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

Re-Admission/Hospitalization Form (ADM)

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

Segment *(PROTSEG)*: A
Date of Admission *(ADMITDT)*:

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

2. Patient discharge status:*(DISCPTST)*
☐ 1 - Alive ☐ 2 - Dead
If Dead, a Death Form must be submitted.

3. Record PRIMARY discharge diagnosis:*(PHSPREAS)*
01 - GVHD
02 - Relapse/Progression
03 - Graft Failure
04 - Infection
05 - Fungal Infection
*Additional Options Listed Below

Specify organ:(ADM4SPEC)* _____

**Specify other:*(ADM1SPEC)* _____

4. Record secondary discharge diagnoses:

a. GVHD:*(REASGVHD)*	☐ 1 - Contributory	☐ 2 - Noncontributory
b. Relapse/progression:*(REASRLPS)*	☐ 1 - Contributory	☐ 2 - Noncontributory
c. Graft failure:*(REASGF)*	☐ 1 - Contributory	☐ 2 - Noncontributory
d. Infection:*(REASINF)*	☐ 1 - Contributory	☐ 2 - Noncontributory
e. Fever:*(REASFVR)*	☐ 1 - Contributory	☐ 2 - Noncontributory
f. Seizure:*(REASSZR)*	☐ 1 - Contributory	☐ 2 - Noncontributory
g. Bleeding/hemorrhage:*(REASGIBL)*	☐ 1 - Contributory	☐ 2 - Noncontributory
h. Diarrhea:*(REASDRH)*	☐ 1 - Contributory	☐ 2 - Noncontributory
i. Nausea/vomiting:*(REASNV)*	☐ 1 - Contributory	☐ 2 - Noncontributory
j. Organ failure:*(REASORGF)*	☐ 1 - Contributory	☐ 2 - Noncontributory
Specify organ:*(ADM3SPEC)*	_____	
k. Trauma:*(REASTRAM)*	☐ 1 - Contributory	☐ 2 - Noncontributory
l. Psychiatric:*(REASPSYC)*	☐ 1 - Contributory	☐ 2 - Noncontributory
m. Secondary malignancy:*(REASMALG)*	☐ 1 - Contributory	☐ 2 - Noncontributory
n. Scheduled procedure/treatment:*(REASPROC)*	☐ 1 - Contributory	☐ 2 - Noncontributory
o. Thrombosis/thrombus/embolism:*(REASTRMB)*	☐ 1 - Contributory	☐ 2 - Noncontributory
p. Other:*(REASOTHR)*	☐ 1 - Contributory	☐ 2 - Noncontributory
Specify other:*(ADM2SPEC)*	_____	

5. Record re-admission institution:*(ADMCENTR)*
1 - Original Transplant Center
2 - Other Transplant Center
3 - Other Hospital

Comments:*(ADMCOMM1)* _____

Additional Selection Options for ADM

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

Blood and Marrow Transplant Clinical Trials Network

Adverse Event Form (AE1)

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

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

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

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

Comments:*(AE1COMM)*

Additional Selection Options for AE1

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

Blood and Marrow Transplant Clinical Trials Network

AE Summary Form (AE2)

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

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

1. Report activation status:*(AVSTAT_A)*

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

Relevant Past Medical History

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

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

(SEMEDHX)

3. **Event Summary**

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

(SESUMM)

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

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

Blood and Marrow Transplant Clinical Trials Network

AE Therapy Form (AE3)

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

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

1. Report activation status:*(AVSTAT_B)*

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

Medication	Start Date *(mm/dd/yyyy)*	Stop Date *(mm/dd/yyyy)*	Dose, Route, Schedule	Indication
(CONMED1)	*(CM1STDT)*	*(CM1SPDT)*	*(CM1DOSE)*	*(CM1INDIC)* 1 - Treatment of adverse event; 9 - Other
(CONMED2)	*(CM2STDT)*	*(CM2SPDT)*	*(CM2DOSE)*	*(CM2INDIC)* 1 - Treatment of adverse event; 9 - Other
(CONMED3)	*(CM3STDT)*	*(CM3SPDT)*	*(CM3DOSE)*	*(CM3INDIC)* 1 - Treatment of adverse event; 9 - Other
(CONMED4)	*(CM4STDT)*	*(CM4SPDT)*	*(CM4DOSE)*	*(CM4INDIC)* 1 - Treatment of adverse event; 9 - Other
(CONMED5)	*(CM5STDT)*	*(CM5SPDT)*	*(CM5DOSE)*	*(CM5INDIC)* 1 - Treatment of adverse event; 9 - Other
(CONMED6)	*(CM6STDT)*	*(CM6SPDT)*	*(CM6DOSE)*	*(CM6INDIC)* 1 - Treatment of adverse event; 9 - Other
(CONMED7)	*(CM7STDT)*	*(CM7SPDT)*	*(CM7DOSE)*	*(CM7INDIC)* 1 - Treatment of adverse event; 9 - Other
(CONMED8)	*(CM8STDT)*	*(CM8SPDT)*	*(CM8DOSE)*	*(CM8INDIC)* 1 - Treatment of adverse event; 9 - Other

(CONMED9)	*(CM9STDT)*	*(CM9SPDT)*	*(CM9DOSE)*	*(CM9INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED10)	*(CM10STDT)*	*(CM10SPDT)*	*(CM10DOSE)*	*(CM10INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED11)	*(CM11STDT)*	*(CM11SPDT)*	*(CM11DOSE)*	*(CM11INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED12)	*(CM12STDT)*	*(CM12SPDT)*	*(CM12DOSE)*	*(CM12INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED13)	*(CM13STDT)*	*(CM13SPDT)*	*(CM13DOSE)*	*(CM13INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED14)	*(CM14STDT)*	*(CM14SPDT)*	*(CM14DOSE)*	*(CM14INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED15)	*(CM15STDT)*	*(CM15SPDT)*	*(CM15DOSE)*	*(CM15INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED16)	*(CM16STDT)*	*(CM16SPDT)*	*(CM16DOSE)*	*(CM16INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED17)	*(CM17STDT)*	*(CM17SPDT)*	*(CM17DOSE)*	*(CM17INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED18)	*(CM18STDT)*	*(CM18SPDT)*	*(CM18DOSE)*	*(CM18INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED19)	*(CM19STDT)*	*(CM19SPDT)*	*(CM19DOSE)*	*(CM19INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED20)	*(CM20STDT)*	*(CM20SPDT)*	*(CM20DOSE)*	*(CM20INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED21)	*(CM21STDT)*	*(CM21SPDT)*	*(CM21DOSE)*	*(CM21INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED22)	*(CM22STDT)*	*(CM22SPDT)*	*(CM22DOSE)*	*(CM22INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED23)	*(CM23STDT)*	*(CM23SPDT)*	*(CM23DOSE)*	*(CM23INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED24)	*(CM24STDT)*	*(CM24SPDT)*	*(CM24DOSE)*	*(CM24INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED25)	*(CM25STDT)*	*(CM25SPDT)*	*(CM25DOSE)*	*(CM25INDI)* 1 - Treatment of adverse event 9 - Other

Comments:*(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

AE Laboratory/Diagnostics Form (AE4)

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

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

1. Report activation status:*(AVSTAT_C)*

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

Laboratory Test Results

2. Were relevant laboratory tests performed?*(LABTSTPF)* ☐ 1 - Yes ☐ 2 - No

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

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

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

3. Were relevant diagnostic tests performed?*(DXSTPF)* ☐ 1 - Yes ☐ 2 - No

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

Test	Date Performed *(mm/dd/yyyy)*	Results/Comments
(ADDTS1)	*(AD1DTDAT)*	*(AD1DTRES)*
(ADDTS2)	*(AD2DTDAT)*	*(AD2DTRES)*
(ADDTS3)	*(AD3DTDAT)*	*(AD3DTRES)*
(ADDTS4)	*(AD4DTDAT)*	*(AD4DTRES)*
(ADDTS5)	*(AD5DTDAT)*	*(AD5DTRES)*
(ADDTS6)	*(AD6DTDAT)*	

		(AD6DTRES)
(ADDTS7)	*(AD7DTDAT)*	*(AD7DTRES)*
(ADDTS8)	*(AD8DTDAT)*	*(AD8DTRES)*
(ADDTS9)	*(AD9DTDAT)*	*(AD9DTRES)*
(ADDTS10)	*(AD10DTDT)*	*(AD10DTRS)*

Comments:*(AE4COMM)*

Blood and Marrow Transplant Clinical Trials Network

AE Review Form (AE5)

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

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

1. Report activation status:*(AVSTAT_D)*

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

2. Reviewed:*(AEREVIEW)* ☐ 1 - Yes ☐ 2 - No
3. Reviewed by:*(ARFREVBY)*
4. Review date:*(ARFREVDT)* *(mm/dd/yyyy)*
5. Comment 1 - For Distribution:*(ARCM1DIS)*
6. Comment 2 - All Other Reviewers/Data Coordinating Center*(ARCM2ALL)*

Blood and Marrow Transplant Clinical Trials Network

AE Medical Monitor Reviewer Form (AE6)

Web Version: 1.0; 10.00; 02-20-18

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

1. Adverse event status:*(AVSTAT_E)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason
2. Has this event been determined to be an unexpected, grade 3-5 adverse event?*(AMDETER)* ☐ 1 - Yes ☐ 2 - No
3. Does this require expedited reporting to the FDA?*(AMEXPFDA)* ☐ 1 - Yes ☐ 2 - No
4. Does this require expedited reporting to the DSMB?*(AMEXPDSM)* ☐ 1 - Yes ☐ 2 - No
5. Do you recommend the patient be withdrawn from further protocol therapy?*(AMWITHDR)* ☐ 1 - Yes ☐ 2 - No
6. Is the review complete?*(AMREVDNE)* ☐ 1 - Yes ☐ 2 - No
   7. If **No**, what additional information is required:*(AMREVINF)*
8. Medical Monitor event description:*(AMMMEVDS)*
9. Medical Monitor CTCAE grade of event:*(CTCAEGRD)*
   - 1 - Grade 1
   - 2 - Grade 2
   - 3 - Grade 3
   - 4 - Grade 4
   - 5 - Grade 5

Comments:*(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Anthropomorphic Measurement Form - 0702 (ANT)

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

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

1. Date of Assessment:*(ANTDATE)* *(mm/dd/yyyy)*

Height and Weight Measurements

2. Record the patient's height:*(ANTHTCM)* *(xxx.x)* cm *(ANTHTIN)***OR** *(xx.x)* in
3. Record the patient's weight:*(ANTWGTKG)* *(xxx.x)* kg *(ANTWGTLB)***OR** *(xxx.x)* lbs
4. Calculated Body Mass Index (BMI):*(ANTBMI)* *(xx.xx)*

Waist and Hip Measurements

5. Record the patient's waist circumference:*(ANTWSTCM)* *(xxx.x)* cm *(ANTWSTIN)***OR** *(xx.x)* in
6. Record the patient's hip circumference:*(ANTHIPCM)* *(xxx.x)* cm *(ANTHIPIN)***OR** *(xx.x)* in
7. Calculated Waist/Hip Ratio (WHR):*(ANTWHR)* *(x.xx)*

Comments:*(ANTCOMM)*

Baseline Form - 0702 (BL3)

Web Version: 1.0; 6.01; 10-16-15

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

Risk Status

Risk status is assessed at the time of diagnosis. Cytogenetics and serum beta-2 microglobulin values should be from the patient's initial diagnosis of multiple myeloma, and prior to the start of initial systemic therapy.

1. Date of cytogenetics testing:*(MCYTDT)* _____ *(mm/dd/yyyy)*

Cytogenetics Testing (Standard or FISH)

Abnormality	
2. Was t(4;14) present?	1 - Yes, by standard cytogenetics only 2 - Yes, by FISH only 3 - Yes, by both standard cytogenetics and FISH 4 - No 5 - Not done *(M414T)*
3. Was t(14;20) present?	1 - Yes, by standard cytogenetics only 2 - Yes, by FISH only 3 - Yes, by both standard cytogenetics and FISH 4 - No 5 - Not done *(M1420T)*
4. Was t(14;16) present?	1 - Yes, by standard cytogenetics only 2 - Yes, by FISH only 3 - Yes, by both standard cytogenetics and FISH 4 - No 5 - Not done *(M1416T)*
5. Was deletion of chromosome 17 (del (17p)) detected?	1 - Yes, by standard cytogenetics only 2 - Yes, by FISH only 3 - Yes, by both standard cytogenetics and FISH 4 - No 5 - Not done *(M17CYT)*
6. Was deletion of chromosome 13 (del 13q)) detected?	1 - Yes, by standard cytogenetics only 2 - Yes, by FISH only 3 - Yes, by both standard cytogenetics and FISH 4 - No 5 - Not done *(M13CYT)*
7. Was a change in the number of chromosomes (aneuploidy or hypodiploid) detected?	1 - Yes, by standard cytogenetics only 2 - Yes, by FISH only 3 - Yes, by both standard cytogenetics and FISH 4 - No 5 - Not done *(MANEUP)*

Submit a copy of the cytogenetics analysis report. Be sure to remove patient identifiers prior to uploading.

8. Serum beta-2 microglobulin value:*(MSBTA2MG)* _____ *(xxx.xxx)* mg/L

Multiple Myeloma Diagnosis Information

Record the following information from the time of the patient's initial diagnosis of multiple myeloma.

9. Date of multiple myeloma diagnosis:*(MDIAGDT)* _____ *(mm/dd/yyyy)*
10. Serum m-protein spike result at diagnosis:*(MDXSPRES)*
    1 - Positive
    2 - Negative
    3 - Present but Not Quantifiable
11. Serum m-protein spike value at diagnosis:*(MDXSMSG)* _____ *(x.xxx)* g/dL *(MDXSMSMG)***OR** _____ *(xxxx.xx)* mg/dL
12. Urine m-protein result at diagnosis:*(MDXUPRES)*
    1 - Positive
    2 - Negative
    3 - Present but Not Quantifiable
13. Urine m-protein spike value at diagnosis:*(MDXUMS)*
    _____ *(xxxx.xxx)* Units:*(MDXUMSUN)*
    1- g/dL
    2- mg/dL
    3- mg/24hrs
14. Plasma cells present in bone marrow at diagnosis:*(MDXBMPLS)*

1 - Yes
2 - No
3 - Plasma Cells Present but Not Quantifiable

15. Percent plasma cells in bone marrow at diagnosis:*(MDXBMPCT)* *(xxx)* %

16. Bone marrow result source at diagnosis:*(MDXBMSRC)*
1- Bone Marrow Biopsy
2- Bone Marrow Aspirate
3- Sample Source Unknown

17. Kappa Free Light Chain value at diagnosis:*(MDXKMGL)* *(xxxxxx.xx)* mg/L *(MDXKMGDL)***OR** *(xxxxx.xxx)* mg/dL

18. Lambda Free Light Chain value at diagnosis:*(MDXLMGL)* *(xxxxxx.xx)* mg/L *(MDXLMGDL)***OR** *(xxxxx.xxx)* mg/dL

19. Serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MDXHVG)* 1 - Yes 2 - No	*(MDXHGK)* 1 - Yes / 2 - No	*(MDXHGL)* 1 - Yes / 2 - No
IgA	*(MDXHVA)* 1 - Yes 2 - No	*(MDXHAK)* 1 - Yes / 2 - No	*(MDXHAL)* 1 - Yes / 2 - No
IgM	*(MDXHVM)* 1 - Yes 2 - No	*(MDXHMK)* 1 - Yes / 2 - No	*(MDXHML)* 1 - Yes / 2 - No
IgD	*(MDXHVD)* 1 - Yes 2 - No	*(MDXHDK)* 1 - Yes / 2 - No	*(MDXHDL)* 1 - Yes / 2 - No
IgE	*(MDXHVE)* 1 - Yes 2 - No	*(MDXHEK)* 1 - Yes / 2 - No	*(MDXHEL)* 1 - Yes / 2 - No

20. Record quantitative serum immunoglobulin values at diagnosis:

	Laboratory Value (mg/dL)	Laboratory Value (g/dL)
Quantitative IgG	*(MDXIGGMG)* *(xxxxx.xx)* mg/dL	*(MDXIGGG)* **OR** *(xx.xxx)* g/dL
Quantitative IgA	*(MDXIGAMG)* *(xxxxx.xx)* mg/dL	*(MDXIGAG)* **OR** *(xx.xxx)* g/dL
Quantitative IgM	*(MDXIGMMG)* *(xxxxx.xx)* mg/dL	*(MDXIGMG)* **OR** *(xx.xxx)* g/dL
If serum heavy chain type is IgD or IgE, record values below:		
Quantitative IgD	*(MDXIGDMG)* *(x.xxx)* mg/dL	*(MDXIGDG)* **OR** *(x.xxxxxx)* g/dL
Quantitative IgE	*(MDXIGEMG)* *(x.xxx)* mg/dL	*(MDXIGEG)* **OR** *(x.xxxxxx)* g/dL

Submit a copy of any laboratory reports that support the diagnosis of multiple myeloma (such as SPEP, SIFE, UPEP, UIFE, bone marrow reports, and/or health and physical exam notes). Be sure to remove patient identifiers prior to uploading. If unable to upload documents, submit reports via fax to ***240-306-0963****.*

Comments:*(MCOMM)*

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- 0702 (E02)

Web Version: 1.0; 9.00; 01-04-17

Case ID *(CASEID)*:

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

Patient ID:*(EXXPATID)* _____

1. Review Date:*(REVIEWDT)* _____ *(mm/dd/yyyy)*
2. Primary Reviewer Name:*(REVNAME)*
   - Dan Vogl
   - David Vesole
   - Heather Landau
   - Marcelo Pasquini
   - Nina Shah
   - *Additional Options Listed Below
3. Case Status:*(CASESTAT)*
   - Baseline Review Complete (BC)
   - Final Review Complete (C)
   - Primary Endpoint Complete (PC)
   - Query (Q)
   - Ready for Baseline Review (RB)
   - *Additional Options Listed Below
4. Review Committee Comments:*(REVCOMM)*
5. EMMES Comments:*(EMMCOMM)*
6. Internal Consistency Review:*(ICREVIEW)*
   - 1 - Yes
   - 2 - No
   - 3 - Not Applicable

   a. Internal Consistency Review Comments:*(ICRCOMM)*

Reviewer Adjudicated Fields

7. Did the patient die?*(E02PDIED)* ☐ 1 - Yes ☐ 2 - No

   a. Primary cause of death:*(REVCOD)*
   - 1.0 - Graft Rejection or Failure
   - 1.1 - Autologous Recovery
   - Infection (Other than Interstitial Pneumonia)
   - 1.2 - Rejection
   - 2.1 - Bacterial
   - *Additional Options Listed Below

   b. Specify other COD:*(REVCODSP)* _____
8. Progression or relapse:*(PRGRLP)* ☐ 1 - Yes ☐ 2 - No

   a. Specify whether event was a progression or relapse:*(PRGRLPSP)*
   - 1- Progression
   - 2- Relapse
   - 3- Both Progression and Relapse

   b. Date of progression:*(PRGRLPDT)* _____ *(mm/dd/yyyy)*

   c. Date of relapse:*(RLPDT)* _____ *(mm/dd/yyyy)*
9. Was the patient eligible?*(ELIGIBLE)* ☐ 1 - Yes ☐ 2 - No

   a. Specify reason patient was not eligible:*(ELIGIBSP)* _____
10. Were treatment compliance issues identified?*(TRTCMPLY)* ☐ 1 - Yes ☐ 2 - No

    a. Specify compliance issues:*(TRTCMPSP)* _____
11. Non-protocol therapy received:*(THERAPY)* ☐ 1 - Yes ☐ 2 - No

    a. Date of non-protocol therapy:*(THERPYDT)* _____ *(mm/dd/yyyy)*

Disease Status

12. Disease Status at **Study Entry**:*(ENTRYDS)*
    - 1- Stringent Complete Response (sCR)
    - 2- Complete Response (CR)
    - 3- Near Complete Response (nCR)
    - 4- Very Good Partial Response (VGPR)
    - 5- Partial Response (PR)
    - *Additional Options Listed Below
13. Disease Status Post **1st Transplant (~Day 56)**:*(PRIOR2DS)*

1- Stringent Complete Response (sCR)
2- Complete Response (CR)
3- Near Complete Response (nCR)
4- Very Good Partial Response (VGPR)
5- Partial Response (PR)
*Additional Options Listed Below

14. Disease Status Prior to **Maintenance**:*(PRIOR3DS)*

1- Stringent Complete Response (sCR)
2- Complete Response (CR)
3- Near Complete Response (nCR)
4- Very Good Partial Response (VGPR)
5- Partial Response (PR)
*Additional Options Listed Below

15. Disease Status at **1 Year Post Randomization**:*(D0365DS)*

1- Stringent Complete Response (sCR)
2- Complete Response (CR)
3- Near Complete Response (nCR)
4- Very Good Partial Response (VGPR)
5- Partial Response (PR)
*Additional Options Listed Below

16. Disease Status at **2 Years Post Randomization**:*(D0730DS)*

1- Stringent Complete Response (sCR)
2- Complete Response (CR)
3- Near Complete Response (nCR)
4- Very Good Partial Response (VGPR)
5- Partial Response (PR)
*Additional Options Listed Below

17. Disease Status at **3 Years Post Randomization**:*(D1095DS)*

1- Stringent Complete Response (sCR)
2- Complete Response (CR)
3- Near Complete Response (nCR)
4- Very Good Partial Response (VGPR)
5- Partial Response (PR)
*Additional Options Listed Below

18. Disease Status at **38 Months Post Randomization**:*(D1155DS)*

1- Stringent Complete Response (sCR)
2- Complete Response (CR)
3- Near Complete Response (nCR)
4- Very Good Partial Response (VGPR)
5- Partial Response (PR)
*Additional Options Listed Below

19. Disease Status at **4 Years Post Randomization**:*(D1460DS)*

1- Stringent Complete Response (sCR)
2- Complete Response (CR)
3- Near Complete Response (nCR)
4- Very Good Partial Response (VGPR)
5- Partial Response (PR)
*Additional Options Listed Below

20. **Best** Disease Response from Study Entry:*(BESTDR)*

1- Stringent Complete Response (sCR)
2- Complete Response (CR)
3- Near Complete Response (nCR)
4- Very Good Partial Response (VGPR)
5- Partial Response (PR)
*Additional Options Listed Below

a. Date of Best Response from Study Entry:*(BESTDRDT)* *(mm/dd/yyyy)*

21. **Best** Disease Response from Diagnosis:*(BESTDX)*

1- Stringent Complete Response (sCR)
2- Complete Response (CR)
3- Near Complete Response (nCR)
4- Very Good Partial Response (VGPR)
5- Partial Response (PR)
*Additional Options Listed Below

a. Date of Best Response from Diagnosis:*(BESTDDT)* *(mm/dd/yyyy)*

22. CR achieved **Post Maintenance?**
(Post Enrollment into Segment C if no Maintenance)*(CRPSTMAI)*

1- Yes
2 - No
10 - N/E; No Data Available
12 - Achieved CR Pre-Maintenance
88 - N/A; Progression/Death

a. Date CR achieved:*(CRPSMTDT)* *(mm/dd/yyyy)*

23. 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 E02

Primary Reviewer Name:
Phil McCarthy
Yvonne Efebera
Amrita Krishnan
Craig Hofmeister

Case Status:
Ready for Full Review (RF)

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

Disease Status at Study Entry:
7- Stable Disease (SD)
8- Progression
9- Relapse
10- Not Evaluable
11- Continuing Response
88- Not Applicable

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

Blood and Marrow Transplant Clinical Trials Network

0702A (ENR)

Web Version: 1.0; 6.01; 10-16-15

Multiple Myeloma Follow-On Enrollment Form - Segment A

1. Date informed consent signed:*(MMCONDT)* *(mm/dd/yyyy)*
2. Patient zip code:*(MMZIPCDE)*
3. Patient method of payment:*(MMPAYMNT)*
   - 1 - Private Insurance
   - 2 - Medicare
   - 3 - Medicare and Private Insurance
   - 4 - Medicaid
   - 5 - Medicaid and Medicare
   - *Additional Options Listed Below

Inclusion Criteria

4. Does the patient meet the criteria for symptomatic multiple myeloma?*(MMSYMP)* 1 - Yes 2 - No
5. Patient's date of birth:*(MMPTDOB)* *(mm/dd/yyyy)*
6. Has the patient received at least two cycles of initial systemic therapy?*(MM2CYC)* 1 - Yes 2 - No
   7. Date systemic therapy began:*(MM1THRDT)* *(mm/dd/yyyy)*
   8. Date systemic therapy ended:*(MM2THRDT)* *(mm/dd/yyyy)*
9. Start date of mobilization therapy:*(MMMOBDT)* *(mm/dd/yyyy)*
10. Proposed start date of conditioning:*(MMCNDDT)* *(mm/dd/yyyy)*
11. Left ventricular ejection fraction at rest (LVEF):*(MMLVEF)* *(xxx)* %
12. Date LVEF performed:*(MMLVEFDT)* *(mm/dd/yyyy)*
13. Does the patient have Gilbert's Disease?*(MMGILDIS)* 1 - Yes 2 - No

	Most Recent Value	Upper Limit Normal	Date Sample Obtained
14. Bilirubin:	*(MMBILI)* *(xx.x)* mg/dL	*(MMBILIUL)* *(xx.x)* mg/dL	*(MMBILIDT)* *(mm/dd/yyyy)*
15. SGPT (ALT):	*(MMALT)* *(xxx)* Units/L	*(MMALTUL)* *(xxx)* Units/L	*(MMALTDT)* *(mm/dd/yyyy)*
16. SGOT (AST):	*(MMAST)* *(xxx)* Units/L	*(MMASTUL)* *(xxx)* Units/L	*(MMASTDT)* *(mm/dd/yyyy)*

17. Creatinine clearance:*(MMCRECL)* *(xxx)* ml/min
18. Date creatinine clearance sample obtained:*(MMCREDT)* *(mm/dd/yyyy)*

	Most Recent Value (corrected for hemoglobin)	Date Sample Obtained
19. DLCO:	*(MMDLCO)* *(xxx)* %	*(MMDLCODT)* *(mm/dd/yyyy)*
20. FEV1:	*(MMFEV)* *(xxx)* %	*(MMFEVDT)* *(mm/dd/yyyy)*
21. FVC:	*(MMFVC)* *(xxx)* %	*(MMFVCDT)* *(mm/dd/yyyy)*

22. Patient weight:*(MMPTWT)* *(xxx.x)* kg
23. Date patient's weight assessed:*(MMPTWTDT)* *(mm/dd/yyyy)*
24. Total number of CD34+ cells (or CD34+ cells/kg) in the autograft:*(MMCD34C)*
    - 1 - x 10^6 CD34+ Cells
    - 2 - x 10^6 CD34+ Cells/Kg

    (xxxx.x) Units:*(MMCD34UN)*

Exclusion Criteria

25. Does the patient have non-secretory multiple myeloma?*(MMNONSEC)* 1 - Yes 2 - No
26. Does the patient have plasma cell leukemia?*(MMPLSLK)* 1 - Yes 2 - No
27. What is the patient's Karnofsky score?*(MMKPS)*
    - 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

28. Does the patient have > grade 2 sensory neuropathy?*(MMSENSRY)* ☐ 1 - Yes ☐ 2 - No

According to the CTCAE v3.0, grade 3 sensory neuropathy is sensory alteration or paresthesia that interferes with activities of daily living.

29. Does the patient have an uncontrolled viral, bacterial or fungal infection?*(MMINF)* ☐ 1 - Yes ☐ 2 - No

30. Is the patient HIV seropositive?*(MMHIV)* ☐ 1 - Yes ☐ 2 - No

31. Did the patient experience a myocardial infarction within the past 6 months, Class III or IV heart failure, uncontrolled angina, severe uncontrolled ventricular arrhythmias, or electrocardiographic evidence of acute ischemia or active conduction system abnormalities?*(MMMYOAB)* ☐ 1 - Yes ☐ 2 - No

32. Does the patient have known hypersensitivity to bortezomib, boron, or mannitol?*(MMBRTSEN)* ☐ 1 - Yes ☐ 2 - No

33. Has the patient received other investigational agents within the past 14 days?*(MMOTHINV)* ☐ 1 - Yes ☐ 2 - No

34. Does the patient have a history of any malignant diseases other than multiple myeloma, basal cell carcinoma or cervical carcinoma in situ?*(MMHXMAL)*
1 - Yes
2 - Yes, Approved by Study Chair/MM
3 - No

35. Date confirmed by study chair:*(MMCONFDT)* *(mm/dd/yyyy)*

36. Was the malignancy treated with curative intent >5 years previously?*(MMTRTMAL)* ☐ 1 - Yes ☐ 2 - No

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

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

39. Is the patient willing to use contraceptive techniques during the length of lenalidomide maintenance therapy?*(MMCONTR)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

40. Has the patient had a previous autologous or allogeneic stem cell transplant?*(MMPRVTXP)* ☐ 1 - Yes ☐ 2 - No

41. Did the patient receive mid-intensity melphalan (>50 mg IV) as prior systemic therapy?*(MMRECMEL)* ☐ 1 - Yes ☐ 2 - No

42. Has the patient received a prior organ transplant requiring immunosuppressive therapy?*(MMPRORG)* ☐ 1 - Yes ☐ 2 - No

43. Did the patient experience disease progression prior to enrollment?*(MMDISPRG)* ☐ 1 - Yes ☐ 2 - No

44. Did the patient receive lenalidomide as initial therapy for multiple myeloma and experience toxicities resulting in treatment discontinuation?*(MMLENTOX)* ☐ 1 - Yes ☐ 2 - No

45. Did the patient experience thromboembolic events while on full anticoagulaton during prior therapy with lenalidomide or thalidomide?*(MMTHROMB)* ☐ 1 - Yes ☐ 2 - No

46. Is the patient willing to take deep vein thrombosis prophylaxis?*(MMDVTPRO)* ☐ 1 - Yes ☐ 2 - No

47. Did the patient get denied for medical cost coverage by third party payers to undergo an intervention on any of the treatment arms?*(MMINSURE)* ☐ 1 - Yes ☐ 2 - No

Consent for Use of Biological Samples for Research

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

49. Did the patient consent to provide bone marrow for future research?*(MMFRBM)* ☐ 1 - Yes ☐ 2 - No

50. Did the patient consent to provide bone marrow for the PRIMeR ancillary study?*(MMPRBM)* ☐ 1 - Yes ☐ 2 - No

51. Date the bone marrow aspirate for future research was obtained:*(MMBMDT)* *(mm/dd/yyyy)*

52. Date the bone marrow aspirate for the PRIMeR ancillary study was obtained:*(MMPRSDT)* *(mm/dd/yyyy)*

53. Date the serum sample was obtained:*(MMSERDT)* *(mm/dd/yyyy)*

54. Date the plasma sample was obtained:*(MMPLASDT)* *(mm/dd/yyyy)*

55. Date the PBMC sample was obtained:*(MMPBMCDT)* *(mm/dd/yyyy)*

Risk Status

56. Patient risk status:*(MMPTRISK)*
1 - High risk
2 - Standard risk

Comments:*(MMCOMM)*

Submit patient's pathology, molecular, and/or cytogenetics reports. Remember to de-identify all documents before uploading.

Additional Selection Options for ENR

Patient method of payment:
6 - Self Pay (No Insurance)
7 - No Means of Payment (No Insurance)
8 - Other
9 - Unknown
10 - Veterans Sponsored
11 - Military Sponsored (Including Champus &Tricare)
12 - Military or Veterans Sponsored NOS

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

Blood and Marrow Transplant Clinical Trials Network

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 Status Form - 0702 (FU5)

Web Version: 1.0; 6.00; 10-16-15

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

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

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

2. Has the patient died?*(MMPTDTH)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Death Form must be submitted.
3. Date of patient death:*(MMDTHDT)* *(mm/dd/yyyy)*
4. Has the patient experienced disease progression?*(MMRELPR)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Progression Form must be submitted.
5. Date of progression:*(MMRELDT)* *(mm/dd/yyyy)*
6. Has the patient initiated any non-protocol anti-myeloma therapy?*(MMRECTHP)* ☐ 1 - Yes ☐ 2 - No

If yes, record type of therapy:

7.

	Receiving:	Start Date:	Has Treatment been Discontinued?	Stop Date:
Dexamethasone:	*(MMDEXTH)* ☐ 1 - Yes ☐ 2 - No	*(MMDEXST)* *(mm/dd/yyyy)*	*(MMDEXDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMDEXSTP)* *(mm/dd/yyyy)*
Thalidomide:	*(MMTHALTH)* ☐ 1 - Yes ☐ 2 - No	*(MMTHALST)* *(mm/dd/yyyy)*	*(MMTHLDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMTHLSTP)* *(mm/dd/yyyy)*
Lenalidomide:	*(MMLENTH)* ☐ 1 - Yes ☐ 2 - No	*(MMLENST)* *(mm/dd/yyyy)*	*(MMLENDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMLENSTP)* *(mm/dd/yyyy)*
Bortezomib:	*(MMBORTH)* ☐ 1 - Yes ☐ 2 - No	*(MMBORST)* *(mm/dd/yyyy)*	*(MMBORDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMBORSTP)* *(mm/dd/yyyy)*
Other:	*(MMRCVOTH)* ☐ 1 - Yes ☐ 2 - No	*(MMOTHST)* *(mm/dd/yyyy)*	*(MMOTHDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMOTHSTP)* *(mm/dd/yyyy)*

8. Specify other type of anti-myeloma therapy:*(MMOTHSPE)*
9. Record reason for initiation of anti-myeloma therapy:*(MMRSNTHR)*
10. Has the patient experienced any new clinically significant infections?*(MMNEWIN)* ☐ 1 - Yes ☐ 2 - No
If Yes, an Infection Form must be submitted.
11. Date of infection:*(MMINFDT)* *(mm/dd/yyyy)*
12. Has the patient been hospitalized other than for a protocol-specified transplant?*(MMHOSP)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Re-Admission Form must be submitted.
13. Date of hospitalization:*(MMHOSDT)* *(mm/dd/yyyy)*
14. Has the patient received a non-protocol specified transplant?*(MMNONTXP)* ☐ 1 - Yes ☐ 2 - No
15. Date of non-protocol specified transplant:*(MMTXPDT)* *(mm/dd/yyyy)*
16. Has the patient experienced a thromboembolic event?*(MMTHRMBO)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Thromboembolism Form must be submitted.
17. Date of thromboembolic event:*(MMTHRMDT)* *(mm/dd/yyyy)*
18. Has the patient experienced any unexpected grade 3-5 adverse events?*(MMUAE)* ☐ 1 - Yes ☐ 2 - No
If Yes, an Unexpected, Grade 3-5 Adverse Event Form must be submitted.
19. Date of onset of unexpected grade 3-5 adverse event:*(MMUAEDT)* *(mm/dd/yyyy)*
20. Was the patient diagnosed with a second cancer?*(MMSECCAN)* ☐ 1 - Yes ☐ 2 - No
21. Date of second cancer diagnosis:*(MMSECCDT)* *(mm/dd/yyyy)*

Comments:*(MMCMNT)*

Blood and Marrow Transplant Clinical Trials Network

Hematology/Chemistry Form - 0702 (HCF)

Web Version: 1.0; 2.05; 10-16-15

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

1. Record the date of assessment:*(HCASMTDT)* _____ *(mm/dd/yyyy)*

CBC

Record the most recent CBC lab results:

	Most Recent Value	Date of Sample
2. Hemoglobin:	*(HCFHGB)* _____ *(xx.x)* g/dL	*(HCFHGBDT)* _____ *(mm/dd/yyyy)*
3. WBC:	*(HCFWBC)* _____ *(xxxxxx)* /mm^3	*(HCFWBCDT)* _____ *(mm/dd/yyyy)*
4. Platelet Count:	*(HCFPLT)* _____ *(xxxxxx)* /mm^3	*(HCFPLTDT)* _____ *(mm/dd/yyyy)*
5. Neutrophils:	*(HCFNEUT)* _____ *(xxxxx)* /mm^3	*(HCFNEUDT)* _____ *(mm/dd/yyyy)*
6. Eosinophils:	*(HCFEOS)* _____ *(xxxx)* /mm^3	*(HCFEOSDT)* _____ *(mm/dd/yyyy)*

Chemistry

Record the most recent chemistry lab results:

	Most Recent Value	Date of Sample
7. Creatinine:	*(HCFCREAT)* _____ *(x.x)* mg/dL	*(HCFCRTDT)* _____ *(mm/dd/yyyy)*
8. Estimated Creatinine Clearance:	*(HCFCRCL)* _____ *(xxx)* mL/min	*(HCFCRCDT)* _____ *(mm/dd/yyyy)*
9. Bilirubin:	*(HCFBILI)* _____ *(xx.x)* mg/dL	*(HCFBILDT)* _____ *(mm/dd/yyyy)*
10. Alkaline Phosphatase:	*(HCFALKPH)* _____ *(xxxx)* IU/L	*(HCFALKDT)* _____ *(mm/dd/yyyy)*
11. AST:	*(HCFAST)* _____ *(xxxx)* IU/L	*(HCFASTDT)* _____ *(mm/dd/yyyy)*
12. ALT:	*(HCFALT)* _____ *(xxxx)* IU/L	*(HCFALTDT)* _____ *(mm/dd/yyyy)*
13. Glucose:	*(HCFGLUC)* _____ *(xxxx)* mg/dL	*(HCFGLUDT)* _____ *(mm/dd/yyyy)*
14. Sodium:	*(HCSODIUM)* _____ *(xxx)* mmol/L	*(HCFSDDT)* _____ *(mm/dd/yyyy)*
15. Potassium:	*(HCFPOTAS)* _____ *(x.x)* mmol/L	*(HCFPTSDT)* _____ *(mm/dd/yyyy)*
16. Calcium:	*(HCFCALCI)* _____ *(xx.x)* mg/dL	*(HCFCALDT)* _____ *(mm/dd/yyyy)*

Comments:*(HCFCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Infection Form (INF)

Web Version: 1.0; 4.01; 10-16-15

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

INFECTION I

1. Type of infection:*(INFTYP01)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other

2. Organism I:*(ORGN01)*
   - 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

   If other specify:*(INFSPEC1)*

3. Record the level of certainty of the fungal infection diagnosis:*(CERTNTY1)*
   - 1 - Proven Fungal Infection
   - 2 - Probable Fungal Infection
   - 3 - Possible Fungal Infection

4. Severity of infection:*(SVRTY01)*
   - 1 - Moderate
   - 2 - Severe
   - 3 - Life-Threatening/Fatal

INFECTION II

5. Type of infection:*(INFTYP02)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other

6. Organism II:*(ORGN02)*
   - 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

   If other specify:*(INFSPEC2)*

7. Record the level of certainty of the fungal infection diagnosis:*(CERTNTY2)*
   - 1 - Proven Fungal Infection
   - 2 - Probable Fungal Infection
   - 3 - Possible Fungal Infection

8. Severity of infection:*(SVRTY02)*
   - 1 - Moderate
   - 2 - Severe
   - 3 - Life-Threatening/Fatal

INFECTION III

9. Type of infection:*(INFTYP03)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other

10. Organism III:*(ORGN03)*
    - 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

    If other specify:*(INFSPEC3)*

11. Record the level of certainty of the fungal infection diagnosis:*(CERTNTY3)*
    - 1 - Proven Fungal Infection
    - 2 - Probable Fungal Infection
    - 3 - Possible Fungal Infection

12. Severity of infection:*(SVRTY03)*

1 - Moderate
2 - Severe
3 - Life-Threatening/Fatal

13. Was an agent(s) administered to treat the infection(s)?*(TRTINF)*

☐ 1 - Yes ☐ 2 - No

Provide agent(s) administered for this infectious period:

14. 1st agent:*(AGENT1)*

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

If other specify:*(AGTSPEC1)*

15. 2nd agent:*(AGENT2)*

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

If other specify:*(AGTSPEC2)*

16. 3rd agent:*(AGENT3)*

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

If other specify:*(AGTSPEC3)*

17. Were additional agents administered for this infectious period?*(ADDAGENT)*

☐ 1 - Yes ☐ 2 - No

If yes, specify additional agents administered:*(INFSPEC4)*

Comments:*(INFCOM)*

Additional Selection Options for INF

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

Myeloma Status Form - 0702 (MSF)

Web Version: 1.0; 6.02; 10-16-15

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

The purpose of this form is to capture the BMT CTN 0702 myeloma assessments required at 4 years post randomization.

1. Start of assessment period:*(MMSTRTDT)* *(mm/dd/yyyy)*
2. End of assessment period:*(MMENDDT)* *(mm/dd/yyyy)*

3. Indicate the patient's current disease response:*(MMCURDZR)*
   - 1 - Stringent Complete Response (sCR)
   - 2 - Complete Response (CR)
   - 3 - Near Complete Response (nCR)
   - 4 - Very Good Partial Response (VGPR)
   - 5 - Partial Response (PR)
   - *Additional Options Listed Below

If patient's current disease status is progression, a Progression form must be submitted.

Serum Protein Electrophoresis (SPEP)

4. How many SPEPs were performed during this assessment period?*(MMSPEPNM)*
5. Record the reason no SPEPs were performed:*(MMNOSPEP)*

6. For each SPEP performed, record the following:

	Date of SPEP	Serum total protein value	M-protein spike result	M-protein spike value
SPEP 1	*(MMSP1DT)* *(mm/dd/yyyy)*	*(MMSP1TG)* *(xx.xxx)* g/dL	*(MMSP1RES)* 1 - Positive; 2 - Negative; 3 - Present but Not Quantifiable	*(MMSP1MSG)* *(x.xxx)* g/dL
		(MMSP1TMG) **OR** *(xxxxx.xx)* mg/dL		*(MSP1MSMG)* **OR** *(xxxx.xx)* mg/dL
SPEP 2	*(MMSP2DT)* *(mm/dd/yyyy)*	*(MMSP2TG)* *(xx.xxx)* g/dL	*(MMSP2RES)* 1 - Positive; 2 - Negative; 3 - Present but Not Quantifiable	*(MMSP2MSG)* *(x.xxx)* g/dL
		(MMSP2TMG) **OR** *(xxxxx.xx)* mg/dL		*(MSP2MSMG)* **OR** *(xxxx.xx)* mg/dL
SPEP 3	*(MMSP3DT)* *(mm/dd/yyyy)*	*(MMSP3TG)* *(xx.xxx)* g/dL	*(MMSP3RES)* 1 - Positive; 2 - Negative; 3 - Present but Not Quantifiable	*(MMSP3MSG)* *(x.xxx)* g/dL
		(MMSP3TMG) **OR** *(xxxxx.xx)* mg/dL		*(MSP3MSMG)* **OR** *(xxxx.xx)* mg/dL

Serum Free Light Chain (FLC)

7. Was serum FLC measured?*(MMSFLC)* ☐ 1 - Yes ☐ 2 - No
8. Date of serum FLC assessment:*(MMSFLCDT)* *(mm/dd/yyyy)*
9. Kappa Free Light Chain value:*(MMSKMGL)* *(xxxxxx.xx)* mg/L *(MMSKMGDL)***OR** *(xxxxx.xxx)* mg/dL
10. Lambda Free Light Chain value:*(MMSLMGL)* *(xxxxxx.xx)* mg/L *(MMSLMGDL)***OR** *(xxxxx.xxx)* mg/dL
11. Free Light Chain Ratio (κ/λ):*(MMSFLCR)* *(xxxxxx.xxxxxx)*

Serum Immunofixation (Serum IFE)

12. How many serum IFEs were performed during this assessment period?*(MMSIFENM)*
13. Record the reason no serum IFEs were performed:*(MMNOSIFE)*

Serum IFE 1

14. Date of serum IFE 1:*(MMSI1DT)* *(mm/dd/yyyy)*
15. Serum IFE 1 Result:*(MMSI1RES)*
    - 1 - Positive
    - 2 - Negative
16. Was there mention of oligoclonal banding in the report?*(MMSI1OB)* ☐ 1 - Yes ☐ 2 - No

17. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MMSI1HVG)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HGK)* 1 - Yes / 2 - No	*(MMSI1HGL)* 1 - Yes / 2 - No
IgA	*(MMSI1HVA)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HAK)* 1 - Yes / 2 - No	*(MMSI1HAL)* 1 - Yes / 2 - No
IgM	*(MMSI1HVM)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HMK)* 1 - Yes / 2 - No	*(MMSI1HML)* 1 - Yes / 2 - No
IgD	*(MMSI1HVD)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HDK)* 1 - Yes / 2 - No	*(MMSI1HDL)* 1 - Yes / 2 - No
IgE	*(MMSI1HVE)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HEK)* 1 - Yes / 2 - No	*(MMSI1HEL)* 1 - Yes / 2 - No

18. Did serum IFE 1 indicate light chain disease?*(MMSI1LCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

19. Kappa:*(MMSI1KLC)* ☐ 1 - Yes ☐ 2 - No

20. Lambda:*(MMSI1LLC)* ☐ 1 - Yes ☐ 2 - No

Serum IFE 2

21. Date of serum IFE 2:*(MMSI2DT)* *(mm/dd/yyyy)*

22. Serum IFE 2 Result:*(MMSI2RES)* 1 - Positive / 2 - Negative

23. Was there mention of oligoclonal banding in the report?*(MMSI2OB)* ☐ 1 - Yes ☐ 2 - No

24. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MMSI2HVG)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HGK)* 1 - Yes / 2 - No	*(MMSI2HGL)* 1 - Yes / 2 - No
IgA	*(MMSI2HVA)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HAK)* 1 - Yes / 2 - No	*(MMSI2HAL)* 1 - Yes / 2 - No
IgM	*(MMSI2HVM)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HMK)* 1 - Yes / 2 - No	*(MMSI2HML)* 1 - Yes / 2 - No
IgD	*(MMSI2HVD)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HDK)* 1 - Yes / 2 - No	*(MMSI2HDL)* 1 - Yes / 2 - No
IgE	*(MMSI2HVE)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HEK)* 1 - Yes / 2 - No	*(MMSI2HEL)* 1 - Yes / 2 - No

25. Did serum IFE 2 indicate light chain disease?*(MMSI2LCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

26. Kappa:*(MMSI2KLC)* ☐ 1 - Yes ☐ 2 - No

27. Lambda:*(MMSI2LLC)* ☐ 1 - Yes ☐ 2 - No

Serum IFE 3

28. Date of serum IFE 3:*(MMSI3DT)* *(mm/dd/yyyy)*

29. Serum IFE 3 Result:*(MMSI3RES)* 1 - Positive / 2 - Negative

30. Was there mention of oligoclonal banding in the report?*(MMSI3OB)* ☐ 1 - Yes ☐ 2 - No

31. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MMSI3HVG)* ☐ 1 - Yes ☐ 2 - No	*(MMSI3HGK)* 1 - Yes / 2 - No	*(MMSI3HGL)* 1 - Yes / 2 - No
IgA	*(MMSI3HVA)* ☐ 1 - Yes ☐ 2 - No	*(MMSI3HAK)* 1 - Yes / 2 - No	*(MMSI3HAL)* 1 - Yes / 2 - No
IgM	*(MMSI3HVM)* ☐ 1 - Yes ☐ 2 - No	*(MMSI3HMK)* 1 - Yes / 2 - No	*(MMSI3HML)* 1 - Yes / 2 - No
IgD	*(MMSI3HVD)* ☐ 1 - Yes ☐ 2 - No		

		(MMSI3HDK) 1 - Yes 2 - No	(MMSI3HDL) 1 - Yes 2 - No
IgE	(MMSI3HVE) 1 - Yes 2 - No	(MMSI3HEK) 1 - Yes 2 - No	(MMSI3HEL) 1 - Yes 2 - No

32. Did serum IFE 3 indicate light chain disease?*(MMSI3LCD)* 1 - Yes 2 - No

Record serum light chain type(s):

33. Kappa:*(MMSI3KLC)* 1 - Yes 2 - No

34. Lambda:*(MMSI3LLC)* 1 - Yes 2 - No

Urine Protein Electrophoresis/Urine Immunofixation (UPEP/Urine IFE)

35. How many UPEPs/Urine IFEs were performed during this assessment period?*(MMUPEPNM)*

36. Record the reason no UPEPs/Urine IFEs were performed:*(MMNOUPEP)*

37. For each UPEP/Urine IFE performed, record the following:

	Date of UPEP/Urine IFE	Urine total protein value	Urine total volume	M-protein result (Urine IFE)	M-protein value	M-protein units	Urine light chain type
UPEP/Urine IFE 1	*(MMUP1DT)* *(mm/dd/yyyy)*	*(MMUP1TPG)* *(xx.xxx)* g/24hrs	*(MMUP1TVL)* *(xx.xxx)* L/24hrs	*(MMUP1RES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(MMUP1VAL)* *(xxxx.xxx)*	*(MMUP1UN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(MMUP1KLC)* 1 - Yes 2 - No
		(MMUP1TMG) **OR** *(xxxxx.xx)* mg/24hrs	*(MMUP1VML)* **OR** *(xxxxx.xx)* mL/24hrs				Lambda:*(MMUP1LLC)* 1 - Yes 2 - No
UPEP/Urine IFE 2	*(MMUP2DT)* *(mm/dd/yyyy)*	*(MMUP2TPG)* *(xx.xxx)* g/24hrs	*(MMUP2TVL)* *(xx.xxx)* L/24hrs	*(MMUP2RES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(MMUP2VAL)* *(xxxx.xxx)*	*(MMUP2UN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(MMUP2KLC)* 1 - Yes 2 - No
		(MMUP2TMG) **OR** *(xxxxx.xx)* mg/24hrs	*(MMUP2VML)* **OR** *(xxxxx.xx)* mL/24hrs				Lambda:*(MMUP2LLC)* 1 - Yes 2 - No
UPEP/Urine IFE 3	*(MMUP3DT)* *(mm/dd/yyyy)*	*(MMUP3TPG)* *(xx.xxx)* g/24hrs	*(MMUP3TVL)* *(xx.xxx)* L/24hrs	*(MMUP3RES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(MMUP3VAL)* *(xxxx.xxx)*	*(MMUP3UN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(MMUP3KLC)* 1 - Yes 2 - No
		(MMUP3TMG) **OR** *(xxxxx.xx)* mg/24hrs	*(MMUP3VML)* **OR** *(xxxxx.xx)* mL/24hrs				Lambda:*(MMUP3LLC)* 1 - Yes 2 - No

Bone Marrow

38. How many bone marrow biopsies were performed during this assessment period?*(MMBMBXNM)*

39. Record reason no bone marrow biopsies were performed:*(MMNOBMBX)*

40. For each bone marrow biopsy performed, record the following:

	Date Performed	Date Performed	Plasma Cells Present	Percent Plasma Cells
Bone Marrow Biopsy 1	*(MMBX1DT)* *(mm/dd/yyyy)*	*(MMBX1DT)* *(mm/dd/yyyy)*	*(MMBX1PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMBX1PCT)* *(xxx.x)* %
Bone Marrow Biopsy 2	*(MMBX2DT)* *(mm/dd/yyyy)*	*(MMBX2DT)* *(mm/dd/yyyy)*	*(MMBX2PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMBX2PCT)* *(xxx.x)* %
Bone Marrow Biopsy 3	*(MMBX3DT)* *(mm/dd/yyyy)*	*(MMBX3DT)* *(mm/dd/yyyy)*	*(MMBX3PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMBX3PCT)* *(xxx.x)* %

41. How many bone marrow aspirates were performed during this assessment period?*(MMASPNM)*

42. Record reason no bone marrow aspirates were performed:*(MMNOBMAS)*

43. For each bone marrow aspirate performed, record the following:

	Date Performed	Date Performed	Plasma Cells Present	Percent Plasma Cells
Bone Marrow Aspirate 1	*(MMASP1DT)* *(mm/dd/yyyy)*	*(MMASP1DT)* *(mm/dd/yyyy)*	*(MMAS1PLS)*	*(MMAS1PCT)* *(xxx.x)* %

			1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	
Bone Marrow Aspirate 2	*(MMASP2DT)* *(mm/dd/yyyy)*	*(MMASP2DT)* *(mm/dd/yyyy)*	*(MMAS2PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMAS2PCT)* *(xxx.x)* %
Bone Marrow Aspirate 3	*(MMASP3DT)* *(mm/dd/yyyy)*	*(MMASP3DT)* *(mm/dd/yyyy)*	*(MMAS3PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMAS3PCT)* *(xxx.x)* %

Lytic Lesions

44. Was a lytic lesion assessment performed?*(MMBASMT)* ☐ 1 - Yes ☐ 2 - No

45. Date of lytic bone lesion assessment:*(MMBASMDT)* *(mm/dd/yyyy)*

46. Record most recent information regarding lytic bone lesions:*(MMLESNST)*

1 - No Change
2 - New Lytic Bone Lesions
3 - Definite Size Increase of Existing Lytic Bone Lesions
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

47. Specify other lesion information:*(MMLSNSP)*

Plasmacytomas

48. Was a plasmacytoma assessment performed?*(MMPLCYAS)* ☐ 1 - Yes ☐ 2 - No

49. Date of plasmacytoma assessment:*(MMPLCYDT)* *(mm/dd/yyyy)*

50. Record most recent information regarding soft tissue plasmacytomas:*(MMPLCYST)*

1 - No Change
2 - New Plasmacytomas
3 - Definite Size Increase of Existing Plasmacytomas
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

51. Specify other plasmacytoma information:*(MMPLCYSP)*

Quantitative Serum Immunoglobulins

52. Were serum immunoglobulins obtained?*(MMSIGS)* ☐ 1 - Yes ☐ 2 - No

53. Date immunoglobulins obtained:*(MMSIGSDT)* *(mm/dd/yyyy)*

54. Record immunoglobulin values:

	Laboratory Value (mg/dL)	Laboratory Value (g/dL)
Quantitative IgG	*(MMIGGMG)* *(xxxxx.xx)* mg/dL	*(MMIGGG)* **OR** *(xx.xxx)* g/dL
Quantitative IgA	*(MMIGAMG)* *(xxxxx.xx)* mg/dL	*(MMIGAG)* **OR** *(xx.xxx)* g/dL
Quantitative IgM	*(MMIGMMG)* *(xxxxx.xx)* mg/dL	*(MMIGMG)* **OR** *(xx.xxx)* g/dL
If serum heavy chain type is IgD or IgE, record values below		
Quantitative IgD	*(MMIGDMG)* *(x.xxx)* mg/dL	*(MMIGDG)* **OR** *(x.xxxxxx)* g/dL
Quantitative IgE	*(MMIGEMG)* *(x.xxx)* mg/dL	*(MMIGEG)* **OR** *(x.xxxxxx)* g/dL

Submit a copy of the SPEP, SIFE, UPEP, UIFE, bone marrow reports, and other supporting source documents. Be sure to remove patient identifiers prior to uploading. If unable to upload documents, submit reports via fax to ***(240)306-0963****.*

Comments:*(MSFCOMM)*

Additional Selection Options for MSF

Indicate the patient's current disease response:
7 - Stable Disease (SD)
8 - Progression

Record most recent information regarding lytic bone lesions:
6- Other

Record most recent information regarding soft tissue plasmacytomas:
6- Other

Blood and Marrow Transplant Clinical Trials Network

Progression Form (PRL)

Web Version: 1.0; 4.03; 10-16-15

Segment *(PROTSEG)*: A
Progression/Relapse Date *(PRRELPDT)*:

Select clinical or laboratory findings which indicate progression:

1. Serum Protein Electrophoresis (SPEP)	*(PRSPEPYN)* 1 - Yes / 2 - No / 3 - Not Done
2. Serum Free Light Chain (Serum FLC)	*(PRSFLCYN)*
3. Serum Immunofixation (Serum IFE)	*(PRSIFEYN)*
4. Urine Protein Electrophoresis (UPEP)	*(PRUPEPYN)*
5. Urine Immunofixation (Urine IFE)	*(PRUIFEYN)*
6. Bone Marrow	*(PRBMYN)*
7. Lytic Lesions	*(PRLESNYN)*
8. Plasmacytomas	*(PRPLCYYN)*
9. Corrected Serum Calcium	*(PRCALCYN)*

Serum Protein Electrophoresis (SPEP)

10. How many SPEPs were performed?*(PRLSPNM)* 0 - None / 1 - One SPEP / 2 - Two SPEPs

11. For each SPEP performed, record the following:

	Date of SPEP	Serum total protein value	M-protein spike result	M-protein spike value
Initial SPEP	*(PRLSPDT)* *(mm/dd/yyyy)*	*(PRLSPTPG)* *(xx.xxx)* g/dL	*(PRLSPRES)* 1 - Positive / 2 - Negative / 3 - Present but Not Quantifiable	*(PRLSPMSG)* *(x.xxx)* g/dL
		(PRLSPTMG) **OR** *(xxxxx.xx)* mg/dL		*(PRSPMSMG)* **OR** *(xxxx.xx)* mg/dL
Confirmatory SPEP	*(PRLSPCDT)* *(mm/dd/yyyy)*	*(PRSPCTPG)* *(xx.xxx)* g/dL	*(PRLSPCRS)* 1 - Positive / 2 - Negative / 3 - Present but Not Quantifiable	*(PRSCMSG)* *(x.xxx)* g/dL
		(PRSPCTMG) **OR** *(xxxxx.xx)* mg/dL		*(PRSCMSMG)* **OR** *(xxxx.xx)* mg/dL

Serum Free Light Chain (FLC)

12. Was serum FLC measured?*(PRLSFLC)* 1 - Yes 2 - No
13. Date of serum FLC:*(PRLFLCDT)* *(mm/dd/yyyy)*
14. Kappa Free Light Chain value:*(PRSKMGL)* *(xxxxxx.xx)* mg/L *(PRSKMGDL)***OR** *(xxxxx.xxx)* mg/dL
15. Lambda Free Light Chain value:*(PRSLMGL)* *(xxxxxx.xx)* mg/L *(PRSLMGDL)***OR** *(xxxxx.xxx)* mg/dL
16. Free light chain ratio (κ/ λ):*(PRLSFLCR)* *(xxxxxx.xxxxxx)*

Serum Immunofixation (Serum IFE)

17. How many serum IFEs were performed?*(PRSIFENM)* 0- None / 1- One SIFE / 2- Two SIFEs
18. Date of initial serum IFE:*(PRLSIDT)* *(mm/dd/yyyy)*
19. Initial serum IFE result:*(PRLSIRES)* 1 - Positive / 2 - Negative
20. Was there mention of oligoclonal banding in the report?*(PRLSIOB)* 1 - Yes 2 - No
21. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda

IgG	*(PRLSIHVG)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHGK)* 1 - Yes 2 - No	*(PRLSIHGL)* 1 - Yes 2 - No
IgA	*(PRLSIHVA)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHAK)* 1 - Yes 2 - No	*(PRLSIHAL)* 1 - Yes 2 - No
IgM	*(PRLSIHVM)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHMK)* 1 - Yes 2 - No	*(PRLSIHML)* 1 - Yes 2 - No
IgD	*(PRLSIHVD)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHDK)* 1 - Yes 2 - No	*(PRLSIHDL)* 1 - Yes 2 - No
IgE	*(PRLSIHVE)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHEK)* 1 - Yes 2 - No	*(PRLSIHEL)* 1 - Yes 2 - No

22. Did initial serum IFE indicate light chain disease?*(PRLSILCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

23. Kappa:*(PRLSIKLC)* ☐ 1 - Yes ☐ 2 - No

24. Lambda:*(PRLSILLC)* ☐ 1 - Yes ☐ 2 - No

25. Date of confirmatory serum IFE:*(PRLSICDT)* *(mm/dd/yyyy)*

26. Confirmatory serum IFE result:*(PRLSICRS)* 1 - Positive 2 - Negative

27. Was there mention of oligoclonal banding in the report?*(PRLSICOB)* ☐ 1 - Yes ☐ 2 - No

28. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(PRSICHVG)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHGK)* 1 - Yes 2 - No	*(PRSICHGL)* 1 - Yes 2 - No
IgA	*(PRSICHVA)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHAK)* 1 - Yes 2 - No	*(PRSICHAL)* 1 - Yes 2 - No
IgM	*(PRSICHVM)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHMK)* 1 - Yes 2 - No	*(PRSICHML)* 1 - Yes 2 - No
IgD	*(PRSICHVD)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHDK)* 1 - Yes 2 - No	*(PRSICHDL)* 1 - Yes 2 - No
IgE	*(PRSICHVE)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHEK)* 1 - Yes 2 - No	*(PRSICHEL)* 1 - Yes 2 - No

29. Did confirmatory serum IFE indicate light chain disease?*(PRSICLCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

30. Kappa:*(PRSICKLC)* ☐ 1 - Yes ☐ 2 - No

31. Lambda:*(PRSICLLC)* ☐ 1 - Yes ☐ 2 - No

Urine Protein Electrophoresis/Urine Immunofixation (UPEP/Urine IFE)

32. How many UPEPs/Urine IFEs were performed?*(PRLUPNM)* 0 - None 1 - One UPEP/Urine IFE 2 - Two UPEPs/Urine IFEs

33. For each UPEP/Urine IFE performed, record the following:

	Date of UPEP/Urine IFE	Urine total protein value	Urine total volume	M-protein result (Urine IFE)	M-protein value	M-protein units	Urine light chain type
Initial UPEP/Urine IFE	*(PRLUPDT)* *(mm/dd/yyyy)*	*(PRLUPTPG)* *(xx.xxx)* g/24hrs	*(PRUPTVL)* *(xx.xxx)* L/24hrs	*(PRLUPRES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(PRUPVAL)* *(xxxx.xxx)*	*(PRLUPUN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(PRLUPK)* 1 - Yes 2 - No
		(PRLUPTMG) **OR** *(xxxxx.xx)* mg/24hrs	*(PRUPTVML)* **OR** *(xxxxx.xx)* mL/24hrs				Lambda:*(PRLUPL)* 1 - Yes 2 - No
Confirmatory UPEP/Urine IFE	*(PRLUPCDT)* *(mm/dd/yyyy)*	*(PRUPCTPG)* *(xx.xxx)* g/24hrs	*(PRUPCTVL)* *(xx.xxx)* L/24hrs	*(PRLUPCRS)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(PRUPCVAL)* *(xxxx.xxx)*	*(PRLUPCUN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(PRLUPCK)* 1 - Yes 2 - No
		(PRUPCTMG) **OR**	*(PRUPCVML)* **OR**				Lambda:*(PRLUPCL)*

		(xxxxx.xx) mg/24hrs	(xxxxx.xx) mL/24hrs				1 - Yes 2 - No

Bone Marrow

34. Was a bone marrow biopsy performed? *(PRLBMBX)* ☐ 1 - Yes ☐ 2 - No

35. Date of bone marrow biopsy: *(PRLBXDT)* _____ *(mm/dd/yyyy)*

36. Were plasma cells present in the biopsy? *(PRLBXPLS)*
1 - Yes
2 - No
3 - Plasma Cells Present but Not Quantifiable

37. Record percentage of plasma cells: *(PRLBXPCT)* _____ *(xxx.x)* %

38. Was a bone marrow aspirate performed? *(PRLBMAS)* ☐ 1 - Yes ☐ 2 - No

39. Date of bone marrow aspirate: *(PRLASPDT)* _____ *(mm/dd/yyyy)*

40. Were plasma cells present in the aspirate? *(PRLASPLS)*
1 - Yes
2 - No
3 - Plasma Cells Present but Not Quantifiable

41. Record percentage of plasma cells: *(PRLASPCT)* _____ *(xxx.x)* %

Lytic Lesions

42. Was a lytic lesion assessment performed? *(PRLLSNAS)* ☐ 1 - Yes ☐ 2 - No

43. Date of lytic bone lesion assessment: *(PRLLSNDT)* _____ *(mm/dd/yyyy)*

44. Record most recent information regarding lytic bone lesions: *(PRLLESN)*
1 - No Change
2 - New Lytic Bone Lesions
3 - Definite Size Increase of Existing Lytic Bone Lesions
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

45. Specify other lesion information: *(PRLLSNSP)* _____

Plasmacytomas

46. Was a plasmacytoma assessment performed? *(PRPLCYAS)* ☐ 1 - Yes ☐ 2 - No

47. Date of plasmacytoma assessment: *(PRPLCYDT)* _____ *(mm/dd/yyyy)*

48. Record most recent information regarding soft tissue plasmacytomas: *(PRPLCYT)*
1 - No Change
2 - New Plasmacytomas
3 - Definite Size Increase of Existing Plasmacytomas
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

49. Specify other plasmacytoma information: *(PRPLCYSP)* _____

Corrected Serum Calcium

50. Was a corrected serum calcium value obtained? *(PRLCALC)* ☐ 1 - Yes ☐ 2 - No

51. Date corrected serum calcium sample obtained: *(PRLCADT)* _____ *(mm/dd/yyyy)*

52. Record most recent corrected serum calcium value: *(PRLCAVAL)* _____ *(xx.xx)*

53. Corrected serum calcium value units: *(PRLCAUN)*
1- g/dL
2- mg/dL
3- mmol/L

54. Did the patient develop hypercalcemia? *(PRHYPCAL)* ☐ 1 - Yes ☐ 2 - No

55. Was hypercalcemia attributable to any other cause? *(PRHYPATT)* ☐ 1 - Yes ☐ 2 - No

56. Specify other cause of hypercalcemia: *(PRHYPSP)* _____

Quantitative Serum Immunoglobulins

57. Were serum immunoglobulins obtained? *(PRLSIGS)* ☐ 1 - Yes ☐ 2 - No

58. Date immunoglobulins obtained: *(PRLSIGDT)* _____ *(mm/dd/yyyy)*

59. Record immunoglobulin values:

	Laboratory Value (mg/dL)	Laboratory Value (g/dL)
Quantitative IgG	*(PRLIGGMG)* _____ *(xxxxx.xx)* mg/dL	*(PRLIGGG)* **OR** _____ *(xx.xxx)* g/dL
Quantitative IgA	*(PRLIGAMG)* _____ *(xxxxx.xx)* mg/dL	*(PRLIGAG)* **OR** _____ *(xx.xxx)* g/dL
Quantitative IgM	*(PRLIGMMG)* _____ *(xxxxx.xx)* mg/dL	*(PRLIGMG)* **OR** _____ *(xx.xxx)* g/dL
If serum heavy chain type is IgD or IgE, record values below:		
Quantitative IgD	*(PRLIGDMG)* _____ *(x.xxx)* mg/dL	*(PRLIGDG)* **OR** _____ *(x.xxxxxx)* g/dL
Quantitative IgE	*(PRLIGEMG)* _____ *(x.xxx)* mg/dL	*(PRLIGEG)* **OR** _____ *(x.xxxxxx)* g/dL

Treatment for Progression

60. Has the patient been treated for progression?*(PRLTREAT)* ☐ 1 - Yes ☐ 2 - No

61. Date treatment administered:*(PRLTRTDT)* *(mm/dd/yyyy)*

62. Indicate type of treatment:*(PRTRTTYP)*

- 1- Donor Lymphocyte Infusion (DLI)
- 2- Peripheral Blood Stem Cells (PBSCs)
- 3- Chemotherapy
- 4- Radiation
- 5- Second Transplant
- *Additional Options Listed Below

If other treatment, specify:*(PRLTRTSP)*

Submit a copy of any laboratory reports that support progression (such as SPEP, SIFE, UPEP, UIFE, bone marrow reports, and/or health and physical exam notes). Be sure to remove patient identifiers prior to uploading. If unable to upload documents, submit reports via fax to 240-306-0963.

Comments:*(PRLCOMMT)*

Additional Selection Options for PRL

Record most recent information regarding lytic bone lesions:
6- Other

Record most recent information regarding soft tissue plasmacytomas:
6- Other

Indicate type of treatment:
6- Other

Blood and Marrow Transplant Clinical Trials Network

Endpoint Review Query Form- 0702 (Q02)

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

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

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

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

(BATHING)

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

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

(CUTTIME)

b. Accomplished less than you would like

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

(LESSACC)

c. Were limited in the kind of work or other activities

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

(WORKLMT)

d. Had difficulty performing the work or other activities (for example, it took extra effort)

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

(PRFMDIFF)

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

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

(ECUTTIME)

b. Accomplished less than you would like

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

(ELESSACC)

c. Did work or other activities less carefully than usual

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

(ECARELES)

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 - 0702 (T17)

Web Version: 1.0; 4.00; 12-11-15

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

1. Record date of evaluation:*(T17ASTDT)* _____ *(mm/dd/yyyy)*

Record the highest grade of toxicity diagnosed since the previous evaluation. If this is the first evaluation, record the highest grade of toxicity diagnosed since Day 0. The toxicity grades are based on the NCI CTCAE Version 3.0.

Neurologic Toxicity

2. Tremors:*(T17NTRMS)*
   - 0 - Grades 0-2
   - 3 - Severe Tremor Interfering with ADL
   - 4 - Disabling

3. Ataxia:*(T17ATXIA)*
   - 0 - Grades 0-2
   - 3 - Symptomatic, Interfering with ADL; Mechanical Assistance Indicated
   - 4 - Disabling
   - 5 - Death

4. Somnolence:*(T17SMNLN)*
   - 0 - Grades 0-2
   - 3 - Obtundation or Stupor; Difficult to Arouse; Interfering with ADL
   - 4 - Coma
   - 5 - Death

5. Dizziness:*(T17DIZZY)*
   - 0 - Grades 0-2
   - 3 - Interfering with ADL
   - 4 - Disabling

6. Syncope:*(T17SYNC)*
   - 0 - Grades 0-2
   - 3 - Present
   - 4 - Life-Threatening Consequences
   - 5 - Death

7. Neuropathy - motor:*(T17MOTOR)*
   - 0 - Grades 0-2
   - 3 - Weakness Interfering with ADL; Bracing or Assistance to Walk Indicated
   - 4 - Life-Threatening; Disabling (e.g., Paralysis)
   - 5 - Death

8. Neuropathy - sensory:*(T17SENSR)*
   - 0 - Grades 0-2
   - 3 - Sensory Alteration or Paresthesia Interfering with ADL
   - 4 - Disabling
   - 5 - Death

9. Did the patient experience any seizures during this assessment period?*(T17SEIZR)* ☐ 1 - Yes ☐ 2 - No

10. Record seizure toxicity grade:*(T17SZGRD)*
    - 2 - One Brief Generalized Seizure; Seizure(s) Well Controlled by Anticonvulsants
    - 3 - Seizures in Which Consciousness is Altered; Poorly Controlled Seizure Disorder
    - 4 - Seizures of Any Kind Which are Prolonged, Repetitive or Difficult to Control
    - 5 - Death

Cardiovascular Toxicity

11. Atrial fibrillation:*(T17AFIB)*
    - 0 - Grades 0-2
    - 3 - Symptomatic and Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
    - 4 - Life-Threatening (e.g., Arrhythmia associated with CHF, hypotension, syncope, shock)
    - 5 - Death

12. Atrial flutter:*(T17AFLUT)*
    - 0 - Grades 0-2
    - 3 - Symptomatic and Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
    - 4 - Life-Threatening (e.g., Arrhythmia associated with CHF, hypotension, syncope, shock)
    - 5 - Death

13. Chest pain (cardiac ischemia/infarction):*(T17CHPAN)*
    - 0 - Grades 0-2
    - 3 - Symptomatic and Testing Consistent with Ischemia; Unstable Angina; Intervention Indicated
    - 4 - Acute Myocardial Infarction
    - 5 - Death

14. Hypertension:*(T17HYPRC)*
    - 0 - Grades 0-2
    - 3 - Requiring More than One Drug or More Intensive Therapy than Previously
    - 4 - Life-Threatening Consequences (e.g., Hypertensive Crisis)
    - 5 - Death

15. Hypotension:*(T17HYPOT)*

0 - Grades 0-2
3 - Sustained (> or = 24 Hours) Therapy, Resolves Without Persisting Physiologic Consequences
4 - Shock (e.g., Acidemia; Impairment of Vital Organ Function)
5 - Death

16. Left ventricular systolic dysfunction:*(T17LVSD)*

0 - Grades 0-2
3 - Symptomatic CHF Responsive to Intervention
4 - Refractory CHF or Poorly Controlled; Intervention with Ventricular Assist Device
5 - Death

17. Cardiac arrhythmia:*(T17CRDAR)*

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

GI Toxicity

18. Abdominal pain:*(T17ABPAN)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

19. Constipation:*(T17CNSTP)*

0 - Grades 0-2
3 - Symptoms Interfering with ADL; Obstipation with Manual Evacuation Indicated
4 - Life-Threatening Consequences (e.g., Obstruction, Toxic Megacolon)
5 - Death

20. Diarrhea:*(T17DIARR)*

0 - Grades 0-2
3 - Inc by 7+ stools over baseline; require IVF>or=24hrs; hosp; severe inc in ostomy output
4 - Resulting in hemodynamic Insufficiency or life threatening consequences
5 - Death

21. Dysphagia:*(T17DYSPH)*

0 - Grades 0-2
3 - Symptomatic & Severely Altered Eating/Swallowing (e.g., inadequate oral intake), IVF, Tube Feed,
4 - Life-Threatening Consequences (e.g., Obstruction, Perforation)
5 - Death

22. Heartburn/dyspepsia:*(T17HRTBN)*

0 - Grades 0-2
3 - Severe

23. Nausea:*(T17NAUS)*

0 - Grade 0-2
3 - Inadequate oral intake; IVF; Tube Feedings or TPN indicated >or=24 Hours
4 - Life-Threatening Consequences
5 - Death

24. Vomiting:*(T17VOMIT)*

0 - Grades 0-1
2 - 2-5 Episodes in 24 hrs; IV Fluids Indicated <24 hrs
3 - >/=6 Episodes in 24 hrs; IV Fluids, or TPN Indicated >/=24 hrs
4 - Life-Threatening Consequences
5 - Death

25. Did taste alteration (dysgeusia) occur:*(T17DYSGS)*

☐ 1 - Yes ☐ 2 - No

26. Ulcers:*(T17ULCER)*

0 - Grades 0-2
3 - Severely Altered GI Function; IV Fluids, Tube Feedings or TPN Indicated >/=24 hrs
4 - Life-Threatening Consequences
5 - Death

27. Mucositis/stomatitis (clinical exam):*(T17MUCOS)*

0 - Grades 0-2
3 - Confluent Ulcerations or Pseudomembranes; Bleeding with Minor Trauma
4 - Tissue Necrosis; Significant Spontaneous Bleeding; LT Consequences
5 - Death

Renal Toxicity

28. Did the patient experience renal failure severe enough to warrant dialysis?*(T17RNLFL)*

☐ 1 - Yes ☐ 2 - No

29. Did the patient receive dialysis?*(T17DIALY)*

☐ 1 - Yes ☐ 2 - No

30. Hemorrhagic cystitis:*(T17CYSTI)*

0 - Grades 0-2
3 - Transfusion; IV Pain Medications; Bladder Irrigation Indicated
4 - Catastrophic Bleeding; Major Non-Elective Intervention Indicated
5 - Death

	Peak Value During Interval	ULN for your Institution	Date Sample Obtained
31. Creatinine:	*(T17CREAT)* _____ *(xx.x)* mg/dL	*(T17ULNCR)* _____ *(xx.x)* mg/dL	*(T17CRTDT)* _____ *(mm/dd/yyyy)*

Coagulation Toxicity

32. HUS/TTP/thrombotic microangiopathy:*(T17DCTTP)*

0 - Grades 0-3
4 - Laboratory Findings, Life-Threatening or Disabling Consequences
5 - Death

Metabolic Toxicity

33. Hyperglycemia:*(T17HYPGL)*

0 - Grades 0-2
3 - >250-500 mg/dL; >13.9-27.8 mmol/L
4 - >500 mg/dL; >27.8 mmol/L or Acidosis
5 - Death

Endocrine Toxicity

34. Hypothyroidism:*(T17THYRO)*

0 - Grades 0-2
3 - Symptoms Interfering with ADL; Hospitalization Indicated
4 - Life-Threatening Myxedema Coma
5 - Death

Auditory Toxicity

35. Hearing:*(T17HEAR)*

0 - Grades 0-2
3 - Hearing Loss Requiring Hearing Aid or Intervention (i.e., Interfering with ADL)
4 - Profound Bilateral Hearing Loss (>90 dB)

36. Tinnitus:*(T17TINN)*

0 - Grades 0-2
3 - Tinnitus Interfering with ADL
4 - Disabling

Ocular/Visual Toxicity

37. Blurred vision:*(T17BLRRY)*

0 - Grades 0-2
3 - Symptomatic and Interfering with ADL
4 - Disabling

38. Conjunctivitis:*(T17CONJ)*

0 - Grades 0-2
3 - Symptomatic, Interfering with ADL; Operative Intervention Indicated

Constitutional Toxicity

39. Asthenia (fatigue, lethargy, or malaise):*(T17FATIG)*

0 - Grades 0-2
3 - Severe Fatigue Interfering with ADL
4 - Disabling

40. Fever (without neutropenia):*(T17FEVER)*

0 - Grades 0-1
2 - >39.0-40.0C (102.3-104.0F)
3 - >40C (>104.0F) for <24 hrs
4 - >40C (>104.0F) for >24 hrs
5 - Death

41. Insomnia:*(T17INSOM)*

0 - Grades 0-2
3 - Frequent Difficulty Sleeping, Interfering with ADL
4 - Disabling

Musculoskeletal Toxicity

42. Bone pain:*(T17BNPAN)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

43. Joint pain (arthralgia):*(T17ARTHR)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

44. Muscle pain (myalgia):*(T17MYALG)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

45. Muscle weakness, generalized or specific area (not due to neuropathy):*(T17MUSCL)*

0 - Grades 0-2
3 - Symptomatic and Interfering with ADL
4 - Life-Threatening; Disabling
5 - Death

Dermatologic Toxicity

46. Pruritus/itching:*(T17PRURI)*

0 - Grades 0-2
3 - Intense or Widespread and Interfering with ADL

47. Rash:*(T17RASH)*

0 - Grades 0-2
3 - Severe erythroderma or macular, papular or vesicular eruption; desquamation covering >/= 50% BSA
4 - Generalized Exfoliative Ulcerative or Bullous Dermatitis
5 - Death

48. Urticaria (hives, welts, wheals):*(T17URTIC)*

0 - Grades 0-2
3 - Intervention indicated for >or=24 hours

Hepatobiliary/Pancreas Toxicity

49. Pancreatitis:*(T17PANCR)*

0 - Grades 0-2
3 - Interventional Radiology or Operative Intervention Indicated
4 - Life-Threatening Consequences (e.g., Circulatory Failure, Hemorrhage, Sepsis)
5 - Death

Hemorrhagic Toxicity

50. Hemorrhage:*(T17HEMRH)*
- 0 - Grades 0-2
- 3 - Transfusion, Int Radiology, Endoscopic, or Operative Int Indicated; Hemostatis of Bleeding Site
- 4 - Life-Threatening Consequences; Major Urgent Intervention Indicated
- 5 - Death

51. Which organ system was the hemorrhage associated with?*(T17ORGAN)*
- 1 - CNS
- 2 - Gastrointestinal
- 3 - Genitourinary
- 4 - Pulmonary, Upper Respiratory
- 5 - Other

Specify other organ system:*(T17SPOTH)*

Vascular Toxicity

52. Vascular leak syndrome:*(T17VASCL)*
- 0 - Grades 0-2
- 3 - Respiratory compromise or fluids indicated
- 4 - Life-threatening; pressor support or ventilatory support indicated
- 5 - Death

53. Thrombosis/thrombus/embolism:*(T17THRMB)*
- 0 - Grades 0-2
- 3 - DVT or Cardiac Thrombosis; Intervention (e.g., Anticoagulation, Lysis) Indicated
- 4 - Embolic Event Including Pulmonary Embolism or Life-Threatening Thrombus
- 5 - Death

Pulmonary Toxicity

54. Hypoxia (for more than 24 hours):*(T171HYPX)*
- 0 - Grades 0-2
- 3 - Decreased Oxygen Saturation at Rest; Continuous Oxygen Indicated
- 4 - Life-Threatening; Intubation or Ventilation Indicated
- 5 - Death

55. Dyspnea:*(T17DYSPN)*
- 0 - Grades 0-2
- 3 - Dyspnea with Activities of Daily Living
- 4 - Dyspnea at Rest; Intubation or Ventilator Indicated
- 5 - Death

56. Cough:*(T17COUGH)*
- 0 - Grades 0-2
- 3 - Symptomatic and Significantly Interfering with Sleep or ADL

57. During this assessment period, was an FEV1 performed?*(T17FEVDN)* ☐ 1 - Yes ☐ 2 - No

58. Record FEV1 value obtained:*(T17FEVLV)* _____ *(xxx)* % of predicted value

59. During this assessment period, was an FVC performed?*(T17FVCDN)* ☐ 1 - Yes ☐ 2 - No

60. Record the FVC value obtained:*(T17FVCLV)* _____ *(xxx)* % of predicted value

Hepatic Toxicity

61. Bilirubin:*(T17BILIR)*
- 0 - Grades 0-2
- 3 - >3.0-10.0 x ULN
- 4 - >10.0 x ULN

62. ALT:*(T17ALT)*
- 0 - Grades 0-1
- 2 - > 2.5 - 5.0 x ULN
- 3 - > 5.0 - 20.0 x ULN
- 4 - > 20.0 x ULN

63. AST:*(T17AST)*
- 0 - Grades 0-1
- 2 - > 2.5 - 5.0 x ULN
- 3 - > 5.0 - 20.0 x ULN
- 4 - > 20.0 x ULN

64. Alkaline phosphatase:*(T17ALKPH)*
- 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:

65. Jaundice:*(T17JANDC)* ☐ 1 - Yes ☐ 2 - No

66. Hepatomegaly:*(T17HEPTM)* ☐ 1 - Yes ☐ 2 - No

67. Right upper quadrant pain:*(T17QUADP)* ☐ 1 - Yes ☐ 2 - No

68. Weight gain (>5%) from baseline:*(T17WGTGN)* ☐ 1 - Yes ☐ 2 - No

69. **Indicate the etiology of the abnormal liver function:**

	Etiology	Biopsy Results	Doppler Ultrasound Results
VOD:	*(T17VODET)* 1 - Yes / 2 - No	*(T17VODBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17VODDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
GVHD:			

	1 - Yes 2 - No *(T17GVHET)*	1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done *(T17GVHBI)*	1 - Confirmed 2 - Not Confirmed 3 - Not Done *(T17GVHDP)*
Infection:	1 - Yes 2 - No *(T17INFET)*	1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done *(T17INFBI)*	1 - Confirmed 2 - Not Confirmed 3 - Not Done *(T17INFDP)*
Other:	1 - Yes 2 - No *(T17OTHET)*	1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done *(T17OTHBI)*	1 - Confirmed 2 - Not Confirmed 3 - Not Done *(T17OTHDP)*
Unknown:	1 - Yes 2 - No *(T17UNKET)*	1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done *(T17UNKBI)*	1 - Confirmed 2 - Not Confirmed 3 - Not Done *(T17UNKDP)*

Specify other etiology:*(T172SPEC)*

Comments:*(T17COMM)*

Blood and Marrow Transplant Clinical Trials Network

Thromboembolism Form - 0702 (THR)

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

Segment *(PROTSEG)*: A
Thromboembolic event date *(THROMBDT)*:

Record type of thromboembolism:

1. DVT (Deep Vein Thrombosis):	*(THRDVT)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRDVGDE)* 0 - Grades 0-2 3 - DVT or Cardiac Thrombosis; Intervention (e.g., Anticoagulation, Lysis) Indicated 4 - Embolic Event Including Pulmonary Embolism or Life-Threatening Thrombus 5 - Death
2. Pulmonary Emboli:	*(THRPULM)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THREMGDE)* 0 - Grades 0-2 3 - DVT or Cardiac Thrombosis; Intervention (e.g., Anticoagulation, Lysis) Indicated 4 - Embolic Event Including Pulmonary Embolism or Life-Threatening Thrombus 5 - Death
3. Arterial Thrombosis:	*(THRARTH)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRARGDE)* 0 - Grades 0-2 3 - Laboratory Findings Present with Clinical Consequences 4 - Laboratory Findings and Life-Threatening or Disabling Consequences 5 - Death
4. Cardiac Ischemia/Infarction:	*(THRCRDIS)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRCIGDE)* 0 - Grades 0-2 3 - Symptomatic and Testing Consistent with Ischemia; Unstable Angina; Intervention Indicated 4 - Acute Myocardial Infarction 5 - Death
5. CNS Cerebrovascular Ischemia:	*(THRCVA)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRCVGDE)* 0 - Grades 0-2 3 - Transient Ischemic Event or Attack (TIA) 4 - Cerebral Vascular Accident (CVA, Stroke), Neurologic Deficit >24 hrs 5 - Death

If DVT, specify site:

6. Upper extremity:*(THRDVTUP)* ☐ 1 - Yes ☐ 2 - No
7. Lower extremity:*(THRDVTLO)* ☐ 1 - Yes ☐ 2 - No

8. Was the thrombosis related to the catheter?*(THRCATRL)* ☐ 1 - Yes ☐ 2 - No

9. Was the patient on anti-coagulation therapy?*(THRTHRPY)* ☐ 1 - Yes ☐ 2 - No

If yes, specify all therapies:

10. Aspirin:*(THRASP)* ☐ 1 - Yes ☐ 2 - No
11. Coumadin:*(THRCOUM)* ☐ 1 - Yes ☐ 2 - No
12. Low molecular weight heparin:*(THRHEP)* ☐ 1 - Yes ☐ 2 - No
13. Record type of low molecular weight heparin:*(THRHEPTY)*
    1 - Enoxaparin
    2 - Daltiparin
    3 - Other

If other low molecular weight heparin type, specify:*(THRHPOTS)*

14. Other therapy:*(THROTHER)* ☐ 1 - Yes ☐ 2 - No

If other therapy, specify:*(THROTHSP)*

Comments:*(THRCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

Web Version: 1.0; 18.00; 08-09-18

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

1. Did the patient receive a first transplant?*(FIRSTTXP)* ☐ 1 - Yes ☐ 2 - No

   a. If no, indicate the reason for not receiving a first transplant:*(FRSTXRSN)*

   1 - Patient Withdrew Consent
   2 - Patient Refused Treatment
   3 - Adverse Event, Specify
   4 - Myeloma Progression
   5 - Insurance Coverage Denied
   *Additional Options Listed Below

   If the reason for not receiving a first transplant is Adverse Event (Grades 3-5) **OR** Other, specify:*(FRSTXPOT)*

2. Record date of initiation of conditioning regimen:*(CONDNGDT)* *(mm/dd/yyyy)*
3. Record date of hematopoietic stem cell infusion:*(TXDTTXP)* *(mm/dd/yyyy)*
4. IUBMID for this patient (if available):*(T_IUBMID)*

   Comments:*(COMMTXP1)*

Additional Selection Options for TXP

If no, indicate the reason for not receiving a first transplant:
6 - Physician Decision
9 - Other, Specify

Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

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

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

1. Report activation status:*(AVSTAT_A)*

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

Relevant Past Medical History

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

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

(SEMEDHX)

3. **Event Summary**

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

(SESUMM)

---

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

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

Blood and Marrow Transplant Clinical Trials Network

AE Therapy Form (AE3)

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

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

1. Adverse event status:*(AVSTAT_E)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason
2. Has this event been determined to be an unexpected, grade 3-5 adverse event?*(AMDETER)* ☐ 1 - Yes ☐ 2 - No
3. Does this require expedited reporting to the FDA?*(AMEXPFDA)* ☐ 1 - Yes ☐ 2 - No
4. Does this require expedited reporting to the DSMB?*(AMEXPDSM)* ☐ 1 - Yes ☐ 2 - No
5. Do you recommend the patient be withdrawn from further protocol therapy?*(AMWITHDR)* ☐ 1 - Yes ☐ 2 - No
6. Is the review complete?*(AMREVDNE)* ☐ 1 - Yes ☐ 2 - No
7. If **No**, what additional information is required:*(AMREVINF)*
8. Medical Monitor event description:*(AMMMEVDS)*
9. Medical Monitor CTCAE grade of event:*(CTCAEGRD)*
   - 1 - Grade 1
   - 2 - Grade 2
   - 3 - Grade 3
   - 4 - Grade 4
   - 5 - Grade 5

Comments:*(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

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

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

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

   Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

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

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

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

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

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

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

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

Specify other:*(DTHSPEC1)*

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

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

Specify other:*(DTHSPEC2)*

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

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

Specify other:*(DTHSPEC3)*

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

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

Specify other:*(DTHSPEC4)*

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

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

Specify other:*(DTHSPEC5)*

Comments:*(DTCMMNTS)*

Additional Selection Options for DTH

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

Blood and Marrow Transplant Clinical Trials Network

0702B (ENR)

Web Version: 1.0; 2.03; 10-16-15

Multiple Myeloma Follow-On Enrollment Form - Segment B

1. Record the treatment the patient was randomized to:*(MMTRTRAN)*
   - 1 - Auto/Auto
   - 2 - Auto/RVD Consolidation
   - 3 - Auto/Maintenance

2. Record the treatment the patient will receive:*(MMTRTGET)*
   - 1 - Auto/Auto
   - 2 - Auto/RVD Consolidation
   - 3 - Auto/Maintenance
   - 4 - Other

3. Specify other treatment:*(MMTRTOTH)*

4. Reason patient did not receive assigned treatment:*(MMRSNTRT)*
   - 1 - Patient Withdrew Consent
   - 2 - Patient Refused Treatment
   - 3 - Adverse Event
   - 4 - Myeloma Progression
   - 5 - Insurance Coverage Denied
   - *Additional Options Listed Below

5. Specify other reason patient did not receive assigned treatment:*(MMBRSNSP)*

6. Record the patient's body surface area (BSA):*(MMBSA)* *(x.x)*

7. BSA date:*(MMBSADT)* *(mm/dd/yyyy)*

Comments:*(MMBCOMM)*

Additional Selection Options for ENR

Reason patient did not receive assigned treatment:
6 - Inadequate Recovery from First Transplant
7 - Physician Decision
9 - Other

Blood and Marrow Transplant Clinical Trials Network

FACT-BMT (Version 4) (FCT)

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

Segment *(PROTSEG)*: B
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 uses 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)*

Each of the above items uses 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

10. I get support from my friends*(FRNDSPRT)*

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

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

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

Did the patient answer the following question?(CHECKBOX)

☐ 1 - Yes ☐ 2 - No

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

Emotional Well-Being

15. I feel sad*(FEELSAD)*

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

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

18. I feel nervous*(NERVOUS)*

19. I worry about dying*(WORRYDIE)*

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)*

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

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

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

35. I get tired easily*(GETTIRED)*

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

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

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

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

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

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

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

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

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

40. I can remember things*(MEMORY)*

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

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)*

45. I have tremors*(TREMORS)*

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

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

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

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

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 Status Form - 0702 (FU5)

Web Version: 1.0; 6.00; 10-16-15

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

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

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

2. Has the patient died?*(MMPTDTH)* 1 - Yes 2 - No
If Yes, a Death Form must be submitted.
3. Date of patient death:*(MMDTHDT)* *(mm/dd/yyyy)*
4. Has the patient experienced disease progression?*(MMRELPR)* 1 - Yes 2 - No
If Yes, a Progression Form must be submitted.
5. Date of progression:*(MMRELDT)* *(mm/dd/yyyy)*
6. Has the patient initiated any non-protocol anti-myeloma therapy?*(MMRECTHP)* 1 - Yes 2 - No

If yes, record type of therapy:

7.

	Receiving:	Start Date:	Has Treatment been Discontinued?	Stop Date:
Dexamethasone:	*(MMDEXTH)* 1 - Yes 2 - No	*(MMDEXST)* *(mm/dd/yyyy)*	*(MMDEXDIS)* 1 - Yes 2 - No	*(MMDEXSTP)* *(mm/dd/yyyy)*
Thalidomide:	*(MMTHALTH)* 1 - Yes 2 - No	*(MMTHALST)* *(mm/dd/yyyy)*	*(MMTHLDIS)* 1 - Yes 2 - No	*(MMTHLSTP)* *(mm/dd/yyyy)*
Lenalidomide:	*(MMLENTH)* 1 - Yes 2 - No	*(MMLENST)* *(mm/dd/yyyy)*	*(MMLENDIS)* 1 - Yes 2 - No	*(MMLENSTP)* *(mm/dd/yyyy)*
Bortezomib:	*(MMBORTH)* 1 - Yes 2 - No	*(MMBORST)* *(mm/dd/yyyy)*	*(MMBORDIS)* 1 - Yes 2 - No	*(MMBORSTP)* *(mm/dd/yyyy)*
Other:	*(MMRCVOTH)* 1 - Yes 2 - No	*(MMOTHST)* *(mm/dd/yyyy)*	*(MMOTHDIS)* 1 - Yes 2 - No	*(MMOTHSTP)* *(mm/dd/yyyy)*

8. Specify other type of anti-myeloma therapy:*(MMOTHSPE)*
9. Record reason for initiation of anti-myeloma therapy:*(MMRSNTHR)*
10. Has the patient experienced any new clinically significant infections?*(MMNEWIN)* 1 - Yes 2 - No
If Yes, an Infection Form must be submitted.
11. Date of infection:*(MMINFDT)* *(mm/dd/yyyy)*
12. Has the patient been hospitalized other than for a protocol-specified transplant?*(MMHOSP)* 1 - Yes 2 - No
If Yes, a Re-Admission Form must be submitted.
13. Date of hospitalization:*(MMHOSDT)* *(mm/dd/yyyy)*
14. Has the patient received a non-protocol specified transplant?*(MMNONTXP)* 1 - Yes 2 - No
15. Date of non-protocol specified transplant:*(MMTXPDT)* *(mm/dd/yyyy)*
16. Has the patient experienced a thromboembolic event?*(MMTHRMBO)* 1 - Yes 2 - No
If Yes, a Thromboembolism Form must be submitted.
17. Date of thromboembolic event:*(MMTHRMDT)* *(mm/dd/yyyy)*
18. Has the patient experienced any unexpected grade 3-5 adverse events?*(MMUAE)* 1 - Yes 2 - No
If Yes, an Unexpected, Grade 3-5 Adverse Event Form must be submitted.
19. Date of onset of unexpected grade 3-5 adverse event:*(MMUAEDT)* *(mm/dd/yyyy)*
20. Was the patient diagnosed with a second cancer?*(MMSECCAN)* 1 - Yes 2 - No
21. Date of second cancer diagnosis:*(MMSECCDT)* *(mm/dd/yyyy)*

Comments:*(MMCMNT)*

Blood and Marrow Transplant Clinical Trials Network

Hematology/Chemistry Form - 0702 (HCF)

Web Version: 1.0; 2.05; 10-16-15

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

1. Record the date of assessment:*(HCASMTDT)* _____ *(mm/dd/yyyy)*

CBC

Record the most recent CBC lab results:

	Most Recent Value	Date of Sample
2. Hemoglobin:	*(HCFHGB)* _____ *(xx.x)* g/dL	*(HCFHGBDT)* _____ *(mm/dd/yyyy)*
3. WBC:	*(HCFWBC)* _____ *(xxxxxx)* /mm^3	*(HCFWBCDT)* _____ *(mm/dd/yyyy)*
4. Platelet Count:	*(HCFPLT)* _____ *(xxxxxx)* /mm^3	*(HCFPLTDT)* _____ *(mm/dd/yyyy)*
5. Neutrophils:	*(HCFNEUT)* _____ *(xxxxx)* /mm^3	*(HCFNEUDT)* _____ *(mm/dd/yyyy)*
6. Eosinophils:	*(HCFEOS)* _____ *(xxxx)* /mm^3	*(HCFEOSDT)* _____ *(mm/dd/yyyy)*

Chemistry

Record the most recent chemistry lab results:

	Most Recent Value	Date of Sample
7. Creatinine:	*(HCFCREAT)* _____ *(x.x)* mg/dL	*(HCFCRTDT)* _____ *(mm/dd/yyyy)*
8. Estimated Creatinine Clearance:	*(HCFCRCL)* _____ *(xxx)* mL/min	*(HCFCRCDT)* _____ *(mm/dd/yyyy)*
9. Bilirubin:	*(HCFBILI)* _____ *(xx.x)* mg/dL	*(HCFBILDT)* _____ *(mm/dd/yyyy)*
10. Alkaline Phosphatase:	*(HCFALKPH)* _____ *(xxxx)* IU/L	*(HCFALKDT)* _____ *(mm/dd/yyyy)*
11. AST:	*(HCFAST)* _____ *(xxxx)* IU/L	*(HCFASTDT)* _____ *(mm/dd/yyyy)*
12. ALT:	*(HCFALT)* _____ *(xxxx)* IU/L	*(HCFALTDT)* _____ *(mm/dd/yyyy)*
13. Glucose:	*(HCFGLUC)* _____ *(xxxx)* mg/dL	*(HCFGLUDT)* _____ *(mm/dd/yyyy)*
14. Sodium:	*(HCSODIUM)* _____ *(xxx)* mmol/L	*(HCFSDDT)* _____ *(mm/dd/yyyy)*
15. Potassium:	*(HCFPOTAS)* _____ *(x.x)* mmol/L	*(HCFPTSDT)* _____ *(mm/dd/yyyy)*
16. Calcium:	*(HCFCALCI)* _____ *(xx.x)* mg/dL	*(HCFCALDT)* _____ *(mm/dd/yyyy)*

Comments:*(HCFCOMM)* _____

Blood and Marrow Transplant Clinical Trials Network

Infection Form (INF)

Web Version: 1.0; 4.01; 10-16-15

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

INFECTION I

1. Type of infection:*(INFTYP01)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other
2. Organism I:*(ORGN01)*
   - 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

   If other specify:*(INFSPEC1)*
3. Record the level of certainty of the fungal infection diagnosis:*(CERTNTY1)*
   - 1 - Proven Fungal Infection
   - 2 - Probable Fungal Infection
   - 3 - Possible Fungal Infection
4. Severity of infection:*(SVRTY01)*
   - 1 - Moderate
   - 2 - Severe
   - 3 - Life-Threatening/Fatal

INFECTION II

5. Type of infection:*(INFTYP02)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other
6. Organism II:*(ORGN02)*
   - 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

   If other specify:*(INFSPEC2)*
7. Record the level of certainty of the fungal infection diagnosis:*(CERTNTY2)*
   - 1 - Proven Fungal Infection
   - 2 - Probable Fungal Infection
   - 3 - Possible Fungal Infection
8. Severity of infection:*(SVRTY02)*
   - 1 - Moderate
   - 2 - Severe
   - 3 - Life-Threatening/Fatal

INFECTION III

9. Type of infection:*(INFTYP03)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other
10. Organism III:*(ORGN03)*
    - 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

    If other specify:*(INFSPEC3)*
11. Record the level of certainty of the fungal infection diagnosis:*(CERTNTY3)*

1 - Proven Fungal Infection
2 - Probable Fungal Infection
3 - Possible Fungal Infection

12. Severity of infection:*(SVRTY03)*

1 - Moderate
2 - Severe
3 - Life-Threatening/Fatal

13. Was an agent(s) administered to treat the infection(s)?*(TRTINF)*

☐ 1 - Yes ☐ 2 - No

Provide agent(s) administered for this infectious period:

14. 1st agent:*(AGENT1)*

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

If other specify:*(AGTSPEC1)*

15. 2nd agent:*(AGENT2)*

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

If other specify:*(AGTSPEC2)*

16. 3rd agent:*(AGENT3)*

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

If other specify:*(AGTSPEC3)*

17. Were additional agents administered for this infectious period?*(ADDAGENT)*

☐ 1 - Yes ☐ 2 - No

If yes, specify additional agents administered:*(INFSPEC4)*

Comments:*(INFCOM)*

Additional Selection Options for INF

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

Myeloma Status Form - 0702 (MSF)

Web Version: 1.0; 6.02; 10-16-15

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

The purpose of this form is to capture the BMT CTN 0702 myeloma assessments required at 4 years post randomization.

1. Start of assessment period:*(MMSTRTDT)* *(mm/dd/yyyy)*
2. End of assessment period:*(MMENDDT)* *(mm/dd/yyyy)*

3. Indicate the patient's current disease response:*(MMCURDZR)*
   - 1 - Stringent Complete Response (sCR)
   - 2 - Complete Response (CR)
   - 3 - Near Complete Response (nCR)
   - 4 - Very Good Partial Response (VGPR)
   - 5 - Partial Response (PR)
   - *Additional Options Listed Below

If patient's current disease status is progression, a Progression form must be submitted.

Serum Protein Electrophoresis (SPEP)

4. How many SPEPs were performed during this assessment period?*(MMSPEPNM)*
5. Record the reason no SPEPs were performed:*(MMNOSPEP)*

6. For each SPEP performed, record the following:

	Date of SPEP	Serum total protein value	M-protein spike result	M-protein spike value
SPEP 1	*(MMSP1DT)* *(mm/dd/yyyy)*	*(MMSP1TG)* *(xx.xxx)* g/dL	*(MMSP1RES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(MMSP1MSG)* *(x.xxx)* g/dL
		(MMSP1TMG) **OR** *(xxxxx.xx)* mg/dL		*(MSP1MSMG)* **OR** *(xxxx.xx)* mg/dL
SPEP 2	*(MMSP2DT)* *(mm/dd/yyyy)*	*(MMSP2TG)* *(xx.xxx)* g/dL	*(MMSP2RES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(MMSP2MSG)* *(x.xxx)* g/dL
		(MMSP2TMG) **OR** *(xxxxx.xx)* mg/dL		*(MSP2MSMG)* **OR** *(xxxx.xx)* mg/dL
SPEP 3	*(MMSP3DT)* *(mm/dd/yyyy)*	*(MMSP3TG)* *(xx.xxx)* g/dL	*(MMSP3RES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(MMSP3MSG)* *(x.xxx)* g/dL
		(MMSP3TMG) **OR** *(xxxxx.xx)* mg/dL		*(MSP3MSMG)* **OR** *(xxxx.xx)* mg/dL

Serum Free Light Chain (FLC)

7. Was serum FLC measured?*(MMSFLC)* ☐ 1 - Yes ☐ 2 - No
8. Date of serum FLC assessment:*(MMSFLCDT)* *(mm/dd/yyyy)*
9. Kappa Free Light Chain value:*(MMSKMGL)* *(xxxxxx.xx)* mg/L *(MMSKMGDL)***OR** *(xxxxx.xxx)* mg/dL
10. Lambda Free Light Chain value:*(MMSLMGL)* *(xxxxxx.xx)* mg/L *(MMSLMGDL)***OR** *(xxxxx.xxx)* mg/dL
11. Free Light Chain Ratio (κ/λ):*(MMSFLCR)* *(xxxxxx.xxxxxx)*

Serum Immunofixation (Serum IFE)

12. How many serum IFEs were performed during this assessment period?*(MMSIFENM)*
13. Record the reason no serum IFEs were performed:*(MMNOSIFE)*

Serum IFE 1

14. Date of serum IFE 1:*(MMSI1DT)* *(mm/dd/yyyy)*
15. Serum IFE 1 Result:*(MMSI1RES)*
    - 1 - Positive
    - 2 - Negative

16. Was there mention of oligoclonal banding in the report?*(MMSI1OB)* ☐ 1 - Yes ☐ 2 - No

17. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MMSI1HVG)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HGK)* 1 - Yes 2 - No	*(MMSI1HGL)* 1 - Yes 2 - No
IgA	*(MMSI1HVA)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HAK)* 1 - Yes 2 - No	*(MMSI1HAL)* 1 - Yes 2 - No
IgM	*(MMSI1HVM)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HMK)* 1 - Yes 2 - No	*(MMSI1HML)* 1 - Yes 2 - No
IgD	*(MMSI1HVD)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HDK)* 1 - Yes 2 - No	*(MMSI1HDL)* 1 - Yes 2 - No
IgE	*(MMSI1HVE)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HEK)* 1 - Yes 2 - No	*(MMSI1HEL)* 1 - Yes 2 - No

18. Did serum IFE 1 indicate light chain disease?*(MMSI1LCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

19. Kappa:*(MMSI1KLC)* ☐ 1 - Yes ☐ 2 - No

20. Lambda:*(MMSI1LLC)* ☐ 1 - Yes ☐ 2 - No

Serum IFE 2

21. Date of serum IFE 2:*(MMSI2DT)* *(mm/dd/yyyy)*

22. Serum IFE 2 Result:*(MMSI2RES)* 1 - Positive 2 - Negative

23. Was there mention of oligoclonal banding in the report?*(MMSI2OB)* ☐ 1 - Yes ☐ 2 - No

24. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MMSI2HVG)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HGK)* 1 - Yes 2 - No	*(MMSI2HGL)* 1 - Yes 2 - No
IgA	*(MMSI2HVA)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HAK)* 1 - Yes 2 - No	*(MMSI2HAL)* 1 - Yes 2 - No
IgM	*(MMSI2HVM)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HMK)* 1 - Yes 2 - No	*(MMSI2HML)* 1 - Yes 2 - No
IgD	*(MMSI2HVD)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HDK)* 1 - Yes 2 - No	*(MMSI2HDL)* 1 - Yes 2 - No
IgE	*(MMSI2HVE)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HEK)* 1 - Yes 2 - No	*(MMSI2HEL)* 1 - Yes 2 - No

25. Did serum IFE 2 indicate light chain disease?*(MMSI2LCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

26. Kappa:*(MMSI2KLC)* ☐ 1 - Yes ☐ 2 - No

27. Lambda:*(MMSI2LLC)* ☐ 1 - Yes ☐ 2 - No

Serum IFE 3

28. Date of serum IFE 3:*(MMSI3DT)* *(mm/dd/yyyy)*

29. Serum IFE 3 Result:*(MMSI3RES)* 1 - Positive 2 - Negative

30. Was there mention of oligoclonal banding in the report?*(MMSI3OB)* ☐ 1 - Yes ☐ 2 - No

31. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MMSI3HVG)* ☐ 1 - Yes ☐ 2 - No	*(MMSI3HGK)* 1 - Yes 2 - No	*(MMSI3HGL)* 1 - Yes 2 - No
IgA	*(MMSI3HVA)* ☐ 1 - Yes ☐ 2 - No		

		(MMSI3HAK) 1 - Yes 2 - No	(MMSI3HAL) 1 - Yes 2 - No
IgM	(MMSI3HVM) ☐ 1 - Yes ☐ 2 - No	(MMSI3HMK) 1 - Yes 2 - No	(MMSI3HML) 1 - Yes 2 - No
IgD	(MMSI3HVD) ☐ 1 - Yes ☐ 2 - No	(MMSI3HDK) 1 - Yes 2 - No	(MMSI3HDL) 1 - Yes 2 - No
IgE	(MMSI3HVE) ☐ 1 - Yes ☐ 2 - No	(MMSI3HEK) 1 - Yes 2 - No	(MMSI3HEL) 1 - Yes 2 - No

32. Did serum IFE 3 indicate light chain disease?*(MMSI3LCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

33. Kappa:*(MMSI3KLC)* ☐ 1 - Yes ☐ 2 - No

34. Lambda:*(MMSI3LLC)* ☐ 1 - Yes ☐ 2 - No

Urine Protein Electrophoresis/Urine Immunofixation (UPEP/Urine IFE)

35. How many UPEPs/Urine IFEs were performed during this assessment period?*(MMUPEPNM)*

36. Record the reason no UPEPs/Urine IFEs were performed:*(MMNOUPEP)*

37. For each UPEP/Urine IFE performed, record the following:

	Date of UPEP/Urine IFE	Urine total protein value	Urine total volume	M-protein result (Urine IFE)	M-protein value	M-protein units	Urine light chain type
UPEP/Urine IFE 1	(MMUP1DT) (mm/dd/yyyy)	(MMUP1TPG) (xx.xxx) g/24hrs	(MMUP1TVL) (xx.xxx) L/24hrs	(MMUP1RES) 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	(MMUP1VAL) (xxxx.xxx)	(MMUP1UN) 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:(MMUP1KLC) 1 - Yes 2 - No
		(MMUP1TMG) **OR** (xxxxx.xx) mg/24hrs	(MMUP1VML) **OR** (xxxxx.xx) mL/24hrs				Lambda:(MMUP1LLC) 1 - Yes 2 - No
UPEP/Urine IFE 2	(MMUP2DT) (mm/dd/yyyy)	(MMUP2TPG) (xx.xxx) g/24hrs	(MMUP2TVL) (xx.xxx) L/24hrs	(MMUP2RES) 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	(MMUP2VAL) (xxxx.xxx)	(MMUP2UN) 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:(MMUP2KLC) 1 - Yes 2 - No
		(MMUP2TMG) **OR** (xxxxx.xx) mg/24hrs	(MMUP2VML) **OR** (xxxxx.xx) mL/24hrs				Lambda:(MMUP2LLC) 1 - Yes 2 - No
UPEP/Urine IFE 3	(MMUP3DT) (mm/dd/yyyy)	(MMUP3TPG) (xx.xxx) g/24hrs	(MMUP3TVL) (xx.xxx) L/24hrs	(MMUP3RES) 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	(MMUP3VAL) (xxxx.xxx)	(MMUP3UN) 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:(MMUP3KLC) 1 - Yes 2 - No
		(MMUP3TMG) **OR** (xxxxx.xx) mg/24hrs	(MMUP3VML) **OR** (xxxxx.xx) mL/24hrs				Lambda:(MMUP3LLC) 1 - Yes 2 - No

Bone Marrow

38. How many bone marrow biopsies were performed during this assessment period?*(MMBMBXNM)*

39. Record reason no bone marrow biopsies were performed:*(MMNOBMBX)*

40. For each bone marrow biopsy performed, record the following:

	Date Performed	Plasma Cells Present	Percent Plasma Cells
Bone Marrow Biopsy 1	(MMBX1DT) (mm/dd/yyyy)	(MMBX1PLS) 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	(MMBX1PCT) (xxx.x) %
Bone Marrow Biopsy 2	(MMBX2DT) (mm/dd/yyyy)	(MMBX2PLS) 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	(MMBX2PCT) (xxx.x) %
Bone Marrow Biopsy 3	(MMBX3DT) (mm/dd/yyyy)	(MMBX3PLS) 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	(MMBX3PCT) (xxx.x) %

41. How many bone marrow aspirates were performed during this assessment period?*(MMASPNM)*

42. Record reason no bone marrow aspirates were performed:*(MMNOBMAS)*

43. For each bone marrow aspirate performed, record the following:

	Date Performed	Plasma Cells Present	Percent Plasma Cells
Bone Marrow Aspirate 1	*(MMASP1DT)* *(mm/dd/yyyy)*	*(MMAS1PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMAS1PCT)* *(xxx.x)* %
Bone Marrow Aspirate 2	*(MMASP2DT)* *(mm/dd/yyyy)*	*(MMAS2PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMAS2PCT)* *(xxx.x)* %
Bone Marrow Aspirate 3	*(MMASP3DT)* *(mm/dd/yyyy)*	*(MMAS3PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMAS3PCT)* *(xxx.x)* %

Lytic Lesions

44. Was a lytic lesion assessment performed?*(MMBASMT)* 1 - Yes 2 - No

45. Date of lytic bone lesion assessment:*(MMBASMDT)* *(mm/dd/yyyy)*

46. Record most recent information regarding lytic bone lesions:*(MMLESNST)*
1 - No Change
2 - New Lytic Bone Lesions
3 - Definite Size Increase of Existing Lytic Bone Lesions
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

47. Specify other lesion information:*(MMLSNSP)*

Plasmacytomas

48. Was a plasmacytoma assessment performed?*(MMPLCYAS)* 1 - Yes 2 - No

49. Date of plasmacytoma assessment:*(MMPLCYDT)* *(mm/dd/yyyy)*

50. Record most recent information regarding soft tissue plasmacytomas:*(MMPLCYST)*
1 - No Change
2 - New Plasmacytomas
3 - Definite Size Increase of Existing Plasmacytomas
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

51. Specify other plasmacytoma information:*(MMPLCYSP)*

Quantitative Serum Immunoglobulins

52. Were serum immunoglobulins obtained?*(MMSIGS)* 1 - Yes 2 - No

53. Date immunoglobulins obtained:*(MMSIGSDT)* *(mm/dd/yyyy)*

54. Record immunoglobulin values:

	Laboratory Value (mg/dL)	Laboratory Value (g/dL)
Quantitative IgG	*(MMIGGMG)* *(xxxxx.xx)* mg/dL	*(MMIGGG)* **OR** *(xx.xxx)* g/dL
Quantitative IgA	*(MMIGAMG)* *(xxxxx.xx)* mg/dL	*(MMIGAG)* **OR** *(xx.xxx)* g/dL
Quantitative IgM	*(MMIGMMG)* *(xxxxx.xx)* mg/dL	*(MMIGMG)* **OR** *(xx.xxx)* g/dL
If serum heavy chain type is IgD or IgE, record values below		
Quantitative IgD	*(MMIGDMG)* *(x.xxx)* mg/dL	*(MMIGDG)* **OR** *(x.xxxxxx)* g/dL
Quantitative IgE	*(MMIGEMG)* *(x.xxx)* mg/dL	*(MMIGEG)* **OR** *(x.xxxxxx)* g/dL

*Submit a copy of the SPEP, SIFE, UPEP, UIFE, bone marrow reports, and other supporting source documents. Be sure to remove patient identifiers prior to uploading. If unable to upload documents, submit reports via fax to **(240)306-0963**.*

Comments:*(MSFCOMM)*

Additional Selection Options for MSF

Indicate the patient's current disease response:
7 - Stable Disease (SD)
8 - Progression

Record most recent information regarding lytic bone lesions:
6- Other

Record most recent information regarding soft tissue plasmacytomas:
6- Other

Blood and Marrow Transplant Clinical Trials Network

Neurotoxicity Assessment Tool (NAT)

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

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

1. Date of Assessment:*(NATDATAS)* _____ *(mm/dd/yyyy)*

*By checking one (1) number per line, indicate how true each statement has been for you **during the past 7 days.***

	Not at all	A little bit	Somewhat	Quite a bit	Very much	Not answered
2. I have numbness or tingling in my hands	*(NATNUMBH)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. I have numbness or tingling in my feet	*(NATNUMBF)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. I feel discomfort in my hands	*(NATDISHA)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. I feel discomfort in my feet	*(NATDISFE)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. I have joint pain or muscle cramps	*(NATJOINP)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. I feel weak all over	*(NATWEAK)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. I have trouble hearing	*(NATHEAR)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. I get a ringing or buzzing in my ears	*(NATEARS)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. I have trouble buttoning buttons	*(NATBUTON)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11. I have trouble feeling the shape of small objects when they are in my hand	*(NATOBJHA)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12. I have trouble walking	*(NATTROWA)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Comments:*(NATCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Post Autologous Transplant Checklist - 0702 (PAT)

Web Version: 1.0; 2.01; 10-16-15

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

1. Treatment arm:*(MMRXBARM)*
   - 1 - Auto/Auto
   - 2 - Auto/RVD Consolidation
   - 3 - Auto/Maintenance
2. Record proposed date of initiation of conditioning regimen:*(MMPCNDDT)* *(mm/dd/yyyy)*
3. Record proposed date of tandem autologous transplant:*(MMPTXDTB)* *(mm/dd/yyyy)*
4. Record proposed date of initiation of consolidation:*(MMBPRCON)* *(mm/dd/yyyy)*

Inclusion Criteria

5. Has mucositis resolved?*(MMUCORES)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
6. Is the patient currently receiving hyperalimentation?*(MMRCVHYP)* ☐ 1 - Yes ☐ 2 - No
7. Is the patient currently receiving intravenous hydration?*(MMRCVHYD)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value	ULN for your Institution	Date Sample Obtained
8. Bilirubin:	*(MMBBILI)* *(xx.x)* mg/dL	*(MMBBILUL)* *(xx.x)* mg/dL	*(MMBBILDT)* *(mm/dd/yyyy)*
9. ALT:	*(MMBALT)* *(xxx)* Units/L	*(MMBALTUL)* *(xxx)* Units/L	*(MMBALTDT)* *(mm/dd/yyyy)*
10. AST:	*(MMBAST)* *(xxx)* Units/L	*(MMBASTUL)* *(xxx)* Units/L	*(MMBASTDT)* *(mm/dd/yyyy)*

11. Record creatinine clearance:*(MMBCREAT)* *(xxx)* ml/min
12. Record date creatinine clearance sample obtained:*(MMBCRCL)* *(mm/dd/yyyy)*
13. Is the patient currently taking intravenous antibiotics?*(MMBIVANT)* ☐ 1 - Yes ☐ 2 - No
14. Is the patient currently taking any amphotericin B formulations or voriconazole for possible, probable, or proven fungal infections?*(MMBAMPHO)* ☐ 1 - Yes ☐ 2 - No
15. Did the patient receive radiation therapy post-autologous transplant?*(MMBRDIAT)* ☐ 1 - Yes ☐ 2 - No
    16. Record date radiation therapy ended:*(MMBRADDT)* *(mm/dd/yyyy)*
17. Were Pulmonary Function Tests performed?*(MMBPLMNF)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value Corrected for Hemoglobin:	Date Sample Obtained
18. DLCO:	*(MMBDLCO)* *(xxx)* % of predicted value	*(MMBDLCDT)* *(mm/dd/yyyy)*
19. FEV1:	*(MMBFEV1)* *(xxx)* % of predicted value	*(MMBFEVDT)* *(mm/dd/yyyy)*
20. FVC:	*(MMBFVC)* *(xxx)* % of predicted value	*(MMBFVCDT)* *(mm/dd/yyyy)*

21. O_2 saturation on room air:*(MMBO2SAT)* *(xxx)* Date O_2 saturation was obtained:*(MMBO2SDT)* *(mm/dd/yyyy)*
22. Did the patient develop symptoms of cardiac insufficiency post-autologous transplant? *(MMBCARDI)* ☐ 1 - Yes ☐ 2 - No
    23. Record the left ventricular ejection fraction at rest:*(MMBEJECT)* *(xxx)* %
    24. Record date ejection fraction performed:*(MMBEJFDT)* *(mm/dd/yyyy)*
25. Did the patient develop grade 3 or higher sensory neuropathy within 14 days prior to the start of consolidation?*(MMBSENSN)* ☐ 1 - Yes ☐ 2 - No

Per post-autologous transplant eligibility criteria, platelets must be ≥$75x10^9$/L (or 75000/mm^3).

26. Record the patient's platelet count:*(MMBPLATE)* *(xxxxxx)* /mm^3
27. Record date of platelet count:*(MMBPLADT)* *(mm/dd/yyyy)*

Per post-autologous transplant eligibility criteria, ANC must be ≥$1.5x10^9$/L (or 1500/mm^3).

28. Record the patient's ANC:*(MMBANC)* *(xxxxx)* /mm^3
29. Record date of ANC:*(MMBANCDT)* *(mm/dd/yyyy)*
30. Is the patient pregnant (positive β-HCG) or breastfeeding?*(MMBPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
31. Is the patient pregnant (positive β-HCG) or breastfeeding?*(MMBPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

Comments:*(PATCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Progression Form (PRL)

Web Version: 1.0; 4.03; 10-16-15

Segment *(PROTSEG)*: B
Progression/Relapse Date *(PRRELPDT)*:

Select clinical or laboratory findings which indicate progression:

1. Serum Protein Electrophoresis (SPEP)	*(PRSPEPYN)* 1 - Yes, 2 - No, 3 - Not Done
2. Serum Free Light Chain (Serum FLC)	*(PRSFLCYN)*
3. Serum Immunofixation (Serum IFE)	*(PRSIFEYN)*
4. Urine Protein Electrophoresis (UPEP)	*(PRUPEPYN)*
5. Urine Immunofixation (Urine IFE)	*(PRUIFEYN)*
6. Bone Marrow	*(PRBMYN)*
7. Lytic Lesions	*(PRLESNYN)*
8. Plasmacytomas	*(PRPLCYYN)*
9. Corrected Serum Calcium	*(PRCALCYN)*

Serum Protein Electrophoresis (SPEP)

10. How many SPEPs were performed?*(PRLSPNM)* 0 - None, 1 - One SPEP, 2 - Two SPEPs

11. For each SPEP performed, record the following:

	Date of SPEP	Serum total protein value	M-protein spike result	M-protein spike value
Initial SPEP	*(PRLSPDT)* *(mm/dd/yyyy)*	*(PRLSPTPG)* *(xx.xxx)* g/dL	*(PRLSPRES)* 1 - Positive, 2 - Negative, 3 - Present but Not Quantifiable	*(PRLSPMSG)* *(x.xxx)* g/dL
		(PRLSPTMG) **OR** *(xxxxx.xx)* mg/dL		*(PRSPMSMG)* **OR** *(xxxx.xx)* mg/dL
Confirmatory SPEP	*(PRLSPCDT)* *(mm/dd/yyyy)*	*(PRSPCTPG)* *(xx.xxx)* g/dL	*(PRLSPCRS)* 1 - Positive, 2 - Negative, 3 - Present but Not Quantifiable	*(PRSCMSG)* *(x.xxx)* g/dL
		(PRSPCTMG) **OR** *(xxxxx.xx)* mg/dL		*(PRSCMSMG)* **OR** *(xxxx.xx)* mg/dL

Serum Free Light Chain (FLC)

12. Was serum FLC measured?*(PRLSFLC)* 1 - Yes 2 - No
13. Date of serum FLC:*(PRLFLCDT)* *(mm/dd/yyyy)*
14. Kappa Free Light Chain value:*(PRSKMGL)* *(xxxxxx.xx)* mg/L *(PRSKMGDL)***OR** *(xxxxx.xxx)* mg/dL
15. Lambda Free Light Chain value:*(PRSLMGL)* *(xxxxxx.xx)* mg/L *(PRSLMGDL)***OR** *(xxxxx.xxx)* mg/dL
16. Free light chain ratio (κ/ λ):*(PRLSFLCR)* *(xxxxxx.xxxxxx)*

Serum Immunofixation (Serum IFE)

17. How many serum IFEs were performed?*(PRSIFENM)* 0- None, 1- One SIFE, 2- Two SIFEs
18. Date of initial serum IFE:*(PRLSIDT)* *(mm/dd/yyyy)*
19. Initial serum IFE result:*(PRLSIRES)* 1 - Positive, 2 - Negative

20. Was there mention of oligoclonal banding in the report?*(PRLSIOB)* ☐ 1 - Yes ☐ 2 - No

21. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(PRLSIHVG)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHGK)* 1 - Yes 2 - No	*(PRLSIHGL)* 1 - Yes 2 - No
IgA	*(PRLSIHVA)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHAK)* 1 - Yes 2 - No	*(PRLSIHAL)* 1 - Yes 2 - No
IgM	*(PRLSIHVM)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHMK)* 1 - Yes 2 - No	*(PRLSIHML)* 1 - Yes 2 - No
IgD	*(PRLSIHVD)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHDK)* 1 - Yes 2 - No	*(PRLSIHDL)* 1 - Yes 2 - No
IgE	*(PRLSIHVE)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHEK)* 1 - Yes 2 - No	*(PRLSIHEL)* 1 - Yes 2 - No

22. Did initial serum IFE indicate light chain disease?*(PRLSILCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

23. Kappa:*(PRLSIKLC)* ☐ 1 - Yes ☐ 2 - No

24. Lambda:*(PRLSILLC)* ☐ 1 - Yes ☐ 2 - No

25. Date of confirmatory serum IFE:*(PRLSICDT)* *(mm/dd/yyyy)*

26. Confirmatory serum IFE result:*(PRLSICRS)* 1 - Positive 2 - Negative

27. Was there mention of oligoclonal banding in the report?*(PRLSICOB)* ☐ 1 - Yes ☐ 2 - No

28. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(PRSICHVG)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHGK)* 1 - Yes 2 - No	*(PRSICHGL)* 1 - Yes 2 - No
IgA	*(PRSICHVA)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHAK)* 1 - Yes 2 - No	*(PRSICHAL)* 1 - Yes 2 - No
IgM	*(PRSICHVM)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHMK)* 1 - Yes 2 - No	*(PRSICHML)* 1 - Yes 2 - No
IgD	*(PRSICHVD)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHDK)* 1 - Yes 2 - No	*(PRSICHDL)* 1 - Yes 2 - No
IgE	*(PRSICHVE)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHEK)* 1 - Yes 2 - No	*(PRSICHEL)* 1 - Yes 2 - No

29. Did confirmatory serum IFE indicate light chain disease?*(PRSICLCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

30. Kappa:*(PRSICKLC)* ☐ 1 - Yes ☐ 2 - No

31. Lambda:*(PRSICLLC)* ☐ 1 - Yes ☐ 2 - No

Urine Protein Electrophoresis/Urine Immunofixation (UPEP/Urine IFE)

32. How many UPEPs/Urine IFEs were performed?*(PRLUPNM)* 0 - None 1 - One UPEP/Urine IFE 2 - Two UPEPs/Urine IFEs

33. For each UPEP/Urine IFE performed, record the following:

	Date of UPEP/Urine IFE	Urine total protein value	Urine total volume	M-protein result (Urine IFE)	M-protein value	M-protein units	Urine light chain type
Initial UPEP/Urine IFE	*(PRLUPDT)* *(mm/dd/yyyy)*	*(PRLUPTPG)* *(xx.xxx)* g/24hrs	*(PRUPTVL)* *(xx.xxx)* L/24hrs	*(PRLUPRES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(PRUPVAL)* *(xxxx.xxx)*	*(PRLUPUN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(PRLUPK)* 1 - Yes 2 - No
		(PRLUPTMG) **OR**	*(PRUPTVML)* **OR**				Lambda:*(PRLUPL)*

		(xxxxx.xx) mg/24hrs	(xxxxx.xx) mL/24hrs				1 - Yes 2 - No
Confirmatory UPEP/Urine IFE	*(PRLUPCDT)* *(mm/dd/yyyy)*	*(PRUPCTPG)* *(xx.xxx)* g/24hrs	*(PRUPCTVL)* *(xx.xxx)* L/24hrs	*(PRLUPCRS)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(PRUPCVAL)* *(xxxx.xxx)*	*(PRLUPCUN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(PRLUPCK)* 1 - Yes 2 - No
		(PRUPCTMG) **OR** *(xxxxx.xx)* mg/24hrs	*(PRUPCVML)* **OR** *(xxxxx.xx)* mL/24hrs				Lambda:*(PRLUPCL)* 1 - Yes 2 - No

Bone Marrow

34. Was a bone marrow biopsy performed?*(PRLBMBX)* ☐ 1 - Yes ☐ 2 - No

35. Date of bone marrow biopsy:*(PRLBXDT)* *(mm/dd/yyyy)*

36. Were plasma cells present in the biopsy?*(PRLBXPLS)*
1 - Yes
2 - No
3 - Plasma Cells Present but Not Quantifiable

37. Record percentage of plasma cells:*(PRLBXPCT)* *(xxx.x)* %

38. Was a bone marrow aspirate performed?*(PRLBMAS)* ☐ 1 - Yes ☐ 2 - No

39. Date of bone marrow aspirate:*(PRLASPDT)* *(mm/dd/yyyy)*

40. Were plasma cells present in the aspirate?*(PRLASPLS)*
1 - Yes
2 - No
3 - Plasma Cells Present but Not Quantifiable

41. Record percentage of plasma cells:*(PRLASPCT)* *(xxx.x)* %

Lytic Lesions

42. Was a lytic lesion assessment performed?*(PRLLSNAS)* ☐ 1 - Yes ☐ 2 - No

43. Date of lytic bone lesion assessment:*(PRLLSNDT)* *(mm/dd/yyyy)*

44. Record most recent information regarding lytic bone lesions:*(PRLLESN)*
1 - No Change
2 - New Lytic Bone Lesions
3 - Definite Size Increase of Existing Lytic Bone Lesions
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

45. Specify other lesion information:*(PRLLSNSP)*

Plasmacytomas

46. Was a plasmacytoma assessment performed?*(PRPLCYAS)* ☐ 1 - Yes ☐ 2 - No

47. Date of plasmacytoma assessment:*(PRPLCYDT)* *(mm/dd/yyyy)*

48. Record most recent information regarding soft tissue plasmacytomas:*(PRPLCYT)*
1 - No Change
2 - New Plasmacytomas
3 - Definite Size Increase of Existing Plasmacytomas
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

49. Specify other plasmacytoma information:*(PRPLCYSP)*

Corrected Serum Calcium

50. Was a corrected serum calcium value obtained?*(PRLCALC)* ☐ 1 - Yes ☐ 2 - No

51. Date corrected serum calcium sample obtained:*(PRLCADT)* *(mm/dd/yyyy)*

52. Record most recent corrected serum calcium value:*(PRLCAVAL)* *(xx.xx)*

53. Corrected serum calcium value units:*(PRLCAUN)*
1- g/dL
2- mg/dL
3- mmol/L

54. Did the patient develop hypercalcemia?*(PRHYPCAL)* ☐ 1 - Yes ☐ 2 - No

55. Was hypercalcemia attributable to any other cause?*(PRHYPATT)* ☐ 1 - Yes ☐ 2 - No

56. Specify other cause of hypercalcemia:*(PRHYPSP)*

Quantitative Serum Immunoglobulins

57. Were serum immunoglobulins obtained?*(PRLSIGS)* ☐ 1 - Yes ☐ 2 - No

58. Date immunoglobulins obtained:*(PRLSIGDT)* *(mm/dd/yyyy)*

59. Record immunoglobulin values:

	Laboratory Value (mg/dL)	Laboratory Value (g/dL)
Quantitative IgG		

	(PRLIGGMG) *(xxxxx.xx)* mg/dL	*(PRLIGGG)* **OR** *(xx.xxx)* g/dL
Quantitative IgA	*(PRLIGAMG)* *(xxxxx.xx)* mg/dL	*(PRLIGAG)* **OR** *(xx.xxx)* g/dL
Quantitative IgM	*(PRLIGMMG)* *(xxxxx.xx)* mg/dL	*(PRLIGMG)* **OR** *(xx.xxx)* g/dL
If serum heavy chain type is IgD or IgE, record values below:		
Quantitative IgD	*(PRLIGDMG)* *(x.xxx)* mg/dL	*(PRLIGDG)* **OR** *(x.xxxxxx)* g/dL
Quantitative IgE	*(PRLIGEMG)* *(x.xxx)* mg/dL	*(PRLIGEG)* **OR** *(x.xxxxxx)* g/dL

Treatment for Progression

60. Has the patient been treated for progression?*(PRLTREAT)* ☐ 1 - Yes ☐ 2 - No

61. Date treatment administered:*(PRLTRTDT)* *(mm/dd/yyyy)*

62. Indicate type of treatment:*(PRTRTTYP)*

1- Donor Lymphocyte Infusion (DLI)
2- Peripheral Blood Stem Cells (PBSCs)
3- Chemotherapy
4- Radiation
5- Second Transplant
*Additional Options Listed Below

If other treatment, specify:*(PRLTRTSP)*

Submit a copy of any laboratory reports that support progression (such as SPEP, SIFE, UPEP, UIFE, bone marrow reports, and/or health and physical exam notes). Be sure to remove patient identifiers prior to uploading. If unable to upload documents, submit reports via fax to 240-306-0963.

Comments:*(PRLCOMMT)*

Additional Selection Options for PRL

Record most recent information regarding lytic bone lesions:
6- Other

Record most recent information regarding soft tissue plasmacytomas:
6- Other

Indicate type of treatment:
6- Other

RVD Consolidation Initiation Form - 0702 (RIF)

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

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

1. Record date of initiation of RVD consolidation therapy:*(RIFRVDDT)* *(mm/dd/yyyy)*

Comments:*(RIFCOMM)*

RVD Consolidation Regimen and Toxicity - 0702 (RVD)

Web Version: 1.0; 2.02; 10-16-15

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

1. Record start date of consolidation cycle:*(RVDCSTDT)* *(mm/dd/yyyy)*
2. Record end date of consolidation cycle:*(RVDCENDT)* *(mm/dd/yyyy)*
3. Record the total cumulative dose of **dexamethasone** given on days 1, 8 and 15 of this cycle: *(RVDTODEX)* *(xxx)* mg
   4. Reason dexamethasone dose was reduced:*(RVDRESDX)*
5. Record the total cumulative dose of **lenalidomide** given on days 1 through 14 of this cycle: *(RVDTOLEN)* *(xxx)* mg
   6. Reason lenalidomide dose was reduced:*(RVDRESLN)*
7. Record the total cumulative dose of **bortezomib** given on days 1, 4, 8 and 11 of this cycle: *(RVDTOBOR)* *(xx.x)* mg
8. Was the bortezomib dose reduced?*(RVDBZRED)* ☐ 1 - Yes ☐ 2 - No
   9. Reason bortezomib dose was reduced:*(RVDRESBZ)*

Indicate the highest grade of toxicity for this consolidation cycle below. Grades are based on the NCI CTCAE Version 3.0.

10. Allergic Reaction:*(RVDALRGY)*
    0 - Grades 0-2
    3 - Symptomatic Bronchospasm, with or without Urticaria; Parenteral Med(s) Indicated
    4 - Anaphylaxis
    5 - Death
11. Cardiac Arrhythmia:*(RVDCARD)*
    0 - Grades 0-2
    3 - Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
    4 - Life-Threatening; Disabling (e.g., Arrhythmia Associated with CHF, Syncope, Shock)
    5 - Death
12. Chest Pain:*(RVDCHSTP)*
    0 - Grades 0-2
    3 - Symptomatic and Testing Consistent with Ischemia; Unstable Angina; Intervention Indicated
    4 - Acute Myocardial Infarction
    5 - Death
13. Chills/Rigors:*(RVDCHILL)*
    0 - Grades 0-2
    3 - Severe or Prolonged, not Responsive to Narcotics
14. Fever:*(RVDFEVER)*
    0 - Grades 0-1
    2 - >39.0-40.0C (102.3-104.0F)
    3 - >40C (>104.0F) for <24 hrs
    4 - >40C (>104.0F) for >24 hrs
    5 - Death
15. Injection site irritation, pain or phlebitis:*(RVDINJCT)*
    0- Grade 0-2
    3- Ulceration or Necrosis that is Severe; Operative Intervention Indicated
16. Hypoxia:*(RVDHYPOX)*
    0 - Grades 0-2
    3 - Decreased Oxygen Saturation at Rest; Continuous Oxygen Indicated
    4 - Life-Threatening; Intubation or Ventilation Indicated
    5 - Death
17. Vomiting:*(RVDVOMIT)*
    0 - Grades 0-1
    2 - 2-5 Episodes in 24 hrs; IV Fluids Indicated <24 hrs
    3 - >/=6 Episodes in 24 hrs; IV Fluids, or TPN Indicated >/=24 hrs
    4 - Life-Threatening Consequences
    5 - Death

Comments:*(RVDCOMM)*

Blood and Marrow Transplant Clinical Trials Network

SF36 Quality of Life (SFH)

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

Segment *(PROTSEG)*: B
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	

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

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

(WALK1BLK)

j. Bathing or dressing yourself

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

(BATHING)

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

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

(CUTTIME)

b. Accomplished less than you would like

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

(LESSACC)

c. Were limited in the kind of work or other activities

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

(WORKLMT)

d. Had difficulty performing the work or other activities (for example, it took extra effort)

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

(PRFMDIFF)

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

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

(ECUTTIME)

b. Accomplished less than you would like

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

(ELESSACC)

c. Did work or other activities less carefully than usual

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

(ECARELES)

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

Secondary Graft Failure (SGR)

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

Segment *(PROTSEG)*: B
Secondary Graft Fail Date *(SGFDATE)*:

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

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

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

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

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

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

Comments:*(SGRCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0702 (T17)

Web Version: 1.0; 4.00; 12-11-15

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

1. Record date of evaluation:*(T17ASTDT)* *(mm/dd/yyyy)*

Record the highest grade of toxicity diagnosed since the previous evaluation. If this is the first evaluation, record the highest grade of toxicity diagnosed since Day 0. The toxicity grades are based on the NCI CTCAE Version 3.0.

Neurologic Toxicity

2. Tremors:*(T17NTRMS)*
   - 0 - Grades 0-2
   - 3 - Severe Tremor Interfering with ADL
   - 4 - Disabling

3. Ataxia:*(T17ATXIA)*
   - 0 - Grades 0-2
   - 3 - Symptomatic, Interfering with ADL; Mechanical Assistance Indicated
   - 4 - Disabling
   - 5 - Death

4. Somnolence:*(T17SMNLN)*
   - 0 - Grades 0-2
   - 3 - Obtundation or Stupor; Difficult to Arouse; Interfering with ADL
   - 4 - Coma
   - 5 - Death

5. Dizziness:*(T17DIZZY)*
   - 0 - Grades 0-2
   - 3 - Interfering with ADL
   - 4 - Disabling

6. Syncope:*(T17SYNC)*
   - 0 - Grades 0-2
   - 3 - Present
   - 4 - Life-Threatening Consequences
   - 5 - Death

7. Neuropathy - motor:*(T17MOTOR)*
   - 0 - Grades 0-2
   - 3 - Weakness Interfering with ADL; Bracing or Assistance to Walk Indicated
   - 4 - Life-Threatening; Disabling (e.g., Paralysis)
   - 5 - Death

8. Neuropathy - sensory:*(T17SENSR)*
   - 0 - Grades 0-2
   - 3 - Sensory Alteration or Paresthesia Interfering with ADL
   - 4 - Disabling
   - 5 - Death

9. Did the patient experience any seizures during this assessment period?*(T17SEIZR)* ☐ 1 - Yes ☐ 2 - No

10. Record seizure toxicity grade:*(T17SZGRD)*
    - 2 - One Brief Generalized Seizure, Seizure(s) Well Controlled by Anticonvulsants
    - 3 - Seizures in Which Consciousness is Altered; Poorly Controlled Seizure Disorder
    - 4 - Seizures of Any Kind Which are Prolonged, Repetitive or Difficult to Control
    - 5 - Death

Cardiovascular Toxicity

11. Atrial fibrillation:*(T17AFIB)*
    - 0 - Grades 0-2
    - 3 - Symptomatic and Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
    - 4 - Life-Threatening (e.g., Arrhythmia associated with CHF, hypotension, syncope, shock)
    - 5 - Death

12. Atrial flutter:*(T17AFLUT)*
    - 0 - Grades 0-2
    - 3 - Symptomatic and Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
    - 4 - Life-Threatening (e.g., Arrhythmia associated with CHF, hypotension, syncope, shock)
    - 5 - Death

13. Chest pain (cardiac ischemia/infarction):*(T17CHPAN)*
    - 0 - Grades 0-2
    - 3 - Symptomatic and Testing Consistent with Ischemia; Unstable Angina; Intervention Indicated
    - 4 - Acute Myocardial Infarction
    - 5 - Death

14. Hypertension:*(T17HYPRC)*

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

15. Hypotension:*(T17HYPOT)*

0 - Grades 0-2
3 - Sustained (> or = 24 Hours) Therapy, Resolves Without Persisting Physiologic Consequences
4 - Shock (e.g., Acidemia; Impairment of Vital Organ Function)
5 - Death

16. Left ventricular systolic dysfunction:*(T17LVSD)*

0 - Grades 0-2
3 - Symptomatic CHF Responsive to Intervention
4 - Refractory CHF or Poorly Controlled; Intervention with Ventricular Assist Device
5 - Death

17. Cardiac arrhythmia:*(T17CRDAR)*

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

GI Toxicity

18. Abdominal pain:*(T17ABPAN)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

19. Constipation:*(T17CNSTP)*

0 - Grades 0-2
3 - Symptoms Interfering with ADL; Obstipation with Manual Evacuation Indicated
4 - Life-Threatening Consequences (e.g., Obstruction, Toxic Megacolon)
5 - Death

20. Diarrhea:*(T17DIARR)*

0 - Grades 0-2
3 - Inc by 7+ stools over baseline; require IVF>or=24hrs; hosp; severe inc in ostomy output
4 - Resulting in hemodynamic Insufficiency or life threatening consequences
5 - Death

21. Dysphagia:*(T17DYSPH)*

0 - Grades 0-2
3 - Symptomatic & Severely Altered Eating/Swallowing (e.g., inadequate oral intake), IVF, Tube Feed,
4 - Life-Threatening Consequences (e.g., Obstruction, Perforation)
5 - Death

22. Heartburn/dyspepsia:*(T17HRTBN)*

0 - Grades 0-2
3 - Severe

23. Nausea:*(T17NAUS)*

0 - Grade 0-2
3 - Inadequate oral intake; IVF; Tube Feedings or TPN indicated >or=24 Hours
4 - Life-Threatening Consequences
5 - Death

24. Vomiting:*(T17VOMIT)*

0 - Grades 0-1
2 - 2-5 Episodes in 24 hrs; IV Fluids Indicated <24 hrs
3 - >/=6 Episodes in 24 hrs; IV Fluids, or TPN Indicated >/=24 hrs
4 - Life-Threatening Consequences
5 - Death

25. Did taste alteration (dysgeusia) occur:*(T17DYSGS)*

☐ 1 - Yes ☐ 2 - No

26. Ulcers:*(T17ULCER)*

0 - Grades 0-2
3 - Severely Altered GI Function; IV Fluids, Tube Feedings or TPN Indicated >/=24 hrs
4 - Life-Threatening Consequences
5 - Death

27. Mucositis/stomatitis (clinical exam):*(T17MUCOS)*

0 - Grades 0-2
3 - Confluent Ulcerations or Pseudomembranes; Bleeding with Minor Trauma
4 - Tissue Necrosis; Significant Spontaneous Bleeding; LT Consequences
5 - Death

Renal Toxicity

28. Did the patient experience renal failure severe enough to warrant dialysis?*(T17RNLFL)*

☐ 1 - Yes ☐ 2 - No

29. Did the patient receive dialysis?*(T17DIALY)*

☐ 1 - Yes ☐ 2 - No

30. Hemorrhagic cystitis:*(T17CYSTI)*

0 - Grades 0-2
3 - Transfusion; IV Pain Medications; Bladder Irrigation Indicated
4 - Catastrophic Bleeding; Major Non-Elective Intervention Indicated
5 - Death

	Peak Value During Interval	ULN for your Institution	Date Sample Obtained
31. Creatinine:	*(T17CREAT)* _____ *(xx.x)* mg/dL	*(T17ULNCR)* _____ *(xx.x)* mg/dL	*(T17CRTDT)* _____ *(mm/dd/yyyy)*

Coagulation Toxicity

32. HUS/TTP/thrombotic microangiopathy:*(T17DCTTP)*

0 - Grades 0-3
4 - Laboratory Findings, Life-Threatening or Disabling Consequences
5 - Death

Metabolic Toxicity

33. Hyperglycemia:*(T17HYPGL)*

0 - Grades 0-2
3 - >250-500 mg/dL; >13.9-27.8 mmol/L
4 - >500 mg/dL; >27.8 mmol/L or Acidosis
5 - Death

Endocrine Toxicity

34. Hypothyroidism:*(T17THYRO)*

0 - Grades 0-2
3 - Symptoms Interfering with ADL; Hospitalization Indicated
4 - Life-Threatening Myxedema Coma
5 - Death

Auditory Toxicity

35. Hearing:*(T17HEAR)*

0 - Grades 0-2
3 - Hearing Loss Requiring Hearing Aid or Intervention (i.e., Interfering with ADL)
4 - Profound Bilateral Hearing Loss (>90 dB)

36. Tinnitus:*(T17TINN)*

0 - Grades 0-2
3 - Tinnitus Interfering with ADL
4 - Disabling

Ocular/Visual Toxicity

37. Blurred vision:*(T17BLRRY)*

0 - Grades 0-2
3 - Symptomatic and Interfering with ADL
4 - Disabling

38. Conjunctivitis:*(T17CONJ)*

0 - Grades 0-2
3 - Symptomatic, Interfering with ADL; Operative Intervention Indicated

Constitutional Toxicity

39. Asthenia (fatigue, lethargy, or malaise):*(T17FATIG)*

0 - Grades 0-2
3 - Severe Fatigue Interfering with ADL
4 - Disabling

40. Fever (without neutropenia):*(T17FEVER)*

0 - Grades 0-1
2 - >39.0-40.0C (102.3-104.0F)
3 - >40C (>104.0F) for <24 hrs
4 - >40C (>104.0F) for >24 hrs
5 - Death

41. Insomnia:*(T17INSOM)*

0 - Grades 0-2
3 - Frequent Difficulty Sleeping, Interfering with ADL
4 - Disabling

Musculoskeletal Toxicity

42. Bone pain:*(T17BNPAN)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

43. Joint pain (arthralgia):*(T17ARTHR)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

44. Muscle pain (myalgia):*(T17MYALG)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

45. Muscle weakness, generalized or specific area (not due to neuropathy):*(T17MUSCL)*

0 - Grades 0-2
3 - Symptomatic and Interfering with ADL
4 - Life-Threatening; Disabling
5 - Death

Dermatologic Toxicity

46. Pruritus/itching:*(T17PRURI)*

0 - Grades 0-2
3 - Intense or Widespread and Interfering with ADL

47. Rash:*(T17RASH)*

0 - Grades 0-2
3 - Severe erythroderma or macular, papular or vesicular eruption; desquamation covering >/= 50% BSA
4 - Generalized Exfoliative Ulcerative or Bullous Dermatitis
5 - Death

48. Urticaria (hives, welts, wheals):*(T17URTIC)*

0 - Grades 0-2
3 - Intervention indicated for >or=24 hours

Hepatobiliary/Pancreas Toxicity

49. Pancreatitis:*(T17PANCR)*

0 - Grades 0-2
3 - Interventional Radiology or Operative Intervention Indicated
4 - Life-Threatening Consequences (e.g., Circulatory Failure, Hemorrhage, Sepsis)
5 - Death

Hemorrhagic Toxicity

50. Hemorrhage:*(T17HEMRH)*

0 - Grades 0-2
3 - Transfusion, Int Radiology, Endoscopic, or Operative Int Indicated; Hemostatis of Bleeding Site
4 - Life-Threatening Consequences; Major Urgent Intervention Indicated
5 - Death

51. Which organ system was the hemorrhage associated with?*(T17ORGAN)*

1 - CNS
2 - Gastrointestinal
3 - Genitourinary
4 - Pulmonary, Upper Respiratory
5 - Other

Specify other organ system:*(T17SPOTH)*

Vascular Toxicity

52. Vascular leak syndrome:*(T17VASCL)*

0 - Grades 0-2
3 - Respiratory compromise or fluids indicated
4 - Life-threatening; pressor support or ventilatory support indicated
5 - Death

53. Thrombosis/thrombus/embolism:*(T17THRMB)*

0 - Grades 0-2
3 - DVT or Cardiac Thrombosis; Intervention (e.g., Anticoagulation, Lysis) Indicated
4 - Embolic Event Including Pulmonary Embolism or Life-Threatening Thrombus
5 - Death

Pulmonary Toxicity

54. Hypoxia (for more than 24 hours):*(T171HYPX)*

0 - Grades 0-2
3 - Decreased Oxygen Saturation at Rest; Continuous Oxygen Indicated
4 - Life-Threatening; Intubation or Ventilation Indicated
5 - Death

55. Dyspnea:*(T17DYSPN)*

0 - Grades 0-2
3 - Dyspnea with Activities of Daily Living
4 - Dyspnea at Rest; Intubation or Ventilator Indicated
5 - Death

56. Cough:*(T17COUGH)*

0 - Grades 0-2
3 - Symptomatic and Significantly Interfering with Sleep or ADL

57. During this assessment period, was an FEV1 performed?*(T17FEVDN)*

☐ 1 - Yes ☐ 2 - No

58. Record FEV1 value obtained:*(T17FEVLV)*

(xxx) % of predicted value

59. During this assessment period, was an FVC performed?*(T17FVCDN)*

☐ 1 - Yes ☐ 2 - No

60. Record the FVC value obtained:*(T17FVCLV)*

(xxx) % of predicted value

Hepatic Toxicity

61. Bilirubin:*(T17BILIR)*

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

62. ALT:*(T17ALT)*

0 - Grades 0-1
2 - > 2.5 - 5.0 x ULN
3 - > 5.0 - 20.0 x ULN
4 - > 20.0 x ULN

63. AST:*(T17AST)*

0 - Grades 0-1
2 - > 2.5 - 5.0 x ULN
3 - > 5.0 - 20.0 x ULN
4 - > 20.0 x ULN

64. Alkaline phosphatase:*(T17ALKPH)*

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:

65. Jaundice:*(T17JANDC)* ☐ 1 - Yes ☐ 2 - No

66. Hepatomegaly:*(T17HEPTM)* ☐ 1 - Yes ☐ 2 - No

67. Right upper quadrant pain:*(T17QUADP)* ☐ 1 - Yes ☐ 2 - No

68. Weight gain (>5%) from baseline:*(T17WGTGN)* ☐ 1 - Yes ☐ 2 - No

69. **Indicate the etiology of the abnormal liver function:**

	Etiology	Biopsy Results	Doppler Ultrasound Results
VOD:	*(T17VODET)* 1 - Yes / 2 - No	*(T17VODBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17VODDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
GVHD:	*(T17GVHET)* 1 - Yes / 2 - No	*(T17GVHBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17GVHDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
Infection:	*(T17INFET)* 1 - Yes / 2 - No	*(T17INFBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17INFDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
Other:	*(T17OTHET)* 1 - Yes / 2 - No	*(T17OTHBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17OTHDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
Unknown:	*(T17UNKET)* 1 - Yes / 2 - No	*(T17UNKBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17UNKDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done

Specify other etiology:*(T172SPEC)*

Comments:*(T17COMM)*

Blood and Marrow Transplant Clinical Trials Network

Thromboembolism Form - 0702 (THR)

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

Segment *(PROTSEG)*: B
Thromboembolic event date *(THROMBDT)*:

Record type of thromboembolism:

1. DVT (Deep Vein Thrombosis):	*(THRDVT)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRDVGDE)* 0 - Grades 0-2 3 - DVT or Cardiac Thrombosis; Intervention (e.g., Anticoagulation, Lysis) Indicated 4 - Embolic Event Including Pulmonary Embolism or Life-Threatening Thrombus 5 - Death
2. Pulmonary Emboli:	*(THRPULM)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THREMGDE)* 0 - Grades 0-2 3 - DVT or Cardiac Thrombosis; Intervention (e.g., Anticoagulation, Lysis) Indicated 4 - Embolic Event Including Pulmonary Embolism or Life-Threatening Thrombus 5 - Death
3. Arterial Thrombosis:	*(THRARTH)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRARGDE)* 0 - Grades 0-2 3 - Laboratory Findings Present with Clinical Consequences 4 - Laboratory Findings and Life-Threatening or Disabling Consequences 5 - Death
4. Cardiac Ischemia/Infarction:	*(THRCRDIS)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRCIGDE)* 0 - Grades 0-2 3 - Symptomatic and Testing Consistent with Ischemia; Unstable Angina; Intervention Indicated 4 - Acute Myocardial Infarction 5 - Death
5. CNS Cerebrovascular Ischemia:	*(THRCVA)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRCVGDE)* 0 - Grades 0-2 3 - Transient Ischemic Event or Attack (TIA) 4 - Cerebral Vascular Accident (CVA, Stroke), Neurologic Deficit >24 hrs 5 - Death

If DVT, specify site:

6. Upper extremity:*(THRDVTUP)* ☐ 1 - Yes ☐ 2 - No
7. Lower extremity:*(THRDVTLO)* ☐ 1 - Yes ☐ 2 - No

8. Was the thrombosis related to the catheter?*(THRCATRL)* ☐ 1 - Yes ☐ 2 - No

9. Was the patient on anti-coagulation therapy?*(THRTHRPY)* ☐ 1 - Yes ☐ 2 - No

If yes, specify all therapies:

10. Aspirin:*(THRASP)* ☐ 1 - Yes ☐ 2 - No
11. Coumadin:*(THRCOUM)* ☐ 1 - Yes ☐ 2 - No
12. Low molecular weight heparin:*(THRHEP)* ☐ 1 - Yes ☐ 2 - No
13. Record type of low molecular weight heparin:*(THRHEPTY)*
    1 - Enoxaparin
    2 - Daltiparin
    3 - Other

If other low molecular weight heparin type, specify:*(THRHPOTS)*

14. Other therapy:*(THROTHER)* ☐ 1 - Yes ☐ 2 - No

If other therapy, specify:*(THROTHSP)*

Comments:*(THRCOMM)*

Transplant Form (TXP)

Web Version: 1.0; 18.00; 08-09-18

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

1. Record date of initiation of conditioning regimen:*(CONDNGDT)* *(mm/dd/yyyy)*
2. Record date of hematopoietic stem cell infusion:*(TXDTTXP)* *(mm/dd/yyyy)*

3. IUBMID for this patient (if available):*(T_IUBMID)*

Comments:*(COMMTXP1)*

Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

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

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

1. Adverse event status:*(AVSTAT_E)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason
2. Has this event been determined to be an unexpected, grade 3-5 adverse event?*(AMDETER)* ☐ 1 - Yes ☐ 2 - No
3. Does this require expedited reporting to the FDA?*(AMEXPFDA)* ☐ 1 - Yes ☐ 2 - No
4. Does this require expedited reporting to the DSMB?*(AMEXPDSM)* ☐ 1 - Yes ☐ 2 - No
5. Do you recommend the patient be withdrawn from further protocol therapy?*(AMWITHDR)* ☐ 1 - Yes ☐ 2 - No
6. Is the review complete?*(AMREVDNE)* ☐ 1 - Yes ☐ 2 - No
7. If **No**, what additional information is required:*(AMREVINF)*
8. Medical Monitor event description:*(AMMMEVDS)*
9. Medical Monitor CTCAE grade of event:*(CTCAEGRD)*
   - 1 - Grade 1
   - 2 - Grade 2
   - 3 - Grade 3
   - 4 - Grade 4
   - 5 - Grade 5

Comments:*(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Anthropomorphic Measurement Form - 0702 (ANT)

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

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

1. Date of Assessment:*(ANTDATE)* _____ *(mm/dd/yyyy)*

Height and Weight Measurements

2. Record the patient's height:*(ANTHTCM)* _____ *(xxx.x)* cm *(ANTHTIN)* **OR** _____ *(xx.x)* in
3. Record the patient's weight:*(ANTWGTKG)* _____ *(xxx.x)* kg *(ANTWGTLB)* **OR** _____ *(xxx.x)* lbs
4. Calculated Body Mass Index (BMI):*(ANTBMI)* _____ *(xx.xx)*

Waist and Hip Measurements

5. Record the patient's waist circumference:*(ANTWSTCM)* _____ *(xxx.x)* cm *(ANTWSTIN)* **OR** _____ *(xx.x)* in
6. Record the patient's hip circumference:*(ANTHIPCM)* _____ *(xxx.x)* cm *(ANTHIPIN)* **OR** _____ *(xx.x)* in
7. Calculated Waist/Hip Ratio (WHR):*(ANTWHR)* _____ *(x.xx)*

Comments:*(ANTCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

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

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

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

   Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

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

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

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

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

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

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

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

Specify other:*(DTHSPEC1)*

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

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

Specify other:*(DTHSPEC2)*

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

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

Specify other:*(DTHSPEC3)*

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

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

Specify other:*(DTHSPEC4)*

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

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

Specify other:*(DTHSPEC5)*

Comments:*(DTCMMNTS)*

Additional Selection Options for DTH

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

0702C (ENR)

Web Version: 1.0; 2.02; 10-16-15

Multiple Myeloma Follow On Enrollment Form - Segment C

1. Record the treatment the patient was randomized to:*(MMCTRT)*
   - 1 - Auto/Auto
   - 2 - Auto/RVD Consolidation
   - 3 - Auto/Maintenance

2. Record the treatment the patient will receive:*(MMCTRGET)*
   - 1 - Auto/Auto
   - 2 - Auto/RVD Consolidation
   - 3 - Auto/Maintenance
   - 4 - Other

3. Record the treatment the patient will receive:*(MMCTRGET)*
   - 1 - Auto/Auto
   - 2 - Auto/RVD Consolidation
   - 3 - Auto/Maintenance
   - 4 - Other

4. Specify other treatment:*(MMCTROTH)*

5. Reason patient did not receive assigned treatment:*(MMCRSNTR)*
   - 1 - Patient Withdrew Consent
   - 2 - Patient Refused Treatment
   - 3 - Adverse Event
   - 4 - Myeloma Progression
   - 5 - Insurance Coverage Denied
   - *Additional Options Listed Below

6. Specify other reason patient did not receive assigned treatment:*(MMCRSNSP)*

7. Record the patient's body surface area (BSA):*(MMCBSA)* *(x.x)*

8. BSA date:*(MMCBSADT)* *(mm/dd/yyyy)*

Comments:*(MMCCOMM)*

Additional Selection Options for ENR

Reason patient did not receive assigned treatment:
6 - Inadequate Recovery from First Transplant
7 - Physician Decision
9 - Other

Blood and Marrow Transplant Clinical Trials Network

FACT-BMT (Version 4) (FCT)

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

Segment *(PROTSEG)*: C
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 uses 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)*

Item 8 uses the same response options as above.

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

10. I get support from my friends*(FRNDSPRT)*

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

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

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

Did the patient answer the following question?(CHECKBOX)

☐ 1 - Yes ☐ 2 - No

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

Emotional Well-Being

15. I feel sad*(FEELSAD)*

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

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

18. I feel nervous*(NERVOUS)*

19. I worry about dying*(WORRYDIE)*

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)*

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

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

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

35. I get tired easily*(GETTIRED)*

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

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

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

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

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

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

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

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

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

40. I can remember things*(MEMORY)*

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

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)*

45. I have tremors*(TREMORS)*

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

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

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

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

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

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 Status Form - 0702 (FU5)

Web Version: 1.0; 6.00; 10-16-15

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

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

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

2. Has the patient died?*(MMPTDTH)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Death Form must be submitted.
3. Date of patient death:*(MMDTHDT)* *(mm/dd/yyyy)*
4. Has the patient experienced disease progression?*(MMRELPR)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Progression Form must be submitted.
5. Date of progression:*(MMRELDT)* *(mm/dd/yyyy)*
6. Has the patient initiated any non-protocol anti-myeloma therapy?*(MMRECTHP)* ☐ 1 - Yes ☐ 2 - No

If yes, record type of therapy:

7.

	Receiving:	Start Date:	Has Treatment been Discontinued?	Stop Date:
Dexamethasone:	*(MMDEXTH)* ☐ 1 - Yes ☐ 2 - No	*(MMDEXST)* *(mm/dd/yyyy)*	*(MMDEXDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMDEXSTP)* *(mm/dd/yyyy)*
Thalidomide:	*(MMTHALTH)* ☐ 1 - Yes ☐ 2 - No	*(MMTHALST)* *(mm/dd/yyyy)*	*(MMTHLDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMTHLSTP)* *(mm/dd/yyyy)*
Lenalidomide:	*(MMLENTH)* ☐ 1 - Yes ☐ 2 - No	*(MMLENST)* *(mm/dd/yyyy)*	*(MMLENDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMLENSTP)* *(mm/dd/yyyy)*
Bortezomib:	*(MMBORTH)* ☐ 1 - Yes ☐ 2 - No	*(MMBORST)* *(mm/dd/yyyy)*	*(MMBORDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMBORSTP)* *(mm/dd/yyyy)*
Other:	*(MMRCVOTH)* ☐ 1 - Yes ☐ 2 - No	*(MMOTHST)* *(mm/dd/yyyy)*	*(MMOTHDIS)* ☐ 1 - Yes ☐ 2 - No	*(MMOTHSTP)* *(mm/dd/yyyy)*

8. Specify other type of anti-myeloma therapy:*(MMOTHSPE)*
9. Record reason for initiation of anti-myeloma therapy:*(MMRSNTHR)*
10. Has the patient experienced any new clinically significant infections?*(MMNEWIN)* ☐ 1 - Yes ☐ 2 - No
If Yes, an Infection Form must be submitted.
11. Date of infection:*(MMINFDT)* *(mm/dd/yyyy)*
12. Has the patient been hospitalized other than for a protocol-specified transplant?*(MMHOSP)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Re-Admission Form must be submitted.
13. Date of hospitalization:*(MMHOSDT)* *(mm/dd/yyyy)*
14. Has the patient received a non-protocol specified transplant?*(MMNONTXP)* ☐ 1 - Yes ☐ 2 - No
15. Date of non-protocol specified transplant:*(MMTXPDT)* *(mm/dd/yyyy)*
16. Has the patient experienced a thromboembolic event?*(MMTHRMBO)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Thromboembolism Form must be submitted.
17. Date of thromboembolic event:*(MMTHRMDT)* *(mm/dd/yyyy)*
18. Has the patient experienced any unexpected grade 3-5 adverse events?*(MMUAE)* ☐ 1 - Yes ☐ 2 - No
If Yes, an Unexpected, Grade 3-5 Adverse Event Form must be submitted.
19. Date of onset of unexpected grade 3-5 adverse event:*(MMUAEDT)* *(mm/dd/yyyy)*
20. Was the patient diagnosed with a second cancer?*(MMSECCAN)* ☐ 1 - Yes ☐ 2 - No
21. Date of second cancer diagnosis:*(MMSECCDT)* *(mm/dd/yyyy)*

Lenalidomide Maintenance Therapy

22. Did the patient take lenalidomide during this assessment period?*(MMTAKLEN)* ☐ 1 - Yes ☐ 2 - No
23. If no, record reason:*(MMNOTTAK)*
1 - Lenalidomide withheld during previous assessment period
2 - Toxicity
3 - Other
24. Specify other reason:*(MMNOTOTH)*

25. As of the last day of the assessment period, was the patient still taking lenalidomide? *(MMSTLTAK)*
    ☐ 1 - Yes ☐ 2 - No

26. What was the dose on the last day of the assessment period?*(MMLSTDOS)*
    _____ *(xx)* mg

27. Has the patient been on the same dose level of lenalidomide during the entire assessment period?*(MMSAMEDS)*
    ☐ 1 - Yes ☐ 2 - No

28. If yes, what was the dose?*(MMDOSE)*
    _____ *(xx)* mg

29. Was lenalidomide withheld permanently?*(MMWITHLD)*
    ☐ 1 - Yes ☐ 2 - No

30. Date lenalidomide was permanently withheld:*(MMWITHDT)*
    _____ *(mm/dd/yyyy)*

31. If yes, reason for withholding permanently:*(MMRESWIT)*

    1 - Lenalidomide withheld during previous assessment period
    2 - Toxicity
    3 - Other

32. Specify other reason for withholding permanently:*(MMSPWITH)*

Comments:*(MMCMNT)*

Blood and Marrow Transplant Clinical Trials Network

Hematology/Chemistry Form - 0702 (HCF)

Web Version: 1.0; 2.05; 10-16-15

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

1. Record the date of assessment:*(HCASMTDT)* *(mm/dd/yyyy)*

CBC

Record the most recent CBC lab results:

	Most Recent Value	Date of Sample
2. Hemoglobin:	*(HCFHGB)* *(xx.x)* g/dL	*(HCFHGBDT)* *(mm/dd/yyyy)*
3. WBC:	*(HCFWBC)* *(xxxxxx)* /mm^3	*(HCFWBCDT)* *(mm/dd/yyyy)*
4. Platelet Count:	*(HCFPLT)* *(xxxxxx)* /mm^3	*(HCFPLTDT)* *(mm/dd/yyyy)*
5. Neutrophils:	*(HCFNEUT)* *(xxxxx)* /mm^3	*(HCFNEUDT)* *(mm/dd/yyyy)*
6. Eosinophils:	*(HCFEOS)* *(xxxx)* /mm^3	*(HCFEOSDT)* *(mm/dd/yyyy)*

Chemistry

Record the most recent chemistry lab results:

	Most Recent Value	Date of Sample
7. Creatinine:	*(HCFCREAT)* *(x.x)* mg/dL	*(HCFCRTDT)* *(mm/dd/yyyy)*
8. Estimated Creatinine Clearance:	*(HCFCRCL)* *(xxx)* mL/min	*(HCFCRCDT)* *(mm/dd/yyyy)*
9. Bilirubin:	*(HCFBILI)* *(xx.x)* mg/dL	*(HCFBILDT)* *(mm/dd/yyyy)*
10. Alkaline Phosphatase:	*(HCFALKPH)* *(xxxx)* IU/L	*(HCFALKDT)* *(mm/dd/yyyy)*
11. AST:	*(HCFAST)* *(xxxx)* IU/L	*(HCFASTDT)* *(mm/dd/yyyy)*
12. ALT:	*(HCFALT)* *(xxxx)* IU/L	*(HCFALTDT)* *(mm/dd/yyyy)*
13. Glucose:	*(HCFGLUC)* *(xxxx)* mg/dL	*(HCFGLUDT)* *(mm/dd/yyyy)*
14. Sodium:	*(HCSODIUM)* *(xxx)* mmol/L	*(HCFSDDT)* *(mm/dd/yyyy)*
15. Potassium:	*(HCFPOTAS)* *(x.x)* mmol/L	*(HCFPTSDT)* *(mm/dd/yyyy)*
16. Calcium:	*(HCFCALCI)* *(xx.x)* mg/dL	*(HCFCALDT)* *(mm/dd/yyyy)*

Comments:*(HCFCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Infection Form (INF)

Web Version: 1.0; 4.01; 10-16-15

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

INFECTION I

1. Type of infection:*(INFTYP01)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other
2. Organism I:*(ORGN01)*
   - 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

   If other specify:*(INFSPEC1)*
3. Record the level of certainty of the fungal infection diagnosis:*(CERTNTY1)*
   - 1 - Proven Fungal Infection
   - 2 - Probable Fungal Infection
   - 3 - Possible Fungal Infection
4. Severity of infection:*(SVRTY01)*
   - 1 - Moderate
   - 2 - Severe
   - 3 - Life-Threatening/Fatal

INFECTION II

5. Type of infection:*(INFTYP02)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other
6. Organism II:*(ORGN02)*
   - 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

   If other specify:*(INFSPEC2)*
7. Record the level of certainty of the fungal infection diagnosis:*(CERTNTY2)*
   - 1 - Proven Fungal Infection
   - 2 - Probable Fungal Infection
   - 3 - Possible Fungal Infection
8. Severity of infection:*(SVRTY02)*
   - 1 - Moderate
   - 2 - Severe
   - 3 - Life-Threatening/Fatal

INFECTION III

9. Type of infection:*(INFTYP03)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other
10. Organism III:*(ORGN03)*
    - 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

    If other specify:*(INFSPEC3)*
11. Record the level of certainty of the fungal infection diagnosis:*(CERTNTY3)*

1 - Proven Fungal Infection
2 - Probable Fungal Infection
3 - Possible Fungal Infection

12. Severity of infection:*(SVRTY03)*

1 - Moderate
2 - Severe
3 - Life-Threatening/Fatal

13. Was an agent(s) administered to treat the infection(s)?*(TRTINF)*

☐ 1 - Yes ☐ 2 - No

Provide agent(s) administered for this infectious period:

14. 1st agent:*(AGENT1)*

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

If other specify:*(AGTSPEC1)*

15. 2nd agent:*(AGENT2)*

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

If other specify:*(AGTSPEC2)*

16. 3rd agent:*(AGENT3)*

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

If other specify:*(AGTSPEC3)*

17. Were additional agents administered for this infectious period?*(ADDAGENT)*

☐ 1 - Yes ☐ 2 - No

If yes, specify additional agents administered:*(INFSPEC4)*

Comments:*(INFCOM)*

Additional Selection Options for INF

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

Long Term Follow Up Screening Form - 0702 (LSF)

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

Segment *(PROTSEG)*: C

This is a screening form for the BMT CTN 0702 Long-Term Follow-Up Protocol (Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702). It should be completed when the patient is approached for potential participation in this protocol.

1. Did the patient consent to participate in the Long-Term Follow-Up protocol?*(LSFLTCNS)* ☐ 1 - Yes ☐ 2 - No
2. Date of Long-Term Follow-Up protocol consent:*(LSFLTCDT)* _____ *(mm/dd/yyyy)*
3. Reason patient will not participate in the Long-Term Follow-Up protocol:*(LSFNOLTR)*
   - 1 - Ineligible Due to Myeloma Progression
   - 2 - Ineligible for Other Reason
   - 3 - Patient Refused
   - 4 - Site Not Participating in Long-Term Follow-Up Protocol
   - 5 - Patient Withdrew Consent for BMT CTN 0702 Protocol
   - *Additional Options Listed Below

   a. Specify other reason the patient will not participate in the Long-Term Follow-Up protocol:*(LSFNLTSP)* _____
4. Is the patient eligible to receive long-term lenalidomide maintenance therapy?*(LSFMTELG)* ☐ 1 - Yes ☐ 2 - No
5. Did the patient consent to receive long-term lenalidomide maintenance therapy? *(LSFMTCNS)* ☐ 1 - Yes ☐ 2 - No
6. Date of long-term lenalidomide maintenance therapy consent:*(LSFMTCDT)* _____ *(mm/dd/yyyy)*
7. Reason patient will not receive long-term lenalidomide maintenance therapy: *(LSFNOMTR)*
   - 1 - Patient Refused
   - 2 - Physician Decision
   - 3 - Other, Specify

   a. Specify other reason the patient will not receive long-term lenalidomide maintenance therapy:*(LSFNMTSP)* _____

Comments:*(LSFCOMM)* _____

Additional Selection Options for LSF

Reason patient will not participate in the Long-Term Follow-Up protocol:
6 - Patient Lost to Follow Up
7 - Physician Decision
8 - Other, Specify

Blood and Marrow Transplant Clinical Trials Network

Maintenance Eligibility Checklist - 0702 (MEC)

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

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

1. Treatment arm:*(MMRXCARM)*
   - 1 - Auto/Auto
   - 2 - Auto/RVD Consolidation
   - 3 - Auto/Maintenance
   - 4 - Other

Inclusion Criteria

2. Has mucositis resolved?*(MCMUCRES)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
3. Is the patient currently receiving hyperalimentation?*(MMCRCVHY)* ☐ 1 - Yes ☐ 2 - No
4. Is the patient currently receiving intravenous hydration?*(MMCVHY)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value	ULN for your Institution	Date Sample Obtained
5. Bilirubin:	*(MMCBILI)* *(xx.x)* mg/dL	*(MMCBILUL)* *(xx.x)* mg/dL	*(MMCBILDT)* *(mm/dd/yyyy)*
6. ALT:	*(MMCALT)* *(xxx)* Units/L	*(MMCALTUL)* *(xxx)* Units/L	*(MMCALTDT)* *(mm/dd/yyyy)*
7. AST:	*(MMCAST)* *(xxx)* Units/L	*(MMCASTUL)* *(xxx)* Units/L	*(MMCASTDT)* *(mm/dd/yyyy)*

8. Record creatinine clearance:*(MMCCREAT)* *(xxx)* mL/min
9. Record date creatinine clearance sample obtained:*(MMCCRCL)* *(mm/dd/yyyy)*
10. Is the patient currently taking any antibiotics, amphotericin B formulations, voriconazole or other anti-fungal medication for possible, probable, or proven fungal infections?*(MMINFMED)*
    - 1 - Yes
    - 2 - Yes, Approved by Study Chair/MM
    - 3 - No
11. Date approved by study chair or medical monitor:*(MMCNFRDT)* *(mm/dd/yyyy)*
12. Did the patient receive radiation therapy post-autologous transplant?*(MMCRDIAT)* ☐ 1 - Yes ☐ 2 - No
13. Record date radiation therapy ended:*(MMCRADDT)* *(mm/dd/yyyy)*

Per maintenance eligibility criteria, platelets must be ≥75x10^9/L (or 75000/mm^3).

14. Record the patient's platelet count:*(MMCPLATE)* *(xxxxxx)* /mm^3
15. Has the patient received a platelet transfusion within 7 days of the platelet measurement? *(MMTRANS)* ☐ 1 - Yes ☐ 2 - No

Per maintenance eligibility criteria, ANC must be ≥1.5x10^9/L (or 1500/mm^3)

16. Record the patient's ANC:*(MMCANC)* *(xxxxx)* /mm^3
17. ANC date:*(MMCANCDT)* *(mm/dd/yyyy)*
18. Has the patient received filgrastim within 7 days or pegfilgrastim within 14 days of the ANC measurement?*(MMFILGR)* ☐ 1 - Yes ☐ 2 - No
19. Does the patient have any contraindications to lenalidomide?*(MMCONIND)* ☐ 1 - Yes ☐ 2 - No
20. Is the patient pregnant (positive β-HCG) or breastfeeding?*(MMCPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
21. Is the patient willing to use contraceptive techniques during the length of lenalidomide maintenance therapy?*(MMCNTRAC)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
22. Is the patient willing to begin DVT prophylaxis?*(MMDVTPR)* ☐ 1 - Yes ☐ 2 - No

Comments:*(COMMEC)*

Blood and Marrow Transplant Clinical Trials Network

Maintenance Initiation Form - 0702 (MIF)

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

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

1. Was lenalidomide maintenance therapy initiated?*(MIFMTINI)* ☐ 1 - Yes ☐ 2 - No

2. Record date of initiation of lenalidomide maintenance therapy:*(MIFMTDT)* _____ *(mm/dd/yyyy)*

Comments:*(MIFCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Myeloma Status Form - 0702 (MSF)

Web Version: 1.0; 6.02; 10-16-15

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

The purpose of this form is to capture the BMT CTN 0702 myeloma assessments required at 4 years post randomization.

1. Start of assessment period:*(MMSTRTDT)* *(mm/dd/yyyy)*
2. End of assessment period:*(MMENDDT)* *(mm/dd/yyyy)*

3. Indicate the patient's current disease response:*(MMCURDZR)*
   - 1 - Stringent Complete Response (sCR)
   - 2 - Complete Response (CR)
   - 3 - Near Complete Response (nCR)
   - 4 - Very Good Partial Response (VGPR)
   - 5 - Partial Response (PR)
   - *Additional Options Listed Below

If patient's current disease status is progression, a Progression form must be submitted.

Serum Protein Electrophoresis (SPEP)

4. How many SPEPs were performed during this assessment period?*(MMSPEPNM)*
5. Record the reason no SPEPs were performed:*(MMNOSPEP)*
6. For each SPEP performed, record the following:

	Date of SPEP	Serum total protein value	M-protein spike result	M-protein spike value
SPEP 1	*(MMSP1DT)* *(mm/dd/yyyy)*	*(MMSP1TG)* *(xx.xxx)* g/dL	*(MMSP1RES)* 1 - Positive; 2 - Negative; 3 - Present but Not Quantifiable	*(MMSP1MSG)* *(x.xxx)* g/dL
		(MMSP1TMG) **OR** *(xxxxx.xx)* mg/dL		*(MSP1MSMG)* **OR** *(xxxx.xx)* mg/dL
SPEP 2	*(MMSP2DT)* *(mm/dd/yyyy)*	*(MMSP2TG)* *(xx.xxx)* g/dL	*(MMSP2RES)* 1 - Positive; 2 - Negative; 3 - Present but Not Quantifiable	*(MMSP2MSG)* *(x.xxx)* g/dL
		(MMSP2TMG) **OR** *(xxxxx.xx)* mg/dL		*(MSP2MSMG)* **OR** *(xxxx.xx)* mg/dL
SPEP 3	*(MMSP3DT)* *(mm/dd/yyyy)*	*(MMSP3TG)* *(xx.xxx)* g/dL	*(MMSP3RES)* 1 - Positive; 2 - Negative; 3 - Present but Not Quantifiable	*(MMSP3MSG)* *(x.xxx)* g/dL
		(MMSP3TMG) **OR** *(xxxxx.xx)* mg/dL		*(MSP3MSMG)* **OR** *(xxxx.xx)* mg/dL

Serum Free Light Chain (FLC)

7. Was serum FLC measured?*(MMSFLC)* ☐ 1 - Yes ☐ 2 - No
8. Date of serum FLC assessment:*(MMSFLCDT)* *(mm/dd/yyyy)*
9. Kappa Free Light Chain value:*(MMSKMGL)* *(xxxxxx.xx)* mg/L *(MMSKMGDL)***OR** *(xxxxx.xxx)* mg/dL
10. Lambda Free Light Chain value:*(MMSLMGL)* *(xxxxxx.xx)* mg/L *(MMSLMGDL)***OR** *(xxxxx.xxx)* mg/dL
11. Free Light Chain Ratio (κ/λ):*(MMSFLCR)* *(xxxxxx.xxxxxx)*

Serum Immunofixation (Serum IFE)

12. How many serum IFEs were performed during this assessment period?*(MMSIFENM)*
13. Record the reason no serum IFEs were performed:*(MMNOSIFE)*

Serum IFE 1

14. Date of serum IFE 1:*(MMSI1DT)* *(mm/dd/yyyy)*
15. Serum IFE 1 Result:*(MMSI1RES)*
    - 1 - Positive
    - 2 - Negative

16. Was there mention of oligoclonal banding in the report?*(MMSI1OB)* ☐ 1 - Yes ☐ 2 - No

17. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MMSI1HVG)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HGK)* 1 - Yes 2 - No	*(MMSI1HGL)* 1 - Yes 2 - No
IgA	*(MMSI1HVA)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HAK)* 1 - Yes 2 - No	*(MMSI1HAL)* 1 - Yes 2 - No
IgM	*(MMSI1HVM)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HMK)* 1 - Yes 2 - No	*(MMSI1HML)* 1 - Yes 2 - No
IgD	*(MMSI1HVD)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HDK)* 1 - Yes 2 - No	*(MMSI1HDL)* 1 - Yes 2 - No
IgE	*(MMSI1HVE)* ☐ 1 - Yes ☐ 2 - No	*(MMSI1HEK)* 1 - Yes 2 - No	*(MMSI1HEL)* 1 - Yes 2 - No

18. Did serum IFE 1 indicate light chain disease?*(MMSI1LCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

19. Kappa:*(MMSI1KLC)* ☐ 1 - Yes ☐ 2 - No

20. Lambda:*(MMSI1LLC)* ☐ 1 - Yes ☐ 2 - No

Serum IFE 2

21. Date of serum IFE 2:*(MMSI2DT)* *(mm/dd/yyyy)*

22. Serum IFE 2 Result:*(MMSI2RES)* 1 - Positive 2 - Negative

23. Was there mention of oligoclonal banding in the report?*(MMSI2OB)* ☐ 1 - Yes ☐ 2 - No

24. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MMSI2HVG)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HGK)* 1 - Yes 2 - No	*(MMSI2HGL)* 1 - Yes 2 - No
IgA	*(MMSI2HVA)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HAK)* 1 - Yes 2 - No	*(MMSI2HAL)* 1 - Yes 2 - No
IgM	*(MMSI2HVM)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HMK)* 1 - Yes 2 - No	*(MMSI2HML)* 1 - Yes 2 - No
IgD	*(MMSI2HVD)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HDK)* 1 - Yes 2 - No	*(MMSI2HDL)* 1 - Yes 2 - No
IgE	*(MMSI2HVE)* ☐ 1 - Yes ☐ 2 - No	*(MMSI2HEK)* 1 - Yes 2 - No	*(MMSI2HEL)* 1 - Yes 2 - No

25. Did serum IFE 2 indicate light chain disease?*(MMSI2LCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

26. Kappa:*(MMSI2KLC)* ☐ 1 - Yes ☐ 2 - No

27. Lambda:*(MMSI2LLC)* ☐ 1 - Yes ☐ 2 - No

Serum IFE 3

28. Date of serum IFE 3:*(MMSI3DT)* *(mm/dd/yyyy)*

29. Serum IFE 3 Result:*(MMSI3RES)* 1 - Positive 2 - Negative

30. Was there mention of oligoclonal banding in the report?*(MMSI3OB)* ☐ 1 - Yes ☐ 2 - No

31. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(MMSI3HVG)* ☐ 1 - Yes ☐ 2 - No	*(MMSI3HGK)* 1 - Yes 2 - No	*(MMSI3HGL)* 1 - Yes 2 - No
IgA	*(MMSI3HVA)* ☐ 1 - Yes ☐ 2 - No		

		(MMSI3HAK) 1 - Yes 2 - No	(MMSI3HAL) 1 - Yes 2 - No
IgM	(MMSI3HVM) ☐ 1 - Yes ☐ 2 - No	(MMSI3HMK) 1 - Yes 2 - No	(MMSI3HML) 1 - Yes 2 - No
IgD	(MMSI3HVD) ☐ 1 - Yes ☐ 2 - No	(MMSI3HDK) 1 - Yes 2 - No	(MMSI3HDL) 1 - Yes 2 - No
IgE	(MMSI3HVE) ☐ 1 - Yes ☐ 2 - No	(MMSI3HEK) 1 - Yes 2 - No	(MMSI3HEL) 1 - Yes 2 - No

32. Did serum IFE 3 indicate light chain disease?*(MMSI3LCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

33. Kappa:*(MMSI3KLC)* ☐ 1 - Yes ☐ 2 - No

34. Lambda:*(MMSI3LLC)* ☐ 1 - Yes ☐ 2 - No

Urine Protein Electrophoresis/Urine Immunofixation (UPEP/Urine IFE)

35. How many UPEPs/Urine IFEs were performed during this assessment period?*(MMUPEPNM)*

36. Record the reason no UPEPs/Urine IFEs were performed:*(MMNOUPEP)*

37. For each UPEP/Urine IFE performed, record the following:

	Date of UPEP/Urine IFE	Urine total protein value	Urine total volume	M-protein result (Urine IFE)	M-protein value	M-protein units	Urine light chain type
UPEP/Urine IFE 1	*(MMUP1DT)* *(mm/dd/yyyy)*	*(MMUP1TPG)* *(xx.xxx)* g/24hrs	*(MMUP1TVL)* *(xx.xxx)* L/24hrs	*(MMUP1RES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(MMUP1VAL)* *(xxxx.xxx)*	*(MMUP1UN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(MMUP1KLC)* 1 - Yes 2 - No
		(MMUP1TMG) **OR** *(xxxxx.xx)* mg/24hrs	*(MMUP1VML)* **OR** *(xxxxx.xx)* mL/24hrs				Lambda:*(MMUP1LLC)* 1 - Yes 2 - No
UPEP/Urine IFE 2	*(MMUP2DT)* *(mm/dd/yyyy)*	*(MMUP2TPG)* *(xx.xxx)* g/24hrs	*(MMUP2TVL)* *(xx.xxx)* L/24hrs	*(MMUP2RES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(MMUP2VAL)* *(xxxx.xxx)*	*(MMUP2UN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(MMUP2KLC)* 1 - Yes 2 - No
		(MMUP2TMG) **OR** *(xxxxx.xx)* mg/24hrs	*(MMUP2VML)* **OR** *(xxxxx.xx)* mL/24hrs				Lambda:*(MMUP2LLC)* 1 - Yes 2 - No
UPEP/Urine IFE 3	*(MMUP3DT)* *(mm/dd/yyyy)*	*(MMUP3TPG)* *(xx.xxx)* g/24hrs	*(MMUP3TVL)* *(xx.xxx)* L/24hrs	*(MMUP3RES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(MMUP3VAL)* *(xxxx.xxx)*	*(MMUP3UN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(MMUP3KLC)* 1 - Yes 2 - No
		(MMUP3TMG) **OR** *(xxxxx.xx)* mg/24hrs	*(MMUP3VML)* **OR** *(xxxxx.xx)* mL/24hrs				Lambda:*(MMUP3LLC)* 1 - Yes 2 - No

Bone Marrow

38. How many bone marrow biopsies were performed during this assessment period?*(MMBMBXNM)*

39. Record reason no bone marrow biopsies were performed:*(MMNOBMBX)*

40. For each bone marrow biopsy performed, record the following:

	Date Performed	Plasma Cells Present	Percent Plasma Cells
Bone Marrow Biopsy 1	*(MMBX1DT)* *(mm/dd/yyyy)*	*(MMBX1PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMBX1PCT)* *(xxx.x)* %
Bone Marrow Biopsy 2	*(MMBX2DT)* *(mm/dd/yyyy)*	*(MMBX2PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMBX2PCT)* *(xxx.x)* %
Bone Marrow Biopsy 3	*(MMBX3DT)* *(mm/dd/yyyy)*	*(MMBX3PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMBX3PCT)* *(xxx.x)* %

41. How many bone marrow aspirates were performed during this assessment period?*(MMASPNM)*

42. Record reason no bone marrow aspirates were performed:*(MMNOBMAS)*

43. For each bone marrow aspirate performed, record the following:

	Date Performed	Plasma Cells Present	Percent Plasma Cells
Bone Marrow Aspirate 1	*(MMASP1DT)* *(mm/dd/yyyy)*	*(MMAS1PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMAS1PCT)* *(xxx.x)* %
Bone Marrow Aspirate 2	*(MMASP2DT)* *(mm/dd/yyyy)*	*(MMAS2PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMAS2PCT)* *(xxx.x)* %
Bone Marrow Aspirate 3	*(MMASP3DT)* *(mm/dd/yyyy)*	*(MMAS3PLS)* 1 - Yes 2 - No 3 - Plasma Cells Present but Not Quantifiable	*(MMAS3PCT)* *(xxx.x)* %

Lytic Lesions

44. Was a lytic lesion assessment performed?*(MMBASMT)* 1 - Yes 2 - No

45. Date of lytic bone lesion assessment:*(MMBASMDT)* *(mm/dd/yyyy)*

46. Record most recent information regarding lytic bone lesions:*(MMLESNST)*

1 - No Change
2 - New Lytic Bone Lesions
3 - Definite Size Increase of Existing Lytic Bone Lesions
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

47. Specify other lesion information:*(MMLSNSP)*

Plasmacytomas

48. Was a plasmacytoma assessment performed?*(MMPLCYAS)* 1 - Yes 2 - No

49. Date of plasmacytoma assessment:*(MMPLCYDT)* *(mm/dd/yyyy)*

50. Record most recent information regarding soft tissue plasmacytomas:*(MMPLCYST)*

1 - No Change
2 - New Plasmacytomas
3 - Definite Size Increase of Existing Plasmacytomas
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

51. Specify other plasmacytoma information:*(MMPLCYSP)*

Quantitative Serum Immunoglobulins

52. Were serum immunoglobulins obtained?*(MMSIGS)* 1 - Yes 2 - No

53. Date immunoglobulins obtained:*(MMSIGSDT)* *(mm/dd/yyyy)*

54. Record immunoglobulin values:

	Laboratory Value (mg/dL)	Laboratory Value (g/dL)
Quantitative IgG	*(MMIGGMG)* *(xxxxx.xx)* mg/dL	*(MMIGGG)* **OR** *(xx.xxx)* g/dL
Quantitative IgA	*(MMIGAMG)* *(xxxxx.xx)* mg/dL	*(MMIGAG)* **OR** *(xx.xxx)* g/dL
Quantitative IgM	*(MMIGMMG)* *(xxxxx.xx)* mg/dL	*(MMIGMG)* **OR** *(xx.xxx)* g/dL
If serum heavy chain type is IgD or IgE, record values below		
Quantitative IgD	*(MMIGDMG)* *(x.xxx)* mg/dL	*(MMIGDG)* **OR** *(x.xxxxxx)* g/dL
Quantitative IgE	*(MMIGEMG)* *(x.xxx)* mg/dL	*(MMIGEG)* **OR** *(x.xxxxxx)* g/dL

*Submit a copy of the SPEP, SIFE, UPEP, UIFE, bone marrow reports, and other supporting source documents. Be sure to remove patient identifiers prior to uploading. If unable to upload documents, submit reports via fax to **(240)306-0963**.*

Comments:*(MSFCOMM)*

Additional Selection Options for MSF

Indicate the patient's current disease response:
7 - Stable Disease (SD)
8 - Progression

Record most recent information regarding lytic bone lesions:
6- Other

Record most recent information regarding soft tissue plasmacytomas:
6- Other

Blood and Marrow Transplant Clinical Trials Network

Neurotoxicity Assessment Tool (NAT)

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

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

1. Date of Assessment:*(NATDATAS)* _____ *(mm/dd/yyyy)*

*By checking one (1) number per line, indicate how true each statement has been for you **during the past 7 days.***

	Not at all	A little bit	Somewhat	Quite a bit	Very much	Not answered
2. I have numbness or tingling in my hands	*(NATNUMBH)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. I have numbness or tingling in my feet	*(NATNUMBF)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. I feel discomfort in my hands	*(NATDISHA)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. I feel discomfort in my feet	*(NATDISFE)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. I have joint pain or muscle cramps	*(NATJOINP)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. I feel weak all over	*(NATWEAK)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. I have trouble hearing	*(NATHEAR)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. I get a ringing or buzzing in my ears	*(NATEARS)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. I have trouble buttoning buttons	*(NATBUTON)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11. I have trouble feeling the shape of small objects when they are in my hand	*(NATOBJHA)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12. I have trouble walking	*(NATTROWA)* ☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Comments:*(NATCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Progression Form (PRL)

Web Version: 1.0; 4.03; 10-16-15

Segment *(PROTSEG)*: C
Progression/Relapse Date *(PRRELPDT)*:

Select clinical or laboratory findings which indicate progression:

1. Serum Protein Electrophoresis (SPEP)	*(PRSPEPYN)* 1 - Yes, 2 - No, 3 - Not Done
2. Serum Free Light Chain (Serum FLC)	*(PRSFLCYN)*
3. Serum Immunofixation (Serum IFE)	*(PRSIFEYN)*
4. Urine Protein Electrophoresis (UPEP)	*(PRUPEPYN)*
5. Urine Immunofixation (Urine IFE)	*(PRUIFEYN)*
6. Bone Marrow	*(PRBMYN)*
7. Lytic Lesions	*(PRLESNYN)*
8. Plasmacytomas	*(PRPLCYYN)*
9. Corrected Serum Calcium	*(PRCALCYN)*

Serum Protein Electrophoresis (SPEP)

10. How many SPEPs were performed?*(PRLSPNM)* 0 - None, 1 - One SPEP, 2 - Two SPEPs

11. For each SPEP performed, record the following:

	Date of SPEP	Serum total protein value	M-protein spike result	M-protein spike value
Initial SPEP	*(PRLSPDT)* *(mm/dd/yyyy)*	*(PRLSPTPG)* *(xx.xxx)* g/dL	*(PRLSPRES)* 1 - Positive, 2 - Negative, 3 - Present but Not Quantifiable	*(PRLSPMSG)* *(x.xxx)* g/dL
		(PRLSPTMG) **OR** *(xxxxx.xx)* mg/dL		*(PRSPMSMG)* **OR** *(xxxx.xx)* mg/dL
Confirmatory SPEP	*(PRLSPCDT)* *(mm/dd/yyyy)*	*(PRSPCTPG)* *(xx.xxx)* g/dL	*(PRLSPCRS)* 1 - Positive, 2 - Negative, 3 - Present but Not Quantifiable	*(PRSCMSG)* *(x.xxx)* g/dL
		(PRSPCTMG) **OR** *(xxxxx.xx)* mg/dL		*(PRSCMSMG)* **OR** *(xxxx.xx)* mg/dL

Serum Free Light Chain (FLC)

12. Was serum FLC measured?*(PRLSFLC)* 1 - Yes 2 - No
13. Date of serum FLC:*(PRLFLCDT)* *(mm/dd/yyyy)*
14. Kappa Free Light Chain value:*(PRSKMGL)* *(xxxxxx.xx)* mg/L *(PRSKMGDL)***OR** *(xxxxx.xxx)* mg/dL
15. Lambda Free Light Chain value:*(PRSLMGL)* *(xxxxxx.xx)* mg/L *(PRSLMGDL)***OR** *(xxxxx.xxx)* mg/dL
16. Free light chain ratio (κ/ λ):*(PRLSFLCR)* *(xxxxxx.xxxxxx)*

Serum Immunofixation (Serum IFE)

17. How many serum IFEs were performed?*(PRSIFENM)* 0- None, 1- One SIFE, 2- Two SIFEs
18. Date of initial serum IFE:*(PRLSIDT)* *(mm/dd/yyyy)*
19. Initial serum IFE result:*(PRLSIRES)* 1 - Positive, 2 - Negative

20. Was there mention of oligoclonal banding in the report?*(PRLSIOB)* ☐ 1 - Yes ☐ 2 - No

21. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(PRLSIHVG)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHGK)* 1 - Yes 2 - No	*(PRLSIHGL)* 1 - Yes 2 - No
IgA	*(PRLSIHVA)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHAK)* 1 - Yes 2 - No	*(PRLSIHAL)* 1 - Yes 2 - No
IgM	*(PRLSIHVM)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHMK)* 1 - Yes 2 - No	*(PRLSIHML)* 1 - Yes 2 - No
IgD	*(PRLSIHVD)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHDK)* 1 - Yes 2 - No	*(PRLSIHDL)* 1 - Yes 2 - No
IgE	*(PRLSIHVE)* ☐ 1 - Yes ☐ 2 - No	*(PRLSIHEK)* 1 - Yes 2 - No	*(PRLSIHEL)* 1 - Yes 2 - No

22. Did initial serum IFE indicate light chain disease?*(PRLSILCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

23. Kappa:*(PRLSIKLC)* ☐ 1 - Yes ☐ 2 - No

24. Lambda:*(PRLSILLC)* ☐ 1 - Yes ☐ 2 - No

25. Date of confirmatory serum IFE:*(PRLSICDT)* *(mm/dd/yyyy)*

26. Confirmatory serum IFE result:*(PRLSICRS)* 1 - Positive 2 - Negative

27. Was there mention of oligoclonal banding in the report?*(PRLSICOB)* ☐ 1 - Yes ☐ 2 - No

28. Specify serum IFE results:

	Heavy Chain Present	Kappa	Lambda
IgG	*(PRSICHVG)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHGK)* 1 - Yes 2 - No	*(PRSICHGL)* 1 - Yes 2 - No
IgA	*(PRSICHVA)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHAK)* 1 - Yes 2 - No	*(PRSICHAL)* 1 - Yes 2 - No
IgM	*(PRSICHVM)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHMK)* 1 - Yes 2 - No	*(PRSICHML)* 1 - Yes 2 - No
IgD	*(PRSICHVD)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHDK)* 1 - Yes 2 - No	*(PRSICHDL)* 1 - Yes 2 - No
IgE	*(PRSICHVE)* ☐ 1 - Yes ☐ 2 - No	*(PRSICHEK)* 1 - Yes 2 - No	*(PRSICHEL)* 1 - Yes 2 - No

29. Did confirmatory serum IFE indicate light chain disease?*(PRSICLCD)* ☐ 1 - Yes ☐ 2 - No

Record serum light chain type(s):

30. Kappa:*(PRSICKLC)* ☐ 1 - Yes ☐ 2 - No

31. Lambda:*(PRSICLLC)* ☐ 1 - Yes ☐ 2 - No

Urine Protein Electrophoresis/Urine Immunofixation (UPEP/Urine IFE)

32. How many UPEPs/Urine IFEs were performed?*(PRLUPNM)* 0 - None 1 - One UPEP/Urine IFE 2 - Two UPEPs/Urine IFEs

33. For each UPEP/Urine IFE performed, record the following:

	Date of UPEP/Urine IFE	Urine total protein value	Urine total volume	M-protein result (Urine IFE)	M-protein value	M-protein units	Urine light chain type
Initial UPEP/Urine IFE	*(PRLUPDT)* *(mm/dd/yyyy)*	*(PRLUPTPG)* *(xx.xxx)* g/24hrs	*(PRUPTVL)* *(xx.xxx)* L/24hrs	*(PRLUPRES)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(PRUPVAL)* *(xxxx.xxx)*	*(PRLUPUN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(PRLUPK)* 1 - Yes 2 - No
		(PRLUPTMG) **OR**	*(PRUPTVML)* **OR**				Lambda:*(PRLUPL)*

		(xxxxx.xx) mg/24hrs	*(xxxxx.xx)* mL/24hrs				1 - Yes 2 - No
Confirmatory UPEP/Urine IFE	*(PRLUPCDT)* *(mm/dd/yyyy)*	*(PRUPCTPG)* *(xx.xxx)* g/24hrs	*(PRUPCTVL)* *(xx.xxx)* L/24hrs	*(PRLUPCRS)* 1 - Positive 2 - Negative 3 - Present but Not Quantifiable	*(PRUPCVAL)* *(xxxx.xxx)*	*(PRLUPCUN)* 1- g/dL 2- mg/dL 3- mg/24hrs	Kappa:*(PRLUPCK)* 1 - Yes 2 - No
		(PRUPCTMG) **OR** *(xxxxx.xx)* mg/24hrs	*(PRUPCVML)* **OR** *(xxxxx.xx)* mL/24hrs				Lambda:*(PRLUPCL)* 1 - Yes 2 - No

Bone Marrow

34. Was a bone marrow biopsy performed?*(PRLBMBX)* ☐ 1 - Yes ☐ 2 - No

35. Date of bone marrow biopsy:*(PRLBXDT)* *(mm/dd/yyyy)*

36. Were plasma cells present in the biopsy?*(PRLBXPLS)*
1 - Yes
2 - No
3 - Plasma Cells Present but Not Quantifiable

37. Record percentage of plasma cells:*(PRLBXPCT)* *(xxx.x)* %

38. Was a bone marrow aspirate performed?*(PRLBMAS)* ☐ 1 - Yes ☐ 2 - No

39. Date of bone marrow aspirate:*(PRLASPDT)* *(mm/dd/yyyy)*

40. Were plasma cells present in the aspirate?*(PRLASPLS)*
1 - Yes
2 - No
3 - Plasma Cells Present but Not Quantifiable

41. Record percentage of plasma cells:*(PRLASPCT)* *(xxx.x)* %

Lytic Lesions

42. Was a lytic lesion assessment performed?*(PRLLSNAS)* ☐ 1 - Yes ☐ 2 - No

43. Date of lytic bone lesion assessment:*(PRLLSNDT)* *(mm/dd/yyyy)*

44. Record most recent information regarding lytic bone lesions:*(PRLLESN)*
1 - No Change
2 - New Lytic Bone Lesions
3 - Definite Size Increase of Existing Lytic Bone Lesions
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

45. Specify other lesion information:*(PRLLSNSP)*

Plasmacytomas

46. Was a plasmacytoma assessment performed?*(PRPLCYAS)* ☐ 1 - Yes ☐ 2 - No

47. Date of plasmacytoma assessment:*(PRPLCYDT)* *(mm/dd/yyyy)*

48. Record most recent information regarding soft tissue plasmacytomas:*(PRPLCYT)*
1 - No Change
2 - New Plasmacytomas
3 - Definite Size Increase of Existing Plasmacytomas
4 - Both, New and Definite Size Increase
5 - Not Applicable
*Additional Options Listed Below

49. Specify other plasmacytoma information:*(PRPLCYSP)*

Corrected Serum Calcium

50. Was a corrected serum calcium value obtained?*(PRLCALC)* ☐ 1 - Yes ☐ 2 - No

51. Date corrected serum calcium sample obtained:*(PRLCADT)* *(mm/dd/yyyy)*

52. Record most recent corrected serum calcium value:*(PRLCAVAL)* *(xx.xx)*

53. Corrected serum calcium value units:*(PRLCAUN)*
1- g/dL
2- mg/dL
3- mmol/L

54. Did the patient develop hypercalcemia?*(PRHYPCAL)* ☐ 1 - Yes ☐ 2 - No

55. Was hypercalcemia attributable to any other cause?*(PRHYPATT)* ☐ 1 - Yes ☐ 2 - No

56. Specify other cause of hypercalcemia:*(PRHYPSP)*

Quantitative Serum Immunoglobulins

57. Were serum immunoglobulins obtained?*(PRLSIGS)* ☐ 1 - Yes ☐ 2 - No

58. Date immunoglobulins obtained:*(PRLSIGDT)* *(mm/dd/yyyy)*

59. Record immunoglobulin values:

	Laboratory Value (mg/dL)	Laboratory Value (g/dL)
Quantitative IgG		

	(PRLIGGMG) _____ *(xxxxx.xx)* mg/dL	*(PRLIGGG)* **OR** _____ *(xx.xxx)* g/dL
Quantitative IgA	*(PRLIGAMG)* _____ *(xxxxx.xx)* mg/dL	*(PRLIGAG)* **OR** _____ *(xx.xxx)* g/dL
Quantitative IgM	*(PRLIGMMG)* _____ *(xxxxx.xx)* mg/dL	*(PRLIGMG)* **OR** _____ *(xx.xxx)* g/dL
If serum heavy chain type is IgD or IgE, record values below:		
Quantitative IgD	*(PRLIGDMG)* _____ *(x.xxx)* mg/dL	*(PRLIGDG)* **OR** _____ *(x.xxxxxx)* g/dL
Quantitative IgE	*(PRLIGEMG)* _____ *(x.xxx)* mg/dL	*(PRLIGEG)* **OR** _____ *(x.xxxxxx)* g/dL

Treatment for Progression

60. Has the patient been treated for progression?*(PRLTREAT)* ☐ 1 - Yes ☐ 2 - No

61. Date treatment administered:*(PRLTRTDT)* _____ *(mm/dd/yyyy)*

62. Indicate type of treatment:*(PRTRTTYP)*

1- Donor Lymphocyte Infusion (DLI)
2- Peripheral Blood Stem Cells (PBSCs)
3- Chemotherapy
4- Radiation
5- Second Transplant
*Additional Options Listed Below

If other treatment, specify:*(PRLTRTSP)* _____

Submit a copy of any laboratory reports that support progression (such as SPEP, SIFE, UPEP, UIFE, bone marrow reports, and/or health and physical exam notes). Be sure to remove patient identifiers prior to uploading. If unable to upload documents, submit reports via fax to 240-306-0963.

Comments:*(PRLCOMMT)*

Additional Selection Options for PRL

Record most recent information regarding lytic bone lesions:
6- Other

Record most recent information regarding soft tissue plasmacytomas:
6- Other

Indicate type of treatment:
6- Other

Blood and Marrow Transplant Clinical Trials Network

Specimen Acquisition Form - 0702 (SA4)

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

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

Patient Sample for Future Testing- Bone Marrow Aspirate

1. Was a bone marrow aspirate sample collected for future testing?*(SA4BMASP)* ☐ 1 - Yes ☐ 2 - No
   2. If yes, record the date the bone marrow aspirate was obtained:*(SA4BMADT)* _____ *(mm/dd/yyyy)*

Patient Samples for Future Testing - Serum, Plasma, and Peripheral Blood Mononuclear Cells (PBMCs)

3. Was a serum sample drawn for future testing?*(SA4SERUM)* ☐ 1 - Yes ☐ 2 - No
   4. If yes, record the date the serum sample was obtained:*(SA4SERDT)* _____ *(mm/dd/yyyy)*

5. Was a plasma sample drawn for future testing?*(SA4PLSMA)* ☐ 1 - Yes ☐ 2 - No
   6. If yes, record the date the plasma sample was obtained:*(SA4PLSDT)* _____ *(mm/dd/yyyy)*

7. Was a Peripheral Blood Mononuclear Cell (PBMC) sample drawn for future testing? *(SA4PBMC)* ☐ 1 - Yes ☐ 2 - No
   8. If yes, record the date the Peripheral Blood Mononuclear Cell (PBMC) sample was collected:*(SA4PBMDT)* _____ *(mm/dd/yyyy)*

IMPORTANT: Remember to enter each of the samples into the GlobalTrace Specimen Tracking System the same day they are collected.

Comments:*(SA4COMM1)*

Blood and Marrow Transplant Clinical Trials Network

SF36 Quality of Life (SFH)

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

Segment *(PROTSEG)*: C
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	

Each Amount of Limitation entry has the options:
- 1 - Yes, limited a lot
- 2 - Yes, limited a little
- 3 - No, not limited at all
- 9 - Subject did not complete

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

(WALK1BLK)

j. Bathing or dressing yourself

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

(BATHING)

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

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

(CUTTIME)

b. Accomplished less than you would like

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

(LESSACC)

c. Were limited in the kind of work or other activities

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

(WORKLMT)

d. Had difficulty performing the work or other activities (for example, it took extra effort)

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

(PRFMDIFF)

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

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

(ECUTTIME)

b. Accomplished less than you would like

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

(ELESSACC)

c. Did work or other activities less carefully than usual

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

(ECARELES)

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

Secondary Graft Failure (SGR)

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

Segment *(PROTSEG)*: C
Secondary Graft Fail Date *(SGFDATE)*:

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

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

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

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

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

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

Comments:*(SGRCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0702 (T17)

Web Version: 1.0; 4.00; 12-11-15

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

1. Record date of evaluation:*(T17ASTDT)* *(mm/dd/yyyy)*

Record the highest grade of toxicity diagnosed since the previous evaluation. If this is the first evaluation, record the highest grade of toxicity diagnosed since Day 0. The toxicity grades are based on the NCI CTCAE Version 3.0.

Neurologic Toxicity

2. Tremors:*(T17NTRMS)*
   - 0 - Grades 0-2
   - 3 - Severe Tremor Interfering with ADL
   - 4 - Disabling

3. Ataxia:*(T17ATXIA)*
   - 0 - Grades 0-2
   - 3 - Symptomatic, Interfering with ADL; Mechanical Assistance Indicated
   - 4 - Disabling
   - 5 - Death

4. Somnolence:*(T17SMNLN)*
   - 0 - Grades 0-2
   - 3 - Obtundation or Stupor; Difficult to Arouse; Interfering with ADL
   - 4 - Coma
   - 5 - Death

5. Dizziness:*(T17DIZZY)*
   - 0 - Grades 0-2
   - 3 - Interfering with ADL
   - 4 - Disabling

6. Syncope:*(T17SYNC)*
   - 0 - Grades 0-2
   - 3 - Present
   - 4 - Life-Threatening Consequences
   - 5 - Death

7. Neuropathy - motor:*(T17MOTOR)*
   - 0 - Grades 0-2
   - 3 - Weakness Interfering with ADL; Bracing or Assistance to Walk Indicated
   - 4 - Life-Threatening; Disabling (e.g., Paralysis)
   - 5 - Death

8. Neuropathy - sensory:*(T17SENSR)*
   - 0 - Grades 0-2
   - 3 - Sensory Alteration or Paresthesia Interfering with ADL
   - 4 - Disabling
   - 5 - Death

9. Did the patient experience any seizures during this assessment period?*(T17SEIZR)* ☐ 1 - Yes ☐ 2 - No

10. Record seizure toxicity grade:*(T17SZGRD)*
    - 2 - One Brief Generalized Seizure, Seizure(s) Well Controlled by Anticonvulsants
    - 3 - Seizures in Which Consciousness is Altered; Poorly Controlled Seizure Disorder
    - 4 - Seizures of Any Kind Which are Prolonged, Repetitive or Difficult to Control
    - 5 - Death

Cardiovascular Toxicity

11. Atrial fibrillation:*(T17AFIB)*
    - 0 - Grades 0-2
    - 3 - Symptomatic and Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
    - 4 - Life-Threatening (e.g., Arrhythmia associated with CHF, hypotension, syncope, shock)
    - 5 - Death

12. Atrial flutter:*(T17AFLUT)*
    - 0 - Grades 0-2
    - 3 - Symptomatic and Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
    - 4 - Life-Threatening (e.g., Arrhythmia associated with CHF, hypotension, syncope, shock)
    - 5 - Death

13. Chest pain (cardiac ischemia/infarction):*(T17CHPAN)*
    - 0 - Grades 0-2
    - 3 - Symptomatic and Testing Consistent with Ischemia; Unstable Angina; Intervention Indicated
    - 4 - Acute Myocardial Infarction
    - 5 - Death

14. Hypertension:*(T17HYPRC)*

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

15. Hypotension:*(T17HYPOT)*

0 - Grades 0-2
3 - Sustained (> or = 24 Hours) Therapy, Resolves Without Persisting Physiologic Consequences
4 - Shock (e.g., Acidemia; Impairment of Vital Organ Function)
5 - Death

16. Left ventricular systolic dysfunction:*(T17LVSD)*

0 - Grades 0-2
3 - Symptomatic CHF Responsive to Intervention
4 - Refractory CHF or Poorly Controlled; Intervention with Ventricular Assist Device
5 - Death

17. Cardiac arrhythmia:*(T17CRDAR)*

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

GI Toxicity

18. Abdominal pain:*(T17ABPAN)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

19. Constipation:*(T17CNSTP)*

0 - Grades 0-2
3 - Symptoms Interfering with ADL; Obstipation with Manual Evacuation Indicated
4 - Life-Threatening Consequences (e.g., Obstruction, Toxic Megacolon)
5 - Death

20. Diarrhea:*(T17DIARR)*

0 - Grades 0-2
3 - Inc by 7+ stools over baseline; require IVF>or=24hrs; hosp; severe inc in ostomy output
4 - Resulting in hemodynamic Insufficiency or life threatening consequences
5 - Death

21. Dysphagia:*(T17DYSPH)*

0 - Grades 0-2
3 - Symptomatic & Severely Altered Eating/Swallowing (e.g., inadequate oral intake), IVF, Tube Feed,
4 - Life-Threatening Consequences (e.g., Obstruction, Perforation)
5 - Death

22. Heartburn/dyspepsia:*(T17HRTBN)*

0 - Grades 0-2
3 - Severe

23. Nausea:*(T17NAUS)*

0 - Grade 0-2
3 - Inadequate oral intake; IVF; Tube Feedings or TPN indicated >or=24 Hours
4 - Life-Threatening Consequences
5 - Death

24. Vomiting:*(T17VOMIT)*

0 - Grades 0-1
2 - 2-5 Episodes in 24 hrs; IV Fluids Indicated <24 hrs
3 - >/=6 Episodes in 24 hrs; IV Fluids, or TPN Indicated >/=24 hrs
4 - Life-Threatening Consequences
5 - Death

25. Did taste alteration (dysgeusia) occur:*(T17DYSGS)*

☐ 1 - Yes ☐ 2 - No

26. Ulcers:*(T17ULCER)*

0 - Grades 0-2
3 - Severely Altered GI Function; IV Fluids, Tube Feedings or TPN Indicated >/=24 hrs
4 - Life-Threatening Consequences
5 - Death

27. Mucositis/stomatitis (clinical exam):*(T17MUCOS)*

0 - Grades 0-2
3 - Confluent Ulcerations or Pseudomembranes; Bleeding with Minor Trauma
4 - Tissue Necrosis; Significant Spontaneous Bleeding; LT Consequences
5 - Death

Renal Toxicity

28. Did the patient experience renal failure severe enough to warrant dialysis?*(T17RNLFL)*

☐ 1 - Yes ☐ 2 - No

29. Did the patient receive dialysis?*(T17DIALY)*

☐ 1 - Yes ☐ 2 - No

30. Hemorrhagic cystitis:*(T17CYSTI)*

0 - Grades 0-2
3 - Transfusion; IV Pain Medications; Bladder Irrigation Indicated
4 - Catastrophic Bleeding; Major Non-Elective Intervention Indicated
5 - Death

	Peak Value During Interval	ULN for your Institution	Date Sample Obtained
31. Creatinine:	*(T17CREAT)* _____ *(xx.x)* mg/dL	*(T17ULNCR)* _____ *(xx.x)* mg/dL	*(T17CRTDT)* _____ *(mm/dd/yyyy)*

Coagulation Toxicity

32. HUS/TTP/thrombotic microangiopathy:*(T17DCTTP)*

0 - Grades 0-3
4 - Laboratory Findings, Life-Threatening or Disabling Consequences
5 - Death

Metabolic Toxicity

33. Hyperglycemia:*(T17HYPGL)*

0 - Grades 0-2
3 - >250-500 mg/dL; >13.9-27.8 mmol/L
4 - >500 mg/dL; >27.8 mmol/L or Acidosis
5 - Death

Endocrine Toxicity

34. Hypothyroidism:*(T17THYRO)*

0 - Grades 0-2
3 - Symptoms Interfering with ADL; Hospitalization Indicated
4 - Life-Threatening Myxedema Coma
5 - Death

Auditory Toxicity

35. Hearing:*(T17HEAR)*

0 - Grades 0-2
3 - Hearing Loss Requiring Hearing Aid or Intervention (i.e., Interfering with ADL)
4 - Profound Bilateral Hearing Loss (>90 dB)

36. Tinnitus:*(T17TINN)*

0 - Grades 0-2
3 - Tinnitus Interfering with ADL
4 - Disabling

Ocular/Visual Toxicity

37. Blurred vision:*(T17BLRRY)*

0 - Grades 0-2
3 - Symptomatic and Interfering with ADL
4 - Disabling

38. Conjunctivitis:*(T17CONJ)*

0 - Grades 0-2
3 - Symptomatic, Interfering with ADL; Operative Intervention Indicated

Constitutional Toxicity

39. Asthenia (fatigue, lethargy, or malaise):*(T17FATIG)*

0 - Grades 0-2
3 - Severe Fatigue Interfering with ADL
4 - Disabling

40. Fever (without neutropenia):*(T17FEVER)*

0 - Grades 0-1
2 - >39.0-40.0C (102.3-104.0F)
3 - >40C (>104.0F) for <24 hrs
4 - >40C (>104.0F) for >24 hrs
5 - Death

41. Insomnia:*(T17INSOM)*

0 - Grades 0-2
3 - Frequent Difficulty Sleeping, Interfering with ADL
4 - Disabling

Musculoskeletal Toxicity

42. Bone pain:*(T17BNPAN)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

43. Joint pain (arthralgia):*(T17ARTHR)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

44. Muscle pain (myalgia):*(T17MYALG)*

0 - Grades 0-2
3 - Severe pain; Pain or Analgesics Severely Interfering with ADL
4 - Disabling

45. Muscle weakness, generalized or specific area (not due to neuropathy):*(T17MUSCL)*

0 - Grades 0-2
3 - Symptomatic and Interfering with ADL
4 - Life-Threatening; Disabling
5 - Death

Dermatologic Toxicity

46. Pruritus/itching:*(T17PRURI)*

0 - Grades 0-2
3 - Intense or Widespread and Interfering with ADL

47. Rash:*(T17RASH)*

0 - Grades 0-2
3 - Severe erythroderma or macular, papular or vesicular eruption; desquamation covering >/= 50% BSA
4 - Generalized Exfoliative Ulcerative or Bullous Dermatitis
5 - Death

48. Urticaria (hives, welts, wheals):*(T17URTIC)*

0 - Grades 0-2
3 - Intervention indicated for >or=24 hours

Hepatobiliary/Pancreas Toxicity

49. Pancreatitis:*(T17PANCR)*

0 - Grades 0-2
3 - Interventional Radiology or Operative Intervention Indicated
4 - Life-Threatening Consequences (e.g., Circulatory Failure, Hemorrhage, Sepsis)
5 - Death

Hemorrhagic Toxicity

50. Hemorrhage:*(T17HEMRH)*

0 - Grades 0-2
3 - Transfusion, Int Radiology, Endoscopic, or Operative Int Indicated; Hemostatis of Bleeding Site
4 - Life-Threatening Consequences; Major Urgent Intervention Indicated
5 - Death

51. Which organ system was the hemorrhage associated with?*(T17ORGAN)*

1 - CNS
2 - Gastrointestinal
3 - Genitourinary
4 - Pulmonary, Upper Respiratory
5 - Other

Specify other organ system:*(T17SPOTH)*

Vascular Toxicity

52. Vascular leak syndrome:*(T17VASCL)*

0 - Grades 0-2
3 - Respiratory compromise or fluids indicated
4 - Life-threatening; pressor support or ventilatory support indicated
5 - Death

53. Thrombosis/thrombus/embolism:*(T17THRMB)*

0 - Grades 0-2
3 - DVT or Cardiac Thrombosis; Intervention (e.g., Anticoagulation, Lysis) Indicated
4 - Embolic Event Including Pulmonary Embolism or Life-Threatening Thrombus
5 - Death

Pulmonary Toxicity

54. Hypoxia (for more than 24 hours):*(T171HYPX)*

0 - Grades 0-2
3 - Decreased Oxygen Saturation at Rest; Continuous Oxygen Indicated
4 - Life-Threatening; Intubation or Ventilation Indicated
5 - Death

55. Dyspnea:*(T17DYSPN)*

0 - Grades 0-2
3 - Dyspnea with Activities of Daily Living
4 - Dyspnea at Rest; Intubation or Ventilator Indicated
5 - Death

56. Cough:*(T17COUGH)*

0 - Grades 0-2
3 - Symptomatic and Significantly Interfering with Sleep or ADL

57. During this assessment period, was an FEV1 performed?*(T17FEVDN)*

☐ 1 - Yes ☐ 2 - No

58. Record FEV1 value obtained:*(T17FEVLV)*

(xxx) % of predicted value

59. During this assessment period, was an FVC performed?*(T17FVCDN)*

☐ 1 - Yes ☐ 2 - No

60. Record the FVC value obtained:*(T17FVCLV)*

(xxx) % of predicted value

Hepatic Toxicity

61. Bilirubin:*(T17BILIR)*

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

62. ALT:*(T17ALT)*

0 - Grades 0-1
2 - > 2.5 - 5.0 x ULN
3 - > 5.0 - 20.0 x ULN
4 - > 20.0 x ULN

63. AST:*(T17AST)*

0 - Grades 0-1
2 - > 2.5 - 5.0 x ULN
3 - > 5.0 - 20.0 x ULN
4 - > 20.0 x ULN

64. Alkaline phosphatase:*(T17ALKPH)*

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:

65. Jaundice:*(T17JANDC)* ☐ 1 - Yes ☐ 2 - No

66. Hepatomegaly:*(T17HEPTM)* ☐ 1 - Yes ☐ 2 - No

67. Right upper quadrant pain:*(T17QUADP)* ☐ 1 - Yes ☐ 2 - No

68. Weight gain (>5%) from baseline:*(T17WGTGN)* ☐ 1 - Yes ☐ 2 - No

69. **Indicate the etiology of the abnormal liver function:**

	Etiology	Biopsy Results	Doppler Ultrasound Results
VOD:	*(T17VODET)* 1 - Yes / 2 - No	*(T17VODBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17VODDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
GVHD:	*(T17GVHET)* 1 - Yes / 2 - No	*(T17GVHBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17GVHDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
Infection:	*(T17INFET)* 1 - Yes / 2 - No	*(T17INFBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17INFDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
Other:	*(T17OTHET)* 1 - Yes / 2 - No	*(T17OTHBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17OTHDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
Unknown:	*(T17UNKET)* 1 - Yes / 2 - No	*(T17UNKBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(T17UNKDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done

Specify other etiology:*(T172SPEC)*

Comments:*(T17COMM)*

Blood and Marrow Transplant Clinical Trials Network

Thromboembolism Form - 0702 (THR)

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

Segment *(PROTSEG)*: C
Thromboembolic event date *(THROMBDT)*:

Record type of thromboembolism:

1. DVT (Deep Vein Thrombosis):	*(THRDVT)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRDVGDE)* 0 - Grades 0-2 3 - DVT or Cardiac Thrombosis; Intervention (e.g., Anticoagulation, Lysis) Indicated 4 - Embolic Event Including Pulmonary Embolism or Life-Threatening Thrombus 5 - Death
2. Pulmonary Emboli:	*(THRPULM)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THREMGDE)* 0 - Grades 0-2 3 - DVT or Cardiac Thrombosis; Intervention (e.g., Anticoagulation, Lysis) Indicated 4 - Embolic Event Including Pulmonary Embolism or Life-Threatening Thrombus 5 - Death
3. Arterial Thrombosis:	*(THRARTH)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRARGDE)* 0 - Grades 0-2 3 - Laboratory Findings Present with Clinical Consequences 4 - Laboratory Findings and Life-Threatening or Disabling Consequences 5 - Death
4. Cardiac Ischemia/Infarction:	*(THRCRDIS)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRCIGDE)* 0 - Grades 0-2 3 - Symptomatic and Testing Consistent with Ischemia; Unstable Angina; Intervention Indicated 4 - Acute Myocardial Infarction 5 - Death
5. CNS Cerebrovascular Ischemia:	*(THRCVA)* ☐ 1 - Yes ☐ 2 - No	Grade:*(THRCVGDE)* 0 - Grades 0-2 3 - Transient Ischemic Event or Attack (TIA) 4 - Cerebral Vascular Accident (CVA, Stroke), Neurologic Deficit >24 hrs 5 - Death

If DVT, specify site:

6. Upper extremity:*(THRDVTUP)* ☐ 1 - Yes ☐ 2 - No
7. Lower extremity:*(THRDVTLO)* ☐ 1 - Yes ☐ 2 - No

8. Was the thrombosis related to the catheter?*(THRCATRL)* ☐ 1 - Yes ☐ 2 - No

9. Was the patient on anti-coagulation therapy?*(THRTHRPY)* ☐ 1 - Yes ☐ 2 - No

If yes, specify all therapies:

10. Aspirin:*(THRASP)* ☐ 1 - Yes ☐ 2 - No
11. Coumadin:*(THRCOUM)* ☐ 1 - Yes ☐ 2 - No
12. Low molecular weight heparin:*(THRHEP)* ☐ 1 - Yes ☐ 2 - No
13. Record type of low molecular weight heparin:*(THRHEPTY)*
    1 - Enoxaparin
    2 - Daltiparin
    3 - Other

If other low molecular weight heparin type, specify:*(THRHPOTS)*

14. Other therapy:*(THROTHER)* ☐ 1 - Yes ☐ 2 - No

If other therapy, specify:*(THROTHSP)*

Comments:*(THRCOMM)*