*(PQLHVMED)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
2. Some foods and smells make me sick to my stomach:	*(PQLFOOD)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
3. I become sick to my stomach when I think of medical treatments:	*(PQLTHINK)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
4. Because I feel sick to my stomach, I do not want to be approached:	*(PQLAPRCH)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered

Worry (problems with...)	Never	Almost Never	Some-times	Often	Almost Always	
1. I worry about side effects from medical treatment:	*(PQLEFFCT)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
2. I worry about whether or not my medical treatments have been or are working:	*(PQLWRKNG)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
3. I get scared when I have to go to the hospital:	*(PQLHOSP)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
4. I am scared of infections:	*(PQLINFXN)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
5. I worry about whether I will grow properly:	*(PQLGROW)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
6. I get scared about needle sticks (e.g. injections, blood tests, IVs):	*(PQLNEEDL)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
7. I think about a later desire to have a child:	*(PQLCHILD)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
8. I worry that my disease will come back or relapse:	*(PQLRLPS)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
9. I worry about whether I can return smoothly into normal life:	*(PQLNORML)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
10. I do not like that my body looks different to that of healthy children or adolescents:	*(PQLBODY)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
11. I worry about whether other people do not want me because of my disease:	*(PQLWANT)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
12. I worry about reaching puberty at the right time:	*(PQLPUBTY)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered

Nutrition (problems with...)	Never	Almost Never	Some-times	Often	Almost Always	
1. Food does not taste very good to me:	*(PQLTASTE)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
2. I am not hungry:	*(PQLHUNGR)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered

3. I have to drink a lot when chewing food:	*(PQLDRINK)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
4. I have constipation:	*(PQLCONST)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
5. I have diarrhea:	*(PQLDIARR)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered

Thinking (problems with...)	Never	Almost Never	Some-times	Often	Almost Always	
1. It is hard for me to remember things that I have heard:	*(PQLHEARD)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
2. It is hard for me to figure out what to do when something bothers me:	*(PQLBOTHR)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
3. It is hard for me to keep my attention on things for a longer time:	*(PQLATTN)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
4. It is hard for me to remember things that I have read:	*(PQLREAD)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered

Communication (problems with...)	Never	Almost Never	Some-times	Often	Almost Always	
1. It is hard for me to ask the doctors or nurses questions:	*(PQLASKQ)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
2. It is hard for me to tell doctors or nurses how I feel:	*(PQLTELL)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
3. It is hard for me to talk about my disease with other people:	*(PQLTALK)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered

Other Complaints (problems with...)	Never	Almost Never	Some-times	Often	Almost Always	
1. I have pruritus:	*(PQLPRURI)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
2. I have painful skin infections:	*(PQLSKIN)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
3. I have a dry mouth:	*(PQLDRMTH)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
4. I have dry or burning eyes:	*(PQLEYE)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
5. I feel lonely:	*(PQLLONE)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered
6. It is hard for me to breathe or I am short of breath:	*(PQLSOB)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ Not Answered

Comments:*(PQLCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Patient Status Change Form (PSF)

Web Version: 1.0; 1.01; 05-23-17

Segment *(PROTSEG)*: A
Status *(STATUS)*:
Status Change Number *(STATSEQ)*:

1. If the patient was withdrawn from the study by physician decision, record the reason:*(PSWDRSN)*

If the patient was withdrawn due to toxicity, specify the toxicity.

2. Record the date the patient was withdrawn from the study:*(PSWDDT)* *(mm/dd/yyyy)*

3. Did withdrawal of the patient result in the discontinuation of an investigational study drug?*(PSWDDRG)* ☐ 1 - Yes ☐ 2 - No

4. Name of the discontinued investigational study drug:*(PSWDDGNM)*

5. Date of the last dose of investigational study drug:*(PSWDDGDT)* *(mm/dd/yyyy)*

1. If the patient was lost to follow up, record the date of last contact:*(PSCNTDT)* *(mm/dd/yyyy)*

1. If an investigational study drug was permanently discontinued, record the reason:*(PSDRGRSN)*

- 1 - Toxicity
- 2 - Disease Relapse or Progression
- 3 - Pregnancy
- 4 - Patient Withdrew Consent
- 9 - Other, Specify

Specify toxicity:*(PSTXYSP)*

Specify other:*(PSDGOTSP)*

2. Name of the discontinued investigational study drug:*(PSDRGNM)*

3. Date of the last dose of investigational study drug:*(PSDRGDT)* *(mm/dd/yyyy)*

1. If the patient did not proceed to the next protocol segment, record the reason: *(PSSEGRSN)*

- 1 - Patient Did Not Meet Segment Eligibility Criteria
- 2 - Patient Withdrew Consent
- 3 - Donor Issue
- 4 - Insurance Issue
- 9 - Other, Specify

Specify the eligibility criteria not met:*(PSELGYSP)*

Specify other:*(PSSEGOSP)*

1. If the patient did not receive transplant, record the reason:*(PSTXPRN)*

- 1 - Toxicity
- 2 - Disease Relapse or Progression
- 3 - Pregnancy
- 4 - Patient Withdrew Consent
- 5 - Donor Issue
- *Additional Options Listed Below

Specify toxicity:*(PSTXPTSP)*

Specify other:*(PSTXPOSP)*

Patient follow up may still be required. Contact the BMT CTN protocol coordinator to verify what is needed.

Comments:*(PSCOMM)*

Additional Selection Options for PSF

Status *(STATUS)* (key field):
01 - Patient withdrawn from study by physician decision
02 - Patient lost to follow up
03 - Investigational study drug permanently discontinued
04 - Patient did not proceed to next protocol segment
05 - Patient did not receive transplant

Status Change Number *(STATSEQ)* (key field):
01
02
03
04
05

If the patient did not receive transplant, record the reason:
6 - Insurance Issue
9 - Other, Specify

Blood and Marrow Transplant Clinical Trials Network

Endpoint Review Query Form - 1501 (Q14)

Web Version: 1.0; 1.00; 03-06-18

Case ID *(CASEID)*:

Site:*(QXXSITE)*

Patient ID:*(QXXPATID)*

Number of queries indicated:*(QRYNUM)*

Queries

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

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

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

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

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT05) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT05)* *(mm/dd/yyyy)*	*(QDESC05)*	*(QRSPDT05)* *(mm/dd/yyyy)*	*(QRSPNS05)*

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Specimen Acquisition Form - 1501 (S16)

Web Version: 1.0; 2.00; 04-04-17

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

Optional Patient Samples for Future Testing

1. Was a serum sample drawn for future Proteomic and miRNA Biomarker research?*(S16SERUM)* ☐ 1 - Yes ☐ 2 - No
2. Date serum sample was collected:*(S16SERDT)* _____ *(mm/dd/yyyy)*
3. Was the serum sample collected prior to the initiation of randomized therapy?*(S16SERTH)* ☐ 1 - Yes ☐ 2 - No
4. Was a Whole Blood sample collected for future Gene Expression Profile research?*(S16WHOBL)* ☐ 1 - Yes ☐ 2 - No
5. Date Whole Blood sample was collected:*(S16WBLDT)* _____ *(mm/dd/yyyy)*
6. Was the Whole Blood sample collected prior to the initiation of randomized therapy? *(S16WBLTH)* ☐ 1 - Yes ☐ 2 - No
7. Was a PBMC sample collected for future Immune Reconstitution research?*(S16PBMC)* ☐ 1 - Yes ☐ 2 - No
8. Date PBMC sample was collected:*(S16PBMDT)* _____ *(mm/dd/yyyy)*
9. Was the PBMC sample collected prior to the initiation of randomized therapy?*(S16PBMTH)* ☐ 1 - Yes ☐ 2 - No

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

Comments:*(S16COMM)*

Blood and Marrow Transplant Clinical Trials Network

SF36 Quality of Life (SFH)

Web Version: 1.0; 3.06; 12-08-15

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

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer each question by selecting the best choice. If you are unsure about how to answer a question, please give the best answer you can.

Date of Evaluation:*(SF36DATE)* _____ *(mm/dd/yyyy)*

1. In general, would you say your health is:*(GENHLTH)*

- 1 - Excellent
- 2 - Very Good
- 3 - Good
- 4 - Fair
- 5 - Poor
- *Additional Options Listed Below

2. Compared to one year ago, how would you rate your health in general now?*(COMPARE)*

- 1 - Much better now than one year ago
- 2 - Somewhat better now than one year ago
- 3 - About the same as one year ago
- 4 - Somewhat worse than one year ago
- 5 - Much worse than one year ago
- *Additional Options Listed Below

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Activities	Amount of Limitation
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	*(VIGOROUS)*
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	*(MODERATE)*
c. Lifting or carrying groceries	*(LIFTING)*
d. Climbing several flights of stairs	*(CLINBSEV)*
e. Climbing one flight of stairs	*(CLIMBONE)*
f. Bending, kneeling, or stooping	*(BENDING)*
g. Walking more than one mile	*(WALKMILE)*
h. Walking several hundred yards	*(WALKSBLK)*
i. Walking one hundred yards	*(WALK1BLK)*

- 1 - Yes, limited a lot
- 2 - Yes, limited a little
- 3 - No, not limited at all
- 9 - Subject did not complete

j. Bathing or dressing yourself

(BATHING)
1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Cut down on the amount of time you spent on work or other activities *(CUTDOWN)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

b. Accomplished less than you would like *(ACCOMPL)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

c. Were limited in the kind of work or other activities *(LIMITED)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

d. Had difficulty performing the work or other activities (for example, it took extra effort) *(DIFFPERF)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems? (such as feeling depressed or anxious)

a. Cut down on the amount of time you spend on work or other activities *(EMOCUT)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

b. Accomplished less than you would like *(EMOACC)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

c. Did work or other activities less carefully than usual *(EMOLESS)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

6. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

a. Cut down on the amount of time you spent on work or other activities *(CUTTIME)*
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

b. Accomplished less than you would like *(LESSACC)*
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

c. Were limited in the kind of work or other activities *(WORKLMT)*
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

d. Had difficulty performing the work or other activities (for example, it took extra effort) *(PRFMDIFF)*
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

7. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

a. Cut down on the amount of time you spent on work or other activities *(ECUTTIME)*
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

b. Accomplished less than you would like *(ELESSACC)*
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

c. Did work or other activities less carefully than usual *(ECARELES)*
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

8. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?*(INTERFER)*

1 - Not at all
2 - Slightly
3 - Moderately
4 - Quite a bit
5 - Extremely
*Additional Options Listed Below

9. How much bodily pain have you had during the **past 4 weeks**?*(BODYPAIN)*

1 - None
2 - Very mild
3 - Mild
4 - Moderate
5 - Severe
*Additional Options Listed Below

10. During the **past 4 weeks**, how much did pain interfere with your normal work? (including both work outside the home and housework)*(WORKPAIN)*

1 - Not at all
2 - A little bit
3 - Moderately
4 - Quite a bit
5 - Extremely
*Additional Options Listed Below

11. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks**:

a. Did you feel full of pep?

1 - All of the time
2 - Most of the time
3 - A good bit of the time
4 - Some of the time
5 - A little of the time
*Additional Options Listed Below

(FULLPEP)

b. Have you been a very nervous person?

1 - All of the time
2 - Most of the time
3 - A good bit of the time
4 - Some of the time
5 - A little of the time
*Additional Options Listed Below

(NERVOUS)

c. Have you felt so down in the dumps that nothing could cheer you up?

1 - All of the time
2 - Most of the time
3 - A good bit of the time
4 - Some of the time
5 - A little of the time
*Additional Options Listed Below

(DUMPS)

d. Have you felt calm and peaceful?

1 - All of the time
2 - Most of the time
3 - A good bit of the time
4 - Some of the time
5 - A little of the time
*Additional Options Listed Below

(CALM)

e. Did you have a lot of energy?

1 - All of the time
2 - Most of the time
3 - A good bit of the time
4 - Some of the time
5 - A little of the time
*Additional Options Listed Below

(LOTSNRG)

f. Have you felt downhearted and blue?

1 - All of the time
2 - Most of the time
3 - A good bit of the time
4 - Some of the time
5 - A little of the time
*Additional Options Listed Below

(BLUE)

g. Did you feel worn out?

1 - All of the time
2 - Most of the time
3 - A good bit of the time
4 - Some of the time
5 - A little of the time
*Additional Options Listed Below

(WORNOUT)

h. Have you been a happy person?

1 - All of the time
2 - Most of the time
3 - A good bit of the time
4 - Some of the time
5 - A little of the time
*Additional Options Listed Below

(HAPPY)

i. Did you feel tired?

1 - All of the time
2 - Most of the time
3 - A good bit of the time
4 - Some of the time
5 - A little of the time
*Additional Options Listed Below

(TIRED)

j. Did you feel full of life?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

(FULLLIFE)

k. Have you been very nervous?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

(FEELNERV)

l. Have you felt so down in the dumps that nothing could cheer you up?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

(FEELDOWN)

m. Have you felt calm and peaceful?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

(FEELCALM)

n. Did you have a lot of energy?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

(FLENERGY)

o. Have you felt downhearted and depressed?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

(FEELDEPR)

p. Did you feel worn out?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

(FEELWORN)

q. Have you been happy?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

(FEELHAP)

r. Did you feel tired?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below

(FEELTIR)

12. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities? (like visiting friends, relatives, etc.)*(EMOTINT)*

- 1 - All of the time
- 2 - Most of the time
- 3 - A good bit of the time
- 4 - Some of the time
- 5 - A little of the time
- *Additional Options Listed Below

13. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)?*(INSOCIAL)*

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

14. How TRUE or FALSE is each of the following statements is for you?

a. I seem to get sick a little easier than other people*(SICKEASY)*

- 1 - Definitely true
- 2 - Mostly true
- 3 - Don't know
- 4 - Mostly false
- 5 - Definitely false
- *Additional Options Listed Below

b. I am as healthy as anybody I know*(HEALTHY)*

- 1 - Definitely true
- 2 - Mostly true
- 3 - Don't know
- 4 - Mostly false
- 5 - Definitely false
- *Additional Options Listed Below

c. I expect my health to get worse*(WORSE)*

- 1 - Definitely true
- 2 - Mostly true
- 3 - Don't know
- 4 - Mostly false
- 5 - Definitely false
- *Additional Options Listed Below

d. My health is excellent*(EXCLNT)*

- 1 - Definitely true
- 2 - Mostly true
- 3 - Don't know
- 4 - Mostly false
- 5 - Definitely false
- *Additional Options Listed Below

Additional Selection Options for SFH

In general, would you say your health is:
9 - Subject did not complete

Compared to one year ago, how would you rate your health in general now?
9 - Subject did not complete

4a. Time cut down
9 - Subject did not complete

During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
9 - Subject did not complete

How much bodily pain have you had during the past 4 weeks?
6 - Very severe
9 - Subject did not complete

During the past 4 weeks, how much did pain interfere with your normal work? (including both work outside the home and housework)
9 - Subject did not complete

9a. Full of pep
6 - None of the time
9 - Subject did not complete

I seem to get sick a little easier than other people
9 - Subject did not complete

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 1501 (T27)

Web Version: 1.0; 1.01; 09-07-16

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

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

Record the highest grade of toxicity diagnosed since the previous evaluation. The toxicity grades are based on the NCI CTCAE Version 4.02, American Heart Association, and protocol codes.
Record the highest grade of toxicity diagnosed in the past 7 days. The toxicity grades are based on the NCI CTCAE Version 4.02, American Heart Association, and protocol codes.

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

Renal Disorders

6. 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

7. 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

8. 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

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

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

Hemorrhagic Disorders

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

12. 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

13. Hypotension:*(HYPOTEN)*
    - 0 - Grades 0-2
    - 3 - Medical intervention or hospitalization indicated
    - 4 - Life-threatening and urgent intervention indicated
    - 5 - Death

14. 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

15. 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

16. Specify arrhythmia:*(CRDARRSP)*

17. 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

Nervous System Disorders

18. Headache:*(T27HEAD)*

0 - Grades 0-1
2 - Moderate pain; limiting instrumental ADL
3 - Severe pain; limiting self care ADL

19. Somnolence:*(SOMNOLN)*

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

20. Seizure:*(TXSEIZR)*

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

Blood and Lymphatic Disorders

21. Anemia:*(ANEMIA)*

0 - Grades 0-2
3 - Hgb <8.0-6.5g/dL; <4.9-4.0mmol/L; <80-65g/L; transfusion indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

22. 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

23. Thrombotic microangiopathy:*(T27TMA)*

0 - No evidence of TMA
1 - Evidence of RBC destruction (schistocytosis) without clinical consequences
2 - Evidence of RBC destruction with increased creatinine ≤ 3 x ULN
3 - Evidence of RBC destruction with creatinine > 3 x ULN not requiring dialysis
4 - Evidence of RBC destruction with renal failure requiring dialysis, and/or encephalopathy
*Additional Options Listed Below

Vascular Disorders

24. Capillary leak syndrome:*(CAPLKSYN)*

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

25. 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

26. 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

27. Arthralgia:*(T27ARTHR)*

0 - Grades 0-1
2 - Moderate pain; limiting instrumental ADL
3 - Severe pain; limiting self care ADL

Respiratory, Thoracic and Mediastinal Disorders

28. 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

29. 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

Metabolism and Nutrition Disorders

30. 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

31. Was the fasting glucose level greater than 126 mg/dL?*(T27FAST)* ☐ 1 - Yes ☐ 2 - No

32. Has the patient started or continued diabetes therapy?*(T27BLSGR)* ☐ 1 - Yes ☐ 2 - No

Chemistry/Investigations

33. Overall 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

34. Has the patient started or continued cholesterol lowering therapy? *(T27CHMED)* ☐ 1 - Yes ☐ 2 - No

35. Has the patient developed rhabdomyolysis?*(T27RHABD)* ☐ 1 - Yes ☐ 2 - No

36. LDL cholesterol:*(T27CHLDL)*
    - 0 - Less than 100 mg/dL
    - 1 - >100 mg/dL and <= 129 mg/dL
    - 2 - >=130 mg/dL and <= 159 mg/dL
    - 3 - >=160 mg/dL and <= 189 mg/dL
    - 4 - >=190 mg/dL

37. HDL cholesterol:*(T27CHHDL)*
    - 0 - > 60 mg/dL
    - 3 - <= 60 mg/dL and >=40 mg/dL
    - 4 - < 40 mg/dL

38. Triglycerides:*(T27TRIGL)*
    - 0 - <150 mg/dL
    - 1 - >=150 mg/dL - 199 mg/dL
    - 2 - >=200 mg/dL - 300 mg/dL
    - 3 - >300 mg/dL - 500 mg/dL
    - 4 - >500 mg/dL - 1000 mg/dL
    - *Additional Options Listed Below

39. Has the patient started or continued triglyceride lowering therapy? *(T27TRMED)* ☐ 1 - Yes ☐ 2 - No

Hepatic Disorders

40. ALT:*(TXALT)*
    - 0 - Grades 0-2
    - 3 - > 5.0 - 20.0 x ULN
    - 4 - > 20.0 x ULN

41. AST:*(TXAST)*
    - 0 - Grade 0-2
    - 3 - > 5.0 - 20.0 x ULN
    - 4 - > 20.0 x ULN

42. Bilirubin:*(TXBILIRB)*
    - 0 - Grades 0-2
    - 3 - >3.0-10.0 x ULN
    - 4 - >10.0 x ULN

43. 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:

44. Jaundice:*(TXJAUND)* ☐ 1 - Yes ☐ 2 - No

45. Hepatomegaly:*(HEPTMGLY)* ☐ 1 - Yes ☐ 2 - No

46. Right upper quadrant pain:*(RTQUADPN)* ☐ 1 - Yes ☐ 2 - No

47. Weight gain (>5%) from baseline:*(TXWGHTGN)* ☐ 1 - Yes ☐ 2 - No

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
48. VOD:	1 - Yes 2 - No *(VODETIOL)*	1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done *(VODBIOP)*	1 - Confirmed 2 - Not Confirmed 3 - Not Done *(VODDOPP)*
49. GVHD:	1 - Yes 2 - No *(GVHETIOL)*	1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done *(GVHBIOP)*	1 - Confirmed 2 - Not Confirmed 3 - Not Done *(GVHDOPP)*
50. Infection:	1 - Yes 2 - No *(INFETIOL)*	1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done *(INFBIOP)*	1 - Confirmed 2 - Not Confirmed 3 - Not Done *(INFDOPP)*
51. Other:	1 - Yes 2 - No *(OTHETIOL)*		

		1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done *(OTHBIOP)*	1 - Confirmed 2 - Not Confirmed 3 - Not Done *(OTHDOPP)*
52. Unknown:	1 - Yes 2 - No *(UNKETIOL)*	N/A	N/A

Specify other etiology:*(OTHETSP)*

Serious Adverse Event Reporting

53. Were there any toxicities that met the definition of a serious adverse event? *(SAEDFMET)* ☐ 1 - Yes ☐ 2 - No

54. Specify which toxicities met the definition of a serious adverse event: *(SAEDFSP)*

Comments:*(TXXCOMM)*

Additional Selection Options for T27

Thrombotic microangiopathy:
5 - Death

Triglycerides:
5 - >1000 mg/dL

Blood and Marrow Transplant Clinical Trials Network

Withdrawal of Consent Form (WOC)

Web Version: 1.0; 2.00; 02-20-18

Complete all questions based on the type(s) of consent withdrawn. If the patient withdraws further consent, update the form as necessary.

1. Did the patient withdraw consent to all study procedures?*(WOCSTP)* ☐ 1 - Yes ☐ 2 - No
2. Date patient withdrew consent:*(WOCSTPDT)* _____ *(mm/dd/yyyy)*
3. Did the patient withdraw consent to receive investigational study drug?*(WOCISD)* ☐ 1 - Yes ☐ 2 - No
4. Date patient withdrew consent:*(WOCISDDT)* _____ *(mm/dd/yyyy)*
5. Did the patient withdraw consent to provide optional blood samples for future research or ancillary studies?*(WOCFRB)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
6. Date patient withdrew consent:*(WOCFRBDT)* _____ *(mm/dd/yyyy)*
7. Did the patient withdraw consent to provide optional bone marrow samples for future research or ancillary studies?*(WOCFBM)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
8. Date patient withdrew consent:*(WOCFBMDT)* _____ *(mm/dd/yyyy)*
9. Did the patient withdraw consent to provide data for the study?*(WOCPDA)* ☐ 1 - Yes ☐ 2 - No
10. Date patient withdrew consent:*(WOCPDADT)* _____ *(mm/dd/yyyy)*
11. Did the patient withdraw consent to provide optional urine samples for research or ancillary studies?*(WOCURSAM)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
12. Date patient withdrew consent:*(WOCUSMDT)* _____ *(mm/dd/yyyy)*

Upload documentation of consent withdrawal with all PHI redacted. Contact the BMT CTN protocol coordinator with any questions.

Comments:*(WOCCOMM)*