

# Blood and Marrow Transplant Clinical Trials Network

## BMT AE Tracking Form (A99)

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

Date of Onset (ADVDATE):

Event description (ADVENT):

**AE1 AE2 AE3 AE4 AE5 AE6**

1. Date event initially reported in AdvantageEDC:(EVENTDT)

(mm/dd/yyyy)

2. Overall event status:(OVSTATUS)

1 - Open  
2 - Closed  
3 - De-activated; Did Not Qualify for Expedited Reporting to Any Entity

3. Is there enough information to send to the Medical Monitor?(INFO TOMM)

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:(OTHRCFSP)

### 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:(DSMBIRD T)

(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:(FDAIRD T)

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

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

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

## Additional Selection Options for A9C

### COM 1 Contact Role

6 - Pharma Rep

99 - Other

Blood and Marrow Transplant Clinical  
Trials Network

Re-Admission/Hospitalization Form (ADM)

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

Segment (PROTSEG): A

Date of Admission (ADMIDT):

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  
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AE Summary Form (AE2)

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

Segment (PROTSEG): A

Date of Onset (ADVDATE):

Event description (ADVENT):

1. Report activation status: (AVSTAT\_A)

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

Relevant Past Medical History

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

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

(SEMEDHX)

3. Event Summary

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

(SESUMM)

4. Initial submitter: (SEISUBBY)

Name:  Date: (SEISUBDT)  (mm/dd /yyy)

5. Authorized submitter: (SEASUBBY)

Name:  Date: (SEASUBDT)  (mm/dd /yyy)

## 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)	(CM5STDY)	(CM5SPDY)	(CM5DOSE)	(CM5INDY) 1 - Treatment of adverse event 9 - Other
(CONMED6)	(CM6STDY)	(CM6SPDY)	(CM6DOSE)	(CM6INDY) 1 - Treatment of adverse event 9 - Other
(CONMED7)	(CM7STDY)	(CM7SPDY)	(CM7DOSE)	(CM7INDY) 1 - Treatment of adverse event 9 - Other
(CONMED8)	(CM8STDY)	(CM8SPDY)	(CM8DOSE)	(CM8INDY) 1 - Treatment of adverse event 9 - Other
(CONMED9)	(CM9STDY)	(CM9SPDY)	(CM9DOSE)	(CM9INDY) 1 - Treatment of adverse event 9 - Other
(CONMED10)	(CM10STDY)	(CM10SPDY)	(CM10DOSE)	(CM10INDY) 1 - Treatment of adverse event 9 - Other
(CONMED11)	(CM11STDY)	(CM11SPDY)	(CM11DOSE)	(CM11INDY) 1 - Treatment of adverse event 9 - Other
(CONMED12)	(CM12STDY)	(CM12SPDY)	(CM12DOSE)	(CM12INDY) 1 - Treatment of adverse event 9 - Other
(CONMED13)	(CM13STDY)	(CM13SPDY)	(CM13DOSE)	(CM13INDY) 1 - Treatment of adverse event 9 - Other
(CONMED14)	(CM14STDY)	(CM14SPDY)	(CM14DOSE)	(CM14INDY) 1 - Treatment of adverse event 9 - Other
(CONMED15)	(CM15STDY)	(CM15SPDY)	(CM15DOSE)	(CM15INDY) 1 - Treatment of adverse event 9 - Other
(CONMED16)	(CM16STDY)	(CM16SPDY)	(CM16DOSE)	(CM16INDY) 1 - Treatment of adverse event 9 - Other
(CONMED17)	(CM17STDY)	(CM17SPDY)	(CM17DOSE)	(CM17INDY) 1 - Treatment of adverse event 9 - Other
(CONMED18)	(CM18STDY)	(CM18SPDY)	(CM18DOSE)	(CM18INDY) 1 - Treatment of adverse event 9 - Other

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

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? (LABSTPF)

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)	<input type="text"/>	(AD2DTDAT)	<input type="text"/>	(AD2DTRES)	<input type="text"/>
(ADDTS3)	<input type="text"/>	(AD3DTDAT)	<input type="text"/>	(AD3DTRES)	<input type="text"/>
(ADDTS4)	<input type="text"/>	(AD4DTDAT)	<input type="text"/>	(AD4DTRES)	<input type="text"/>
(ADDTS5)	<input type="text"/>	(AD5DTDAT)	<input type="text"/>	(AD5DTRES)	<input type="text"/>
(ADDTS6)	<input type="text"/>	(AD6DTDAT)	<input type="text"/>	(AD6DTRES)	<input type="text"/>
(ADDTS7)	<input type="text"/>	(AD7DTDAT)	<input type="text"/>	(AD7DTRES)	<input type="text"/>
(ADDTS8)	<input type="text"/>	(AD8DTDAT)	<input type="text"/>	(AD8DTRES)	<input type="text"/>
(ADDTS9)	<input type="text"/>	(AD9DTDAT)	<input type="text"/>	(AD9DTRES)	<input type="text"/>
(ADDTS10)	<input type="text"/>	(AD10DTDAT)	<input type="text"/>	(AD10DTRES)	<input type="text"/>

Comments:(AE4COMM)

Blood and Marrow Transplant Clinical  
Trials Network

AE Review Form (AE5)

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

Segment (PROTSEG): A

Date of Onset (ADVDATE):

Event description (ADVENT):

1. Report activation status: (AVSTAT\_D)

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

2. Reviewed: (AEREVIEW)

1 - Yes  2 - No

3. Reviewed by: (ARFREVBY)

4. Review date: (ARFREVDT)

 (mm/dd/yyyy)

5. Comment 1 - For Distribution: (ARCM1DIS)

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

Blood and Marrow Transplant Clinical  
Trials Network

AE Medical Monitor Reviewer Form (AE6)

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

Segment (PROTSEG): A

Date of Onset (ADVDATE):

Event description (ADVENT):

1. Adverse event status:(AVSTAT\_E)

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

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

1 - Yes  2 - No

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

1 - Yes  2 - No

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

1 - Yes  2 - No

5. Is the review complete?(AMREVDNE)

1 - Yes  2 - No

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

7. Medical Monitor event description:(AMMMEVDS)

8. Medical Monitor CTCAE grade of event:(CTCAEGRD)

- 1 - Grade 1
- 2 - Grade 2
- 3 - Grade 3
- 4 - Grade 4
- 5 - Grade 5

Comments:(AE6COMM)

**Blood and Marrow Transplant Clinical  
Trials Network**

**Baseline Form - 0801 (BL4)**

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

Segment (PROTSEG): A

Visit Number (VISNO):

**Pre-transplant Status**

Complete the following questions regarding the patient's pre-transplant status.

1. Patient's primary diagnosis pre-transplant: (PM0801DX)

01 - Acute Myelogenous Leukemia (AML or ANLL)  
02 - Acute Lymphoblastic Leukemia (ALL)  
03 - Other Acute Leukemia  
04 - Chronic Myelogenous Leukemia (CML)  
05 - Other Leukemia  
\*Additional Options Listed Below

2. If AML, record the disease status pre-transplant: (AML801SG)

1 - Primary Induction Failure  
2 - First Complete Remission  
3 - First Relapse  
4 - Second Complete Remission  
5 - Second Relapse  
\*Additional Options Listed Below

3. If ALL, record the disease status pre-transplant: (ALL801SG)

1 - Primary Induction Failure  
2 - First Complete Remission  
3 - First Relapse  
4 - Second Complete Remission  
5 - Second Relapse  
\*Additional Options Listed Below

4. If CML, record the disease status pre-transplant: (CML801SG)

1 - First Chronic Phase  
2 - Second or Subsequent Chronic Phase  
3 - Accelerated Phase  
4 - Blast Phase

5. If Other Leukemia, specify primary diagnosis pre-transplant: (BL40TLEU)

6. If Other Leukemia, record disease status pre-transplant: (BL40TLKD)

7. If MDS, record the disease status pre-transplant: (MDS801SG)

1 - Refractory Anemia  
2 - Refractory Anemia with Ringed Sideroblasts  
3 - Refractory Cytopenia with Multilineage Dysplasia  
4 - Refractory Cytopenia with Multilineage Dysplasia and Ringed Sideroblasts  
5 - Refractory Anemia with Excess Blasts - 1 (5-10% blasts)  
\*Additional Options Listed Below

8. If Multiple Myeloma/PCD, record the disease status pre-transplant: (BL4MMST)

01 - Stringent Complete Response (sCR)  
02 - Complete Response (CR)  
03 - Near Complete Response (nCR)  
04 - Very Good Partial Response (VGPR)  
05 - Partial Response (PR)  
\*Additional Options Listed Below

9. If Lymphoma, record the disease status pre-transplant: (LYM801SG)

1 - Complete Remission  
2 - Partial Remission  
3 - Continued Complete Remission  
4 - First Relapse  
5 - Second Relapse  
\*Additional Options Listed Below

10. If Other, specify primary diagnosis pre-transplant: (OPRIMDIA)

11. If Other, record the disease status pre-transplant: (ODISESG)

12. Record the type of conditioning regimen:(CON0801R)

1 - Myeloablative  2 - Non-myeloablative or Reduced Intensity

## Transplant

Complete the following questions regarding the patients transplant status.

13. Date of transplant:(T0801DT)

(mm/dd/yyyy)

14. Patient's CMV status at transplant:(CMV0801S)

1 - Positive  
 2 - Negative

15. Stem cell type:(T0801TY)

1 - Bone Marrow  
 2 - Peripheral Blood Stem Cells  
 3 - Single Cord Blood  
 4 - Double Cord Blood

### Donor 1

16. Source:(REL0801U)

1 - Related  2 - Unrelated

17. Date of birth:(BL4DRBDT)

(mm/dd/yyyy)

18. Gender:(BL4DRGEN)

1 - Male  2 - Female

19. CMV status:(BL4D1CMV)

1 - Positive  
 2 - Negative

20. HLA Typing Method:(HLA801RE)

1 - High Level DNA  
 2 - Low Level DNA  
 3 - Serologic  
 4 - Loci A, B: Serologic, Locus DRB1: Low Level DNA  
 5 - Loci A, B: Low Level DNA, Locus DRB1: High Level DNA  
\*Additional Options Listed Below

21. Record your institutions HLA match score for this patient:(HLA0801S)

3/6  
4/6  
5/6  
6/6  
3/8  
\*Additional Options Listed Below

22. Was the stem cell product T-Cell depleted?(T0801CEL)

1 - Yes  2 - No

23. What was the total nucleated cell dose?(BL4D1TNC)

(xx.x) X 10<sup>7</sup> NC/kg

### Donor 2

24. Gender:(BL4SDGEN)

1 - Male  2 - Female

25. HLA Typing Method:(BL4D2HLT)

1 - High Level DNA  
 2 - Low Level DNA  
 3 - Serologic  
 4 - Loci A, B: Serologic, Locus DRB1: Low Level DNA  
 5 - Loci A, B: Low Level DNA, Locus DRB1: High Level DNA  
\*Additional Options Listed Below

26. Record your institutions HLA match score for this patient:(BL4D2HLM)

3/6  
4/6  
5/6  
6/6  
3/8  
\*Additional Options Listed Below

27. What was the total nucleated cell dose?(BL4D2TNC)

(xx.x) X 10<sup>7</sup> NC/kg

## GVHD History

### Prophylaxis

28. Did the patient receive GVHD prophylaxis post transplant?(BL4GVHPR)

1 - Yes  2 - No

Indicate any immunosuppressant (prophylaxis) received:

29. Cyclosporine:(BL4CYCLO)

1 - Yes  2 - No

30. Tacrolimus:(BL4TACRO)

1 - Yes  2 - No

31. Sirolimus:(BL4SIRO)

1 - Yes  2 - No

32. Corticosteroids:(BL4CORTI)  1 - Yes  2 - No
33. Methotrexate:(BL4METHO)  1 - Yes  2 - No
34. MMF:(BL4PRMMF)  1 - Yes  2 - No
35. AT G (thymoglobulin) or AT GAM (equine):(BL4PRATG)  1 - Yes  2 - No
36. Cytoxan (cyclophosphamide):(BL4PRCYT)  1 - Yes  2 - No
37. Other:(BL4PROT)  1 - Yes  2 - No
38. Specify other:(BL4PROSP)

**Acute GVHD**

39. Did the patient have Acute GVHD prior to enrolling in this study?(BL4PREV)  1 - Yes  2 - No
40. Date of diagnosis of Acute GVHD:(AGVH801D)  (mm/dd/yyyy)
41. Maximum overall grade of Acute GVHD:(AGVH801O)

- 0 - Not Present  
 1 - Grade I  
 2 - Grade II  
 3 - Grade III  
 4 - Grade IV

42. Maximum skin abnormalities:(AGVHSGR)

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

43. Maximum upper GI abnormalities:(AGVHUGI)

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

44. Maximum lower GI abnormalities:(AGVHLGI)

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

45. Maximum liver abnormalities:(AGVHLVGR)

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

**Acute GVHD Treatment**

Indicate if any of the following have been given to the patient for Acute GVHD treatment prior to enrollment in this study.

46. Prednisone:(BL4PRED)  1 - Yes  2 - No
47. Sirolimus:(BL4TRSIR)  1 - Yes  2 - No
48. Methylprednisone:(BL4METHY)  1 - Yes  2 - No
49. MMF:(BL4MMF)  1 - Yes  2 - No
50. MMF/placebo (BMT CTN 0802 study drug):(BL4TRMPL)  1 - Yes  2 - No
51. Infliximab:(BL4INFLX)  1 - Yes  2 - No
52. Daduzimab:(BL4DACLM)  1 - Yes  2 - No
53. Pentostatin:(BL4PENT)  1 - Yes  2 - No
54. Etanercept:(BL4ETAN)  1 - Yes  2 - No
55. Ontak:(BL4ONTAK)  1 - Yes  2 - No
56. Skin topical steroids:(BL4STS)  1 - Yes  2 - No
57. Non-absorbed oral steroids (e.g., Budesonide, Entocort):(BL4ORST)  1 - Yes  2 - No
58. Extracorporeal Photopheresis:(BL4ECP)  1 - Yes  2 - No
59. AT G (thymoglobulin) or AT GAM (equine):(BL4TRATG)  1 - Yes  2 - No
60. Other:(BL4OTHTR)  1 - Yes  2 - No
61. Specify other:(BL4OTHSP)

62. Comments:(B0801COM)

## Additional Selection Options for BL4

### Patient's primary diagnosis pre-transplant:

- 06 - Myelodysplastic (MDS)/ Myeloproliferative (MPS) Disorders
- 07 - Multiple Myeloma/ Plasma Cell Disorder (PCD)
- 08 - Non-Hodgkin Lymphoma
- 09 - Hodgkin Lymphoma
- 10 - Solid Tumors
- 11 - Severe Aplastic Anemia
- 12 - Inherited Abnormalities of Erythrocyte Differentiation or Function
- 13 - Disorders of the Immune System
- 14 - Inherited Abnormalities of Platelets
- 15 - Inherited Disorders of Metabolism
- 16 - Histiocytic Disorders
- 17 - Autoimmune Disorders
- 99 - Other Disease

### If AML, record the disease status pre-transplant:

- 6 - Third or Subsequent Complete Remission
- 7 - Third or Subsequent Relapse
- 8 - Previously Untreated

### If MDS, record the disease status pre-transplant:

- 6 - Refractory Anemia with Excess Blasts - 2 (10-20% blasts)
- 7 - Myelodysplastic Syndrome, Unclassified
- 8 - MDS Associated with Isolated Del(5q)

### If Multiple Myeloma/PCD, record the disease status pre-transplant:

- 06 - Stable Disease (SD)
- 07 - Progressive Disease
- 08 - Relapse from CR

### If Lymphoma, record the disease status pre-transplant:

- 6 - Greater Than Second Relapse

### HLA Typing Method:

- 6 - Loci A, B: Serologic, Locus DRB1: High Level DNA
- 7 - Loci A, B, C: Low Level DNA, Locus DRB1: High Level DNA
- 8 - Loci A, B, C, DQ: Low Level DNA, Locus DRB1: High Level DNA

### Record your institutions HLA match score for this patient:

- 4/8
- 5/8
- 6/8
- 7/8
- 8/8
- 3/10
- 4/10
- 5/10
- 6/10
- 7/10
- 8/10
- 9/10
- 10/10

### Maximum lower GI abnormalities:

- 5 - Severe Abdominal Pain with or without Ileus, or Stool with Frank Blood or Melena

Blood and Marrow Transplant Clinical  
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CIBMTR Recipient ID (CID)

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

Segment (*PROTSEG*): A

Visit Number (*VISNO*):

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

(xxxxxxxxxx)

Comments:(CIDCOMM)

Blood and Marrow Transplant Clinical  
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Demographics (DEM)

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

1. Name Code:(NAMECODE)

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

3. Gender:(GENDER)

 1 - Male  2 - Female

4. Date of Birth:(DOB)

 (mm/dd/yyyy)

5. Ethnicity:(ETHNIC)

1- Hispanic or Latino  
2- Not Hispanic or Latino  
8- Unknown  
9- Not Answered

6. Race:(RACE)

White  
10 - White (Not Otherwise Specified)  
11 - European (Not Otherwise Specified)  
13 - Mediterranean  
14 - White North American  
\*Additional Options Listed Below

Specify race:(RACESP)

7. Secondary Race:(RACE2)

White  
10 - White (Not Otherwise Specified)  
11 - European (Not Otherwise Specified)  
13 - Mediterranean  
14 - White North American  
\*Additional Options Listed Below

Specify secondary race:(RACE2SP)

Comments:(DEMCOMM1)

## Additional Selection Options for DEM

### Race:

15 - South or Central American

16 - Eastern European

17 - Northern European

18 - Western European

81 - White Caribbean

82 - North Coast of Africa

83 - Middle Eastern

### Black

20 - Black (Not Otherwise Specified)

21 - African American

22 - African Black (Both Parents Born in Africa)

23 - Caribbean Black

24 - South or Central American Black

29 - Black, Other Specify

### Asian

30 - Asian (Not Otherwise Specified)

31 - Indian/South Asian

32 - Filipino (Pilipino)

34 - Japanese

35 - Korean

36 - Chinese

37 - Other Southeast Asian

38 - Vietnamese

### American Indian or Alaska Native

50 - Native American (Not Otherwise Specified)

51 - Native Alaskan/Eskimo/Aleut

52 - American Indian (Not Otherwise Specified)

53 - North American Indian

54 - South or Central American Indian

55 - Caribbean Indian

### Native Hawaiian or Other Pacific Islander

60 - Native Pacific Islander (Not Otherwise Specified)

61 - Guamanian

62 - Hawaiian

63 - Samoan

### Other

88 - Unknown

90 - Other, Specify

99 - Not Answered

Blood and Marrow Transplant Clinical  
Trials Network

Death Form (DTH)

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

1. Record date of death:(DTHDT)

(mm/dd/yyyy)

2. Was an autopsy performed?(AUTPERF)

1 - Yes  2 - No

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

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

3. Primary cause of death:(CZDTHPRM)

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

?

Specify other:(DTHSPEC1)

4. Secondary cause of death:(SCNDCZ1)

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

Specify other:(DTHSPEC2)

5. Secondary cause of death:(SCNDCZ2)

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

Specify other:(DTHSPEC3)

6. Secondary cause of death:(SCNDCZ3)

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

Specify other:(DTHSPEC4)

7. Secondary cause of death:(SCNDCZ4)

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

Specify other:(DTHSPEC5)

Comments:(DTCMMNTS)

## Additional Selection Options for DTH

### Primary cause of death:

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

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Trials Network

Endpoint Review Form- 0801 (E06)

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

Case ID (CASEID):

Site:(EXXSITE)  (xxxxx)  
Patient ID:(EXXPATID)

1. Review Date:(REVIEWDT)  (mm/dd/yyyy)

2. Primary Reviewer Name:(REVNAME)  
Aleksandr Lazaryan  
Carrie Kitko  
Javier Bolanos-Meade  
Laura Johnston  
Luciano Costa  
\*Additional Options Listed Below

3. Case Status:(CASESTAT)  
1- Complete (C)  
2- Query (Q)  
3- Ready for Review (R)  
4- Secondary Review (S)

4. Review Committee Comments:(REVCOMM)

5. EMMES Comments:(EMMCOMM)

Reviewer Adjudicated Fields

6. Did the patient die?(PATDIED)  1 - Yes  2 - No

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

b. Specify other COD:(REVCODSP)

7. Progression or relapse:(PRGRLP)  1 - Yes  2 - No

a. Date of progression or relapse:(PRGRLPDT)  (mm/dd/yyyy)

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

a. Specify reason for exclusion:(EXCLUDSP)

9. Was the patient eligible?(ELIGIBLE)  1 - Yes  2 - No

a. Specify reason for ineligibility:(ELIGIBSP)

10. Were treatment compliance issues identified?(TRTCMPLY)  1 - Yes  2 - No

a. Specify compliance issues:(TRTCMPSP)

11. Secondary systemic therapy received:(SECSYSTH)  1 - Yes  2 - No

a. Date of secondary systemic therapy:(SECSYSDT)  (mm/dd/yyyy)

12. Stopped ALL immunosuppressive therapy:(STOPTHRP)  1 - Yes  2 - No

a. Date ALL immunosuppressive therapy stopped:(STOPHDT)  (mm/dd/yyyy)

b. Reason ALL immunosuppressive therapy stopped: (STOPRSN)

- 1 - Toxicity
- 2 - cGVHD Progression/Flare
- 3 - Underlying Malignancy Progression/Relapse
- 4 - Infection
- 5 - Physician Decision
- \*Additional Options Listed Below

c. Specify other reason ALL immunosuppressive therapy stopped: (STPRSNP)

13. Treatment success: (TXSUCCES)

- 1 - Yes     2 - No

a. Treatment success comments: (TXSCOMM)

**Chronic GVHD Status:**

Overall chronic GVHD diagnosis at Day 0: (D000CGD)

- 0 - No GVHD
- 1 - Late Acute GVHD
- 2 - Overlap Acute and Chronic GVHD
- 3 - Classic Chronic GVHD
- 9 - Unknown/Missing

Overall chronic GVHD severity at Day 0: (D000CGS)

- 1 - None
- 2 - Mild
- 3 - Moderate
- 4 - Severe
- 9 - Unknown/Missing

Overall chronic GVHD diagnosis at Day 60: (D0060CGD)

- 0 - No GVHD
- 1 - Late Acute GVHD
- 2 - Overlap Acute and Chronic GVHD
- 3 - Classic Chronic GVHD
- 9 - Unknown/Missing

Overall chronic GVHD severity at Day 60: (D0060CGS)

- 1 - None
- 2 - Mild
- 3 - Moderate
- 4 - Severe
- 9 - Unknown/Missing

Overall chronic GVHD response at Day 60: (D0060CGR)

- 1 - Complete Response
- 2 - Partial Response
- 3 - Unchanged/Stable
- 4 - Progressive
- 9 - Unknown/Missing

Overall chronic GVHD diagnosis at Day 180: (D0180CGD)

- 0 - No GVHD
- 1 - Late Acute GVHD
- 2 - Overlap Acute and Chronic GVHD
- 3 - Classic Chronic GVHD
- 9 - Unknown/Missing

Overall chronic GVHD severity at Day 180: (D0180CGS)

- 1 - None
- 2 - Mild
- 3 - Moderate
- 4 - Severe
- 9 - Unknown/Missing

Overall chronic GVHD response at Day 180: (D0180CGR)

- 1 - Complete Response
- 2 - Partial Response
- 3 - Unchanged/Stable
- 4 - Progressive
- 9 - Unknown/Missing

14. 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 E06

### Primary Reviewer Name:

Mukta Arora  
Paul Carpenter  
Stephanie Lee  
Steven Pavletic

### 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

### Reason ALL immunosuppressive therapy stopped:

6 - Other  
9 - Unknown/Missing

### Number of Queries:

05 - Could Be Worse  
06  
07  
08  
09  
10 - Just Start Over

## Blood and Marrow Transplant Clinical Trials Network

### Extracorporeal Photopheresis (ECP)

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

Segment (PROTSEG): A

Visit Number (VISNO):

1. Assessment period start date:(ECPSTDT)  (mm/dd/yyyy)

2. Assessment period end date:(ECPENDDT)  (mm/dd/yyyy)

**ECP Administration:**

*Provide dates of ECP treatments administered during this assessment period.*

ECP Treatments	ECP Treatment Date:	ECP Device Used
Treatment 1:	(ECPDS01) <input type="text"/> (mm/dd/yyyy)	(ECPDVC1) 1 - CELLEX 2 - UAVR XTS
Treatment 2:	(ECPDS02) <input type="text"/> (mm/dd/yyyy)	(ECPDVC2) 1 - CELLEX 2 - UAVR XTS
Treatment 3:	(ECPDS03) <input type="text"/> (mm/dd/yyyy)	(ECPDVC3) 1 - CELLEX 2 - UAVR XTS
Treatment 4:	(ECPDS04) <input type="text"/> (mm/dd/yyyy)	(ECPDVC4) 1 - CELLEX 2 - UAVR XTS
Treatment 5:	(ECPDS05) <input type="text"/> (mm/dd/yyyy)	(ECPDVC5) 1 - CELLEX 2 - UAVR XTS
Treatment 6:	(ECPDS06) <input type="text"/> (mm/dd/yyyy)	(ECPDVC6) 1 - CELLEX 2 - UAVR XTS
Treatment 7:	(ECPDS07) <input type="text"/> (mm/dd/yyyy)	(ECPDVC7) 1 - CELLEX 2 - UAVR XTS
Treatment 8:	(ECPDS08) <input type="text"/> (mm/dd/yyyy)	(ECPDVC8) 1 - CELLEX 2 - UAVR XTS
Treatment 9:	(ECPDS09) <input type="text"/> (mm/dd/yyyy)	(ECPDVC9) 1 - CELLEX 2 - UAVR XTS
Treatment 10:	(ECPDS10) <input type="text"/> (mm/dd/yyyy)	(ECPDVC10) 1 - CELLEX 2 - UAVR XTS
Treatment 11:	(ECPDS11) <input type="text"/> (mm/dd/yyyy)	(ECPDVC11) 1 - CELLEX 2 - UAVR XTS
Treatment 12:	(ECPDS12) <input type="text"/> (mm/dd/yyyy)	(ECPDVC12) 1 - CELLEX 2 - UAVR XTS

Treatment 13:	(ECPDS13) <input type="text"/> (mm/dd/yyyy)	(ECPDVC13)	1 - CELLEX 2 - UAVR XTS
Treatment 14:	(ECPDS14) <input type="text"/> (mm/dd/yyyy)	(ECPDVC14)	1 - CELLEX 2 - UAVR XTS
Treatment 15:	(ECPDS15) <input type="text"/> (mm/dd/yyyy)	(ECPDVC15)	1 - CELLEX 2 - UAVR XTS
Treatment 16:	(ECPDS16) <input type="text"/> (mm/dd/yyyy)	(ECPDVC16)	1 - CELLEX 2 - UAVR XTS
Treatment 17:	(ECPDS17) <input type="text"/> (mm/dd/yyyy)	(ECPDVC17)	1 - CELLEX 2 - UAVR XTS
Treatment 18:	(ECPDS18) <input type="text"/> (mm/dd/yyyy)	(ECPDVC18)	1 - CELLEX 2 - UAVR XTS
Treatment 19:	(ECPDS19) <input type="text"/> (mm/dd/yyyy)	(ECPDVC19)	1 - CELLEX 2 - UAVR XTS
Treatment 20:	(ECPDS20) <input type="text"/> (mm/dd/yyyy)	(ECPDVC20)	1 - CELLEX 2 - UAVR XTS

3. Has ECP been permanently discontinued? (ECPDSCDT)

1 - Yes  2 - No

4. Date of ECP discontinuation:(ECPDSCDT)

(mm/dd/yyyy)

5. Specify reason for permanent discontinuation of ECP:(ECPDSRSN)

1 - Improvement of cGVHD  
 2 - Progression of cGVHD  
 3 - Loss of intravenous access  
 4 - Infection  
 5 - Toxicity  
 \*Additional Options Listed Below

6. If Other, specify:(ECPDCRO)

Comments:(ECPMMS)

## Additional Selection Options for ECP

Specify reason for permanent discontinuation of ECP:

6 - Hemodynamic instability

7 - Patient refused

9 - Other

## Blood and Marrow Transplant Clinical Trials Network

### 0801A (ENR)

Web Version: 1.0; 3.03; 10-16-15

1. Record date patient informed consent form signed: *(CNSTDT)*  (mm/dd/yyyy)
2. Patient's date of birth: *(BTHDT)*  (mm/dd/yyyy)
3. Patient's body weight: *(PTWGHT)*  (xxx.x) kg
4. Record date patient's body weight obtained: *(PTWGHDT)*  (mm/dd/yyyy)
5. Patient's height: *(PTHGHT)*  (xxx) cm
6. Record date patient's height obtained: *(PTHGHTDT)*  (mm/dd/yyyy)
7. Patient Risk (see 3.1 of protocol): *(PTRISK)*  1 - High risk  2 - Standard risk
8. At the time of diagnosis, was the patient receiving steroids? *(PTSTRDS)*  1 - Yes  2 - No  
*If yes, specify steroid received:*
  9. Methylprednisolone: *(MTPREDDX)*  1 - Yes  2 - No
  10. Record the dose of methylprednisolone at the time of diagnosis: *(MTPDSDX)*  (xxx.xx) mg/kg/day
  11. Prednisone: *(PREDDX)*  1 - Yes  2 - No
  12. Record the dose of prednisone at the time of diagnosis: *(PREDDSDX)*  (xxx.xx) mg/kg/day

### Inclusion Criteria

13. Does the patient have chronic GVHD or overlap syndrome that meets the NIH Consensus Working Group Guidelines? *(CGVHDNIH)*  1 - Yes  2 - No
14. Record the date of chronic GVHD diagnosis: *(CGVHDNT)*  (mm/dd/yyyy)
15. Has the patient received any of the following agents in the last 2 weeks? *(THRPYGVH)*  1 - Yes  2 - No

*If the patient has received any of the following agents, indicate which agents were received, the reason the agents were received and the start dates the agents were received:*

	Agent Received	Reason Agent Given	Start Date
16. Prednisone:	<i>(PREDNISO)</i> <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	<i>(PREDRAS)</i> 1 - Continued Prophylaxis 2 - Acute GVHD Treatment 3 - Chronic GVHD Treatment	<i>(PREDSTR)</i> <input type="text"/> (mm/dd/yyyy)
17. Methylprednisolone:	<i>(METPRED)</i> <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	<i>(MPRERAS)</i> 1 - Continued Prophylaxis 2 - Acute GVHD Treatment 3 - Chronic GVHD Treatment	<i>(MPREDSTR)</i> <input type="text"/> (mm/dd/yyyy)
18. Sirolimus:	<i>(SIROLIM)</i> <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	<i>(SIROREAS)</i> 1 - Continued Prophylaxis 2 - Acute GVHD Treatment 3 - Chronic GVHD Treatment	<i>(SIRLSTR)</i> <input type="text"/> (mm/dd/yyyy)
19. Tacrolimus:	<i>(TACROLIM)</i> <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	<i>(TACREAS)</i> 1 - Continued Prophylaxis 2 - Acute GVHD Treatment 3 - Chronic GVHD Treatment	<i>(TACSTART)</i> <input type="text"/> (mm/dd/yyyy)
20. Cyclosporine:	<i>(CYCLOSP)</i> <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	<i>(CYCLREAS)</i> 1 - Continued Prophylaxis 2 - Acute GVHD Treatment 3 - Chronic GVHD Treatment	<i>(CYCLODT)</i> <input type="text"/> (mm/dd/yyyy)

21. Other:	(OTHERTRT) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(OTRREASO) 1 - Continued Prophylaxis 2 - Acute GVHD Treatment 3 - Chronic GVHD Treatment	(OTRSTDT) <input type="text"/> (mm/dd/yyyy)
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22. If the patient received "other" agent, specify the agent: (SPOTHRTR)
23. Record the most recent dose of prednisone: (PREDDOSE)  (x.xx) mg/kg/day
24. Record the most recent dose of methylprednisolone: (METPREDS)  (x.xx) mg/kg/day
25. Has the patient been treated with extracorporeal photopheresis (ECP)? (EXCORPPH)  1 - Yes  2 - No
26. Record the first date of ECP treatment: (ECPFSTDT)  (mm/dd/yyyy)
27. Record the last date of ECP treatment: (ECPLSTDT)  (mm/dd/yyyy)
28. Record the total number of treatments of ECP received: (NUMECPTR)  (xx)
29. Has the patient been inadequately responding after up to 16 weeks of chronic GVHD therapy? (INADEQUA)  1 - Yes  2 - No

	Most Recent Value	Date Sample Obtained
30. Creatinine:	(CREATN) <input type="text"/> (x.x) mg/dL	(CRTDT) <input type="text"/> (mm/dd/yyyy)
31. Creatinine Clearance:	(CRTCLEAR) <input type="text"/> (xxx) mL/min	
32. Absolute Neutrophil Count (ANC):	(CGVHANC) <input type="text"/> (xxxxx) / $\mu$ L	(ANCGVHDT) <input type="text"/> (mm/dd/yyyy)

33. Is the patient willing to comply with study procedures and reporting requirements? (WILCMPLY)  1 - Yes  2 - No

### Exclusion Criteria

34. Is the patient able to begin prednisone therapy at a dose of 0.5 mg/kg/day? (BEGNPRED)  1 - Yes  2 - No
35. Does the patient have an invasive fungal or viral infection not responding to appropriate antifungal or antiviral therapies? (FUNGVIR)  1 - Yes  2 - No
36. Is the patient unable to tolerate oral medications? (ORALMEDS)  1 - Yes  2 - No
37. Does the patient require platelet transfusions? (PLTTRANS)  1 - Yes  2 - No
38. Is the patient pregnant (positive -HCG) or breastfeeding? (PTPREG)  1 - Yes  2 - No  3 - Not Applicable
39. Is the patient pregnant (positive -HCG) or breastfeeding? (PTPREG)  1 - Yes  2 - No  3 - Not Applicable
40. If the patient is a female of childbearing potential, is the patient willing to use contraception? (CONTRACE)  1 - Yes  2 - No  3 - Not Applicable
41. Has the patient received any therapy to treat persistent, progressive, or recurrent malignancy? (THRPYMLG)  1 - Yes  2 - No
42. Does the patient have any progressive or recurrent malignancy defined other than by quantitative molecular assays? (MALIGNAN)  1 - Yes  2 - No
43. Does the patient have a known hypersensitivity to sirolimus? (HYPERISIR)  1 - Yes  2 - No

### Consent for Biological Samples

44. Has the patient consented to future research samples? (RSRCHSMP)  1 - Yes  2 - No

Comments: (COMMENTS)

**Blood and Marrow Transplant Clinical  
Trials Network**

**Follow Up Status Form - 0801 (FU6)**

Web Version: 1.0; 5.00; 10-16-15

Segment (PROTSEG): A

Visit Number (VISNO):

1. Date of last contact: (FU6LASTC)  (mm/dd/yyyy)

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

2. Has the patient died? (FU6DIED)  1 - Yes  2 - No

If Yes, a Death Form must be submitted.

3. Date of patient death: (FU6DTHDT)  (mm/dd/yyyy)

4. Has the patient's underlying disease (e.g., malignancy) progressed or relapsed? (FU6RLPS)  1 - Yes  2 - No

5. Date of relapse or disease progression: (FU6RLPDT)  (mm/dd/yyyy)

6. Has the patient's underlying disease (e.g., malignancy) been treated for progression or relapse? (FU6RLPTR)  1 - Yes  2 - No

7. Date treatment administered: (FU6RLTDT)  (mm/dd/yyyy)

8. Has the patient experienced any Unexpected, Grade 3-5 Adverse Event? (FU6AE OCC)  1 - Yes  2 - No

If Yes, an Unexpected, Grade 3-5 Adverse Event must be submitted.

9. Date of onset of Unexpected, Grade 3-5 Adverse Event: (FU6AEDT)  (mm/dd/yyyy)

10. Has the patient experienced any new clinically significant infections? (FU6SIGIN)  1 - Yes  2 - No

If Yes, an Infection Form must be submitted.

11. Date of infection: (FU6INFDT)  (mm/dd/yyyy)

12. Has the patient been hospitalized? (FU6HOSPI)  1 - Yes  2 - No

If Yes, a Re-Admission Form must be submitted.

13. Date of hospitalization: (FU6HOSDT)  (mm/dd/yyyy)

14. Has the patient received a DLI? (FU6DLI)  1 - Yes  2 - No

15. Date of DLI: (FU6DLIDT)  (mm/dd/yyyy)

16. Has the patient received a second transplant? (FU6SCTRA)  1 - Yes  2 - No

17. Specify second transplant: (FU6SCTRS)

18. Date of second transplant: (FU6STRDT)  (mm/dd/yyyy)

19. Has the patient started any secondary systemic immunosuppressive therapy to treat chronic GVHD? (FU6SCTPY)  1 - Yes  2 - No

If Yes, a Secondary Therapy Form must be submitted. Secondary immunosuppressive systemic therapy includes any intervention intended to control chronic GVHD through an immunosuppressive effect from oral or parenteral administration of any systemic medication not originally given under the auspices of this protocol for treatment of chronic GVHD. Please see Section 3.3.2 of the protocol for examples.

20. Date patient began secondary systemic immunosuppressive therapy: (FU6TRTDT)  (mm/dd/yyyy)

21. Is the patient currently on  $\leq 5$  mg/day total dose of prednisone? (FU6PRED)  1 - Yes  2 - No  3 - Previously Reported

22. Date prednisone dose of  $\leq 5$  mg/day started: (FU6PRDDT)  (mm/dd/yyyy)

23. Has the patient stopped all SECONDARY systemic immunosuppressive therapy? (FU6SYSTH)  1 - Yes  2 - No  3 - Never Started

24. Date the patient stopped SECONDARY immunosuppressive therapy: (FU6OFFDT)  (mm/dd/yyyy)

25. Has the patient stopped ALL immunosuppressive therapy, including study therapy? (FU6SALLT)  1 - Yes  2 - No  3 - Previously Reported

26. Date the patient stopped ALL immunosuppressive therapy, including study therapy: (FU6SATDT)  (mm/dd/yyyy)

27. Reason patient stopped immunosuppressive therapy, including study therapy: (FU6SATRN)

- 1 - Toxicity
- 2 - cGVHD Progression/Flare
- 3 - Underlying Malignancy Progression/Relapse
- 4 - Infection
- 5 - Physician Decision
- \*Additional Options Listed Below

28. If physician decision or other, specify: (FU6SATRO)

*Peripheral blood samples for plasma BAFF levels and regulatory T-cell and B-cell immunophenotyping must be collected prior to the first time secondary systemic immunosuppressive therapy is administered.*

29. Were blood samples for BAFF levels by ELISA collected? (FU6BAFF)

- 1 - Yes     2 - No

30. Date the blood samples were collected: (FU6BFFDT)

 (mm/dd/yyyy)

31. Were blood samples for Regulatory T-cell and B-cell Immunophenotyping collected? (FU6TBCL)

- 1 - Yes     2 - No

32. Date the blood samples were collected: (FU6TBDT)

 (mm/dd/yyyy)

Comments: (FU6COMM)

## Additional Selection Options for FU6

Reason patient stopped immunosuppressive therapy, including study therapy:

6 - Other

# Blood and Marrow Transplant Clinical Trials Network

## Section 1 - Patient cGVHD Survey (GC1)

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

Segment (PROTSEG): A

Visit Number (VISNO):

### Section 1: Your Chronic Graft vs. Host Disease (GVHD) Symptoms

Date of assessment: (GC1ASDT)  (mm/dd/yyyy)

Please select the number that shows how severe your symptoms have been **in the last week** with 0 representing 'Not Present' and 10 representing 'As Bad As You Can Imagine':

	0	1	2	3	4	5	6	7	8	9	10	Not Answered
1. Your chronic GVHD symptoms <b>overall</b> ? <small>(GC1CGVHD)</small>	<input type="checkbox"/>											
2. Your <b>skin itching</b> at its WORST? <small>(GC1SKIN)</small>	<input type="checkbox"/>											
3. Your <b>mouth dryness</b> at its WORST? <small>(GC1MTDRY)</small>	<input type="checkbox"/>											
4. Your <b>mouth pain</b> at its WORST? <small>(GC1MTPN)</small>	<input type="checkbox"/>											
5. Your <b>mouth sensitivity</b> at its WORST? <small>(GC1MTSEN)</small>	<input type="checkbox"/>											
6. Your <b>eye problem</b> at its WORST? <small>(GC1EYE)</small>	<input type="checkbox"/>											

7. What is your main complaint with regard to your eyes? (GC1EYECO)

8. **Vulvovaginal Symptoms (females only):** Do you have any burning, pain or discomfort in the area of your vagina, vulva or labia? **-OR-** Do you have any discomfort or pain with sexual intercourse? (GC1DCDSX)

1 - Yes    2 - No    3 - N/A    4 - Not Answered

9. Overall, how would you rate the severity of your chronic graft vs host disease? (GC1SGVHD)

- 0 - None
- 1 - Mild
- 2 - Moderate
- 3 - Severe
- 4 - Not Answered

10. Do you think your chronic GVHD symptoms are in good enough control to decrease your immunosuppressive medications? (GC1DMED)

1 - Yes    2 - No    3 - N/A    4 - Not Answered

	0- Not involved with GVHD	1- Completely gone	2- Very much better	3- Moderately better	4- A little better	5- About the same	6- A little worse	7- Moderately worse	8- Very much worse	Not Answered
11. GVHD Symptoms Overall:	--	<small>(GC10GVHD)</small> <input type="checkbox"/>	<input type="checkbox"/>							
12. Mouth:	<small>(GC1MOUTH)</small> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Skin:	<small>(GC1SKN)</small> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Eye:	<small>(GC1YESX)</small> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Joints:	<small>(GC1JNTS)</small> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (GC1COMM)



19. Vomiting	(GC2VOMIT) <input type="checkbox"/>	<input type="checkbox"/>				
20. Weight loss	(GC2WTLS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**MUSCLES AND JOINTS:**

	0 - Not At All	1 - Slightly	2 - Moderately	3 - Quite A Bit	4 - Extremely	Not Answered
21. Joint and muscle aches	(GC2JIONT) <input type="checkbox"/>	<input type="checkbox"/>				
22. Limited joint movement	(GC2LTJTM) <input type="checkbox"/>	<input type="checkbox"/>				
23. Muscle cramps	(GC2MUSCR) <input type="checkbox"/>	<input type="checkbox"/>				
24. Weak Muscles	(GC2WKMUS) <input type="checkbox"/>	<input type="checkbox"/>				

**ENERGY:**

	0 - Not At All	1 - Slightly	2 - Moderately	3 - Quite A Bit	4 - Extremely	Not Answered
25. Loss of energy	(GC2LSERG) <input type="checkbox"/>	<input type="checkbox"/>				
26. Need to sleep more/take naps	(GC2SLEEP) <input type="checkbox"/>	<input type="checkbox"/>				
27. Fevers	(GC2FEVER) <input type="checkbox"/>	<input type="checkbox"/>				

**MENTAL AND EMOTIONAL:**

	0 - Not At All	1 - Slightly	2 - Moderately	3 - Quite A Bit	4 - Extremely	Not Answered
28. Depression	(GC2DEPRS) <input type="checkbox"/>	<input type="checkbox"/>				
29. Anxiety	(GC2ANXY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Difficulty sleeping	(GC2DFSLP) <input type="checkbox"/>	<input type="checkbox"/>				

Comments:(GC2COMM)

**Blood and Marrow Transplant Clinical  
Trials Network**

**Section 3 - Patient cGVHD Survey (GC3)**

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

Segment (PROTSEG): A

Visit Number (VISNO):

**Section 3: Details of Your Eye Symptoms**

Have you experienced any of the following <u>in the last week?</u>	1 - None of the time	2 - Some of the time	3 - Half of the time	4 - Most of the time	5 - All of the time	Not Answered	
1. Eyes that are sensitive to light?	(GC3ELSEN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Eyes that feel gritty?	(GC3EGRIT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Painful or sore eyes?	(GC3EPAIN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Blurred vision?	(GC3EBLUR) <input type="checkbox"/>	<input type="checkbox"/>					
5. Poor vision?	(GC3EPOOR) <input type="checkbox"/>	<input type="checkbox"/>					
Have problems with your eyes limited you in performing any of the following <u>during the last week?</u>	1 - None of the time	2 - Some of the time	3 - Half of the time	4 - Most of the time	5 - All of the time	Not Answered	0 - N/A
6. Reading?	(GC3EREAD) <input type="checkbox"/>	<input type="checkbox"/>					
7. Driving at night?	(GC3EDRIV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Working with a computer or bank machine (ATM)?	(GC3ECOMP) <input type="checkbox"/>	<input type="checkbox"/>					
9. Watching TV?	(GC3ETV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have your eyes felt uncomfortable in any of the following situations <u>during the last week?</u>	1 - None of the time	2 - Some of the time	3 - Half of the time	4 - Most of the time	5 - All of the time	Not Answered	0 - N/A
10. Windy conditions?	(GC3EWIND) <input type="checkbox"/>	<input type="checkbox"/>					
11. Places or areas with low humidity (very dry)?	(GC3EHUMD) <input type="checkbox"/>	<input type="checkbox"/>					
12. Areas that are air conditioned?	(GC3EAIR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(GC3COMM)



**EMOTIONAL WELL-BEING:**

	0 - Not At All	1 - A Little Bit	2 - Somewhat	3 - Quite A Bit	4 - Very Much	Not Answered
15. I feel sad	(GC4SAD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I am satisfied with how I am coping with my illness	(GC4COPE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. I am losing hope in the fight against my illness	(GC4LHOPE) <input type="checkbox"/>	<input type="checkbox"/>				
18. I feel nervous	(GC4NERVE) <input type="checkbox"/>	<input type="checkbox"/>				
19. I worry about dying	(GC4WYDIE) <input type="checkbox"/>	<input type="checkbox"/>				
20. I worry that my condition will get worse	(GC4CNTWS) <input type="checkbox"/>	<input type="checkbox"/>				

**FUNCTIONAL WELL-BEING:**

	0 - Not At All	1 - A Little Bit	2 - Somewhat	3 - Quite A Bit	4 - Very Much	Not Answered
21. I am able to work (include work at home)	(GC4WORK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. My work (include work at home) is fulfilling	(GC4WKFUL) <input type="checkbox"/>	<input type="checkbox"/>				
23. I am able to enjoy life	(GC4ENJOY) <input type="checkbox"/>	<input type="checkbox"/>				
24. I have accepted my illness	(GC4ACPTI) <input type="checkbox"/>	<input type="checkbox"/>				
25. I am sleeping well	(GC4SLPWL) <input type="checkbox"/>	<input type="checkbox"/>				
26. I am enjoying the things I usually do for fun	(GC4FFUN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. I am content with the quality of my life right now	(GC4CNTWL) <input type="checkbox"/>	<input type="checkbox"/>				

**ADDITIONAL CONCERNS:**

	0 - Not At All	1 - A Little Bit	2 - Somewhat	3 - Quite A Bit	4 - Very Much	Not Answered
28. I am concerned about keeping my job (include work at home)	(GC4CNJOB) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. I feel distant from other people	(GC4DISTN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. I worry that the transplant will not work	(GC4WYTRS) <input type="checkbox"/>	<input type="checkbox"/>				
31. The effects of treatment are worse than what I had imagined	(GC4TRTWS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. I have a good appetite	(GC4GAPPT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. I like the appearance of my body	(GC4APBOD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. I am able to get around by myself	(GC4GETAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. I get tired easily	(GC4TIRED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. I am interested in sex	(GC4ITRSX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. I have confidence in my nurse(s)	(GC4CONRN) <input type="checkbox"/>	<input type="checkbox"/>				

Comments:(GC4COMM)





37. My health is excellent

(GC5EXCEL)

Comments: (GC5COMM)

## Additional Selection Options for GC5

Which statement describes how you feel most of the time?

6 - Require considerable assistance and frequent medical care

7 - Disabled, require special care and assistance

8 - Severely disabled, hospitalized

9 - Very sick, hospitalized

10 - Not Answered

## Blood and Marrow Transplant Clinical Trials Network

### Section 6 - Patient cGVHD Survey (GC6)

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

Segment (*PROTSEG*): A

Visit Number (*VISNO*):

#### Section 6: Your Activity Level

	1 - Still Doing This Activity	2 - Have Stopped Doing This Activity	3 - Never Did This Activity	Not Answered
1. Getting in and out of chairs or bed (without assistance)	(GC6GETUP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Listening to the radio	(GC6RADIO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Reading books, magazines or newspapers	(GC6READ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Writing (letters, notes)	(GC6WRITE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Working at a desk or table	(GC6WDESK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Standing (for more than one minute)	(GC6STAND) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Standing (for more than five minutes)	(GC6STNDF) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Dressing or undressing (without assistance)	(GC6DRSWO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Getting clothes from drawers or closets	(GC6CLOTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Getting in or out of a car (without assistance)	(GC6OOCAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Dining at a restaurant	(GC6DINE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Playing cards/table games	(GC6PCARD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Taking a bath (no assistance needed)	(GC6BATHN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Putting on shoes, stockings or socks (no assistance needed)	(GC6SHOES) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Attending a movie, play, church event or sports activity	(GC6MOVIE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Walking 30 yards (27 meters)	(GC6TYWLK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Walking 30 yards (non-stop)	(GC6TYDWK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Dressing/undressing (no rest or break needed)	(GC6DRSNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Using public transportation or driving a car (100 miles or less)	(GC6PUBTR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Using public transportation or driving a car (99 miles or more)	(GC6PTLD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Cooking your own meals	(GC6COOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Washing or drying dishes	(GC6WHDSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Putting groceries on shelves	(GC6GROCS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Ironing or folding clothes	(GC6IRON) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Dusting/polishing furniture or polishing cars	(GC6DUST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Showering	(GC6SHOWR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

27. Climbing six steps	(GC6CLBST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Climbing six steps (non-stop)	(GC6CBSSN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Climbing nine steps	(GC6CLBNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Climbing 12 steps	(GC6CLBTS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. Walking 1/2 block on level ground	(GC6WKGD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Walking 1/2 block on level ground (non-stop)	(GC6WLGNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. Making a bed (not changing sheets)	(GC6MAKEB) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Cleaning windows	(GC6CWIND) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. Kneeling, squatting to do light work	(GC6KNEEL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. Carrying a light load of groceries	(GC6CARYL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Climbing nine steps (non-stop)	(GC6CBNSN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. Climbing 12 steps (non-stop)	(GC6CBTSN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. Walking 1/2 block uphill	(GC6WUPHL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. Walking 1/2 block uphill (non-stop)	(GC6WKUHN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41. Shopping (by yourself)	(GC6SHOP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Washing clothes (by yourself)	(GC6WSHCT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. Walking one block on level ground	(GC6WKOBK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44. Walking two blocks on level ground	(GC6WKTBK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45. Walking one block on level ground (non-stop)	(GC6WOBNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
46. Walking two blocks on level ground	(GC6WTBNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
47. Scrubbing (floors, walls or cars)	(GC6SCRUB) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	1 - Still Doing This Activity	2 - Have Stopped Doing This Activity	3 - Never Did This Activity	Not Answered
48. Making beds (changing sheets)	(GC6CHGST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
49. Sweeping	(GC6SWEEP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
50. Sweeping (five minutes non-stop)	(GC6SWPNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
51. Carrying a large suitcase or bowling (one line)	(GC6CSUIT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
52. Vacuuming carpets	(GC6VACCM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
53. Vacuuming carpets (five minutes non-stop)	(GC6VACFM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54. Painting (interior/exterior)	(GC6PAINT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
55. Walking six blocks on level ground	(GC6WSBGL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
56. Walking six blocks on level ground (non-stop)	(GC6WSBNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
57. Carrying out the garbage	(GC6GARBG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
58. Carrying a heavy load of groceries	(GC6HVYGR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
59. Climbing 24 steps	(GC6TFSTP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
60. Climbing 36 steps	(GC6TSSTP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
61. Climbing 24 steps (non-stop)	(GC6TFNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
62. Climbing 36 steps (non-stop)	(GC6TSNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

63. Walking one mile	(GC6OMILE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
64. Walking one mile (non-stop)	(GC6OMLNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
65. Running 110 yards (100 meters) or playing softball/baseball	(GC6RUNYD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
66. Dancing (social)	(GC6DANCE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
67. Doing calisthenics or aerobic dancing (5 minutes non-stop)	(GC6EXCER) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
68. Mowing the lawn (power mower, but not a riding mower)	(GC6MOWLN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
69. Walking two miles	(GC62MILE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
70. Walking two miles (non-stop)	(GC6TMLNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
71. Climbing 50 steps	(GC6FSTPS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
72. Shoveling, digging or spading	(GC6DIG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
73. Shoveling, digging or spading (five minutes non-stop)	(GC6DIGFM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
74. Climbing 50 steps (non-stop)	(GC6CFSNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
75. Walking three miles or golfing 18 holes without a riding cart	(GC63MILE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
76. Walking three miles (non-stop)	(GC6TMLN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
77. Swimming 25 yards	(GC6SWIM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
78. Swimming 25 yards (non-stop)	(GC6SWIMN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
79. Bicycling one mile	(GC6BIKE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
80. Bicycling two miles	(GC6BIKET) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
81. Bicycling one mile (non-stop)	(GC6BKOMN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
82. Bicycling two miles (non-stop)	(GC6BKTMN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
83. Running or Jogging 1/4 mile	(GC6RUNFM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
84. Running or Jogging 1/2 mile	(GC6RUNHM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
85. Playing tennis or racquetball	(GC6TENNS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
86. Playing basketball (game play)	(GC6BBALL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
87. Running or jogging 1/4 mile (non-stop)	(GC6RNFMN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
88. Running or jogging 1/2 mile (non-stop)	(GC6RNHMN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
89. Running or jogging one mile	(GC6OMRUN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
90. Running or jogging two miles	(GC6TMRUN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
91. Running or jogging three miles	(GC6THRMR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
92. Running or jogging one mile in 12 minutes	(GC6TMMIL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
93. Running or jogging two miles in 20 minutes	(GC6TWMML) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
94. Running or jogging three miles in 30 minutes or less	(GC6TRTMM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(GC6COMM)

Blood and Marrow Transplant Clinical  
Trials Network

Section 7 - Patient cGVHD Survey (GC7)

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

Segment (PROTSEG): A

Visit Number (VISNO):

Section 7: About Yourself

Describe your current work status by checking one box per line:

- 1. In school full time:(GC7SCHFT)  1 - Yes  2 - No  3 - Not Answered
- 2. In school part time:(GC7SCHPT)  1 - Yes  2 - No  3 - Not Answered
- 3. Working full time:(GC7WRKFT)  1 - Yes  2 - No  3 - Not Answered
- 4. Working part time:(GC7WRKPT)  1 - Yes  2 - No  3 - Not Answered
- 5. Homemaker:(GC7HOME)  1 - Yes  2 - No  3 - Not Answered
- 6. Retired:(GC7RETIR)  1 - Yes  2 - No  3 - Not Answered
- 7. On medical leave from work:(GC7MEDLV)  1 - Yes  2 - No  3 - Not Answered
- 8. Disabled, unable to work:(GC7DISAB)  1 - Yes  2 - No  3 - Not Answered
- 9. Unemployed, looking for work:(GC7UNLK)  1 - Yes  2 - No  3 - Not Answered
- 10. Unemployed, not looking for work:(GC7UNNLK)  1 - Yes  2 - No  3 - Not Answered
- 11. Other:(GC7WOTH)  1 - Yes  2 - No  3 - Not Answered
- 12. Specify Other:(GC7WOTSP)

13. What is your marital status?(GC7MRT)

- 1 - Married/Living with partner
  - 2 - Single, Never married
  - 3 - Divorced, Separated
  - 4 - Widowed
  - 5 - Other
  - \*Additional Options Listed Below
- 

If other, specify:(GC7MRTOT)

14. What is the highest grade of school you have completed?(GC7HGGRD)

- 1 - Grade school
  - 2 - Some high school
  - 3 - High school graduate
  - 4 - Some college
  - 5 - College graduate
  - \*Additional Options Listed Below
- 

15. What was your approximate annual family income in the year before you had your transplant?(GC7ANINC)

- 1 - Under \$15,000
  - 2 - \$15,000 - \$24,999
  - 3 - \$25,000 - \$49,999
  - 4 - \$50,000 - \$74,999
  - 5 - \$75,000 - \$99,999
  - \*Additional Options Listed Below
- 

Comments:(GC7COMM)

## Additional Selection Options for GC7

**What is your marital status?**

88 - Not Answered

**What is the highest grade of school you have completed?**

6 - Postgraduate degree

88 - Not Answered

**What was your approximate annual family income in the year before you had your transplant?**

6 - \$100,000 or above

88 - Not Answered

**Blood and Marrow Transplant Clinical  
Trials Network**

**Functional cGVHD Testing (GFX)**

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

Segment (PROTSEG): A

Visit Number (VISNO):

1. Date of assessment:(GFXASDT)  (mm/dd/yyyy)

**Two Minute Walk**

2. Total distance walked in two minutes:(GFX2M WLK)  (xxx.x) ft

**Grip Test**

Trial	Grip Strength (lb)	Grip Strength (kg)
3. Trial #1:	(GFXGS1LB) <input type="text"/> (xxx) lb	(GFXGS1KG) <input type="text"/> (xx) kg
4. Trial #2:	(GFXGS2LB) <input type="text"/> (xxx) lb	(GFXGS2KG) <input type="text"/> (xx) kg
5. Trial #3:	(GFXGS3LB) <input type="text"/> (xxx) lb	(GFXGS3KG) <input type="text"/> (xx) kg
6. Average	(GFXGSA LB) <input type="text"/> (xxx) lb	(GFXGSAKG) <input type="text"/> (xx) kg

**Schirmer's Eye Exam**

7. Right Eye (OD):(GFXREYE)  (xx.x) mm

8. Left Eye (OS):(GFXLEYE)  (xx.x) mm

Comments:(GFXCOMM)

# Blood and Marrow Transplant Clinical Trials Network

## Section 1 - Provider cGVHD Survey (GP1)

Web Version: 1.0; 1.04; 10-16-15

Segment (PROTSEG): A

Visit Number (VISNO):

Date of assessment: (GP1STDT)

[ ] (mm/dd/yyyy)

### Section 1: Skin

#### Dermatological

	Sentinel Lesion	Erythematous rash of any sort	Moveable sclerosis	Non-moveable subcutaneous sclerosis or fasciitis
1. Head/neck/scalp	(GP1HNSSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1HERS) [ ] (xxx.x) %	(GP1HMS) [ ] (xxx.x) %	(GP1HNMS) [ ] (xxx.x) %
2. Anterior torso	(GP1ATRSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1AERS) [ ] (xxx.x) %	(GP1AMS) [ ] (xxx.x) %	(GP1ANMS) [ ] (xxx.x) %
3. Posterior torso	(GP1PTRSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1PERS) [ ] (xxx.x) %	(GP1PMS) [ ] (xxx.x) %	(GP1PNMS) [ ] (xxx.x) %
4. L. upper extremity	(GP1LUESL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LERS) [ ] (xxx.x) %	(GP1LMS) [ ] (xxx.x) %	(GP1LNMS) [ ] (xxx.x) %
5. R. upper extremity	(GP1RUESL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RERS) [ ] (xxx.x) %	(GP1RMS) [ ] (xxx.x) %	(GP1RNMS) [ ] (xxx.x) %
6. L. lower extremity	(GP1LLESL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1EERS) [ ] (xxx.x) %	(GP1EMS) [ ] (xxx.x) %	(GP1ENMS) [ ] (xxx.x) %
7. R. lower extremity	(GP1RLESL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1XERS) [ ] (xxx.x) %	(GP1XMS) [ ] (xxx.x) %	(GP1XNMS) [ ] (xxx.x) %
8. Genitalia (GVP1GENT) <input type="checkbox"/> Not Examined	(GP1GENSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1GERS) [ ] (xxx.x) %	(GP1GMS) [ ] (xxx.x) %	(GP1GNMS) [ ] (xxx.x) %

#### Skin sclerotic changes

9. 0	1	2	3	4
(GP1SKSCL) <input type="checkbox"/> Normal	<input type="checkbox"/> Thickened with pockets of normal skin	<input type="checkbox"/> Thickened over majority of skin	<input type="checkbox"/> Thickened, unable to move	<input type="checkbox"/> Hidebound, unable to pinch

#### Skin Score

10. 0	1	2	3
(GP1SKSCR) <input type="checkbox"/> No Symptoms	<input type="checkbox"/> <18% BSA with disease signs but NO sclerotic features	<input type="checkbox"/> 19-50% BSA OR involvement with superficial sclerotic features not hidebound (able to pinch)	<input type="checkbox"/> >50% BSA OR deep sclerotic feats. hidebound OR impaired mobility, ulceration or severe pruritis

#### Fascia

11. 0	1	2	3
(GP1FASC) <input type="checkbox"/> Normal	<input type="checkbox"/> Tight with normal areas	<input type="checkbox"/> Tight	<input type="checkbox"/> Tight, unable to move

#### Clinical Skin Features

12. Ulcer? (GP1ULCRP) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	13. Location (specify): (GP1ULCRL) [ ]	14. Largest dimension: (GP1ULCRD) [ ] (xx.xx) cm
--	---	---

15. Maculopapular rash	(GP1MRASY) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	16. Keratosis pilaris	(GP1KERPY) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
17. Lichen planus-like lesions	(GP1LICHY) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	18. Papulosquamous lesions or ichthyosis	(GP1PAPLY) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
19. Poikiloderma	(GP1POIKY) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	20. Hair involvement	(GP1HAIRY) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
21. Pruritus	(GP1PRURY) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	22. Nail involvement	(GP1NAILY) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
23. Other	(GP1SKNFT) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	24. Other, specify:	(GP1SKFOS) <input type="text"/>

Region	Sentinel Lesion	Grade (see below)	% Area of Grade	Fraction of Grade 3 or 4 Areas with Erythema	
25. Head, neck and scalp	(GP1HNSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	0(GP1HNS0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1HNS0P) <input type="text"/> (xxx.x) %		
		1(GP1HNS1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1HNS1P) <input type="text"/> (xxx.x) %		
		2(GP1HNS2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1HNS2P) <input type="text"/> (xxx.x) %		
		3(GP1HNS3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1HNS3P) <input type="text"/> (xxx.x) %		(GP1HNS3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1HNS4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1HNS4P) <input type="text"/> (xxx.x) %		(GP1HNS4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%		
26. Chest	(GP1CHSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	0(GP1CH0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1CH0P) <input type="text"/> (xxx.x) %		
		1(GP1CH1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1CH1P) <input type="text"/> (xxx.x) %		
		2(GP1CH2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1CH2P) <input type="text"/> (xxx.x) %		
		3(GP1CH3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1CH3P) <input type="text"/> (xxx.x) %		(GP1CH3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1CH4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1CH4P) <input type="text"/> (xxx.x) %		(GP1CH4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%		
27. Abdomen and Genitals	(GP1AG2SL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	0(GP1AG0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1AG0P) <input type="text"/> (xxx.x) %		
		1(GP1AG1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1AG1P) <input type="text"/> (xxx.x) %		
		2(GP1AG2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1AG2P) <input type="text"/> (xxx.x) %		
		3(GP1AG3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1AG3P) <input type="text"/> (xxx.x) %		(GP1AG3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1AG4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1AG4P) <input type="text"/> (xxx.x) %		(GP1AG4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%		
28. Back and Buttocks	(GP1BBSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	0(GP1BB0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1BB0P) <input type="text"/> (xxx.x) %		
		1(GP1BB1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1BB1P) <input type="text"/> (xxx.x) %		
		2(GP1BB2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1BB2P) <input type="text"/> (xxx.x) %		

		3(GP1BB3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1BB3P) <input type="text"/> (xxx.x) %	(GP1BB3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1BB4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1BB4P) <input type="text"/> (xxx.x) %	(GP1BB4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%	
29. Right Arm	(GP1RASL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	0(GP1RA0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RA0P) <input type="text"/> (xxx.x) %	
		1(GP1RA1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RA1P) <input type="text"/> (xxx.x) %	
		2(GP1RA2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RA2P) <input type="text"/> (xxx.x) %	
		3(GP1RA3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RA3P) <input type="text"/> (xxx.x) %	(GP1RA3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1RA4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RA4P) <input type="text"/> (xxx.x) %	(GP1RA4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%	
30. Right Hand	(GP1RHSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> <input type="checkbox"/> 2 - No	0(GP1RH0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RH0P) <input type="text"/> (xxx.x) %	
		1(GP1RH1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RH1P) <input type="text"/> (xxx.x) %	
		2(GP1RH2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RH2P) <input type="text"/> (xxx.x) %	
		3(GP1RH3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RH3P) <input type="text"/> (xxx.x) %	(GP1RH3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1RH4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RH4P) <input type="text"/> (xxx.x) %	(GP1RH4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%	
31. Left Arm	(GP1LASL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	0(GP1LA0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LA0P) <input type="text"/> (xxx.x) %	
		1(GP1LA1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LA1P) <input type="text"/> (xxx.x) %	
		2(GP1LA2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LA2P) <input type="text"/> (xxx.x) %	
		3(GP1LA3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LA3P) <input type="text"/> (xxx.x) %	(GP1LA3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1LA4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LA4P) <input type="text"/> (xxx.x) %	(GP1LA4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%	
32. Left Hand	(GP1LHSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	0(GP1LH0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LH0P) <input type="text"/> (xxx.x) %	
		1(GP1LH1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LH1P) <input type="text"/> (xxx.x) %	
		2(GP1LH2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LH2P) <input type="text"/> (xxx.x) %	
		3(GP1LH3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LH3P) <input type="text"/> (xxx.x) %	(GP1LH3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1LH4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LH4P) <input type="text"/> (xxx.x) %	(GP1LH4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%	

33. Right Leg and Foot	(GP1RLFSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	0(GP1RLF0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RLF0P) <input type="text"/> (xxx.x) %	
		1(GP1RLF1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RLF1P) <input type="text"/> (xxx.x) %	
		2(GP1RLF2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RLF2P) <input type="text"/> (xxx.x) %	
		3(GP1RLF3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RLF3P) <input type="text"/> (xxx.x) %	(GP1RLF3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1RLF4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1RLF4P) <input type="text"/> (xxx.x) %	(GP1RLF4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%	
34. Left Leg and Foot	(GP1LLFSL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	0(GP1LLF0G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LLF0P) <input type="text"/> (xxx.x) %	
		1(GP1LLF1G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LLF1P) <input type="text"/> (xxx.x) %	
		2(GP1LLF2G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LLF2P) <input type="text"/> (xxx.x) %	
		3(GP1LLF3G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LLF3P) <input type="text"/> (xxx.x) %	(GP1LLF3A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		4(GP1LLF4G) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(GP1LLF4P) <input type="text"/> (xxx.x) %	(GP1LLF4A) <input type="checkbox"/> 0 <input type="checkbox"/> 1/4 <input type="checkbox"/> 1/2 <input type="checkbox"/> 3/4 <input type="checkbox"/> 1
		TOTAL =	100%	

**Grade Description**

0 = normal skin

1 = discolored (hypopigmentation, hyperpigmentation, alopecia, erythema, maculopapular rash)

2 = lichenoid plaque, or skin thickened (unable to move)

3 = skin thickened with limited motion but able to pinch (scleroderma or fasciae involvement)

4 = hidebound skin, unable to move, unable to pinch

Comments: (GP1COMM)

## Blood and Marrow Transplant Clinical Trials Network

### Section 2 - Provider cGVHD Survey (GP2)

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

Segment (*PROTSEG*): A

Visit Number (*VISNO*):

#### Section 2: ROM & Mouth

Please circle this person's current ROM for each joint from 1 = poor motility to 7 = full motility

1. Shoulder	( <i>GP2ROMSH</i> )	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
2. Elbow	( <i>GP2ROMEL</i> )	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
3. Wrist and fingers	( <i>GP2ROMWF</i> )	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
4. Foot Dorsiflexion	( <i>GP2ROMFD</i> )	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4			

	0	1	2	3
5. Mouth Score	( <i>GP2MTHSC</i> ) No Symptoms <input type="checkbox"/>	<input type="checkbox"/> Mild symptoms with disease signs but not limiting oral intake significantly	<input type="checkbox"/> Moderate symptoms with signs with <b>partial</b> limitation of oral intake	<input type="checkbox"/> Severe symptoms with disease signs on examination with <b>major</b> limitation of oral intake
6. Erythema	( <i>GP2MThER</i> ) None <input type="checkbox"/>	<input type="checkbox"/> Mild erythema OR Moderate erythema (<25%)	<input type="checkbox"/> Moderate ( 25%) OR Severe erythema (<25%)	<input type="checkbox"/> Severe erythema ( 25%)
7. Lichenoid	( <i>GP2MThLI</i> ) None <input type="checkbox"/>	<input type="checkbox"/> Hyperkeratotic changes (<25%)	<input type="checkbox"/> Hyperkeratotic changes (25-50%)	<input type="checkbox"/> Hyperkeratotic changes (>50%)
8. Ulcers	( <i>GP2MThUL</i> ) None <input type="checkbox"/>	<input type="checkbox"/> None	<input type="checkbox"/> Ulcers involving ( 20%)	<input type="checkbox"/> Severe ulcerations (>20%)
9. Mucoceles (of lower labia and soft palate only)	( <i>GP2MThMU</i> ) None <input type="checkbox"/>	<input type="checkbox"/> 1-5 mucoceles	<input type="checkbox"/> 6-10 scattered mucoceles	<input type="checkbox"/> Over 10 mucoceles
10. Mouth Pain	( <i>GP2MThPN</i> ) No symptoms <input type="checkbox"/>	<input type="checkbox"/> Food sensitivity	<input type="checkbox"/> Pain requiring narcotics	<input type="checkbox"/> Unable to eat

Comments: (*GP2COMM*)

**Blood and Marrow Transplant Clinical  
Trials Network**

**Section 3 - Provider cGVHD Survey (GP3)**

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

Segment (PROTSEG): A

Visit Number (VISNO):

**Section 3: Gastrointestinal**

	0	1	2	3
1. GI Tract Score	(GP3GITRT) <input type="checkbox"/> No symptoms	<input type="checkbox"/> Symptoms: dysphagia, anorexia, nausea, vomiting, abdominal pain or diarrhea with weight loss (<5%)	<input type="checkbox"/> Symptoms associated with mild to moderate weight loss (5-15%)	<input type="checkbox"/> Symptoms with significant weight loss >15%, requires nutritional supplements OR esophageal dilation
2. Esophagus (Dysphagia OR Odynophagia)	(GP3GIESO) <input type="checkbox"/> No esophageal symptoms	<input type="checkbox"/> Occasional dysphagia or odynophagia w/ solid food or pills	<input type="checkbox"/> Intermittent dysphagia or odynophagia with solid food or pills (but not for liquids/soft foods)	<input type="checkbox"/> Dysphagia or odynophagia for almost all oral intake ( <i>on almost every day</i> )
3. Upper GI (Early satiety OR Anorexia OR Nausea & vomiting)	(GP3UPRG1) <input type="checkbox"/> No symptoms	<input type="checkbox"/> Mild, occasional symptoms with little reduction in oral intake	<input type="checkbox"/> Moderate, intermittent symptoms throughout the day, some reduction in oral intake	<input type="checkbox"/> More severe or persistent symptoms throughout the day, with marked reduction in oral intake
4. Lower GI (Diarrhea)	(GP3LWRG1) <input type="checkbox"/> No loose or liquid stools during the past week	<input type="checkbox"/> Occasional loose or liquid stools, on some days during the past week	<input type="checkbox"/> Intermittent loose or liquid stools throughout the day, without requiring intervention	<input type="checkbox"/> Voluminous diarrhea, on almost every day of the past week requiring intervention

Comments:(GP3COMM)

**Blood and Marrow Transplant Clinical  
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**Section 4 - Provider cGVHD Survey (GP4)**

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

Segment (PROTSEG): A

Visit Number (VISNO):

**Section 4: Other Organs**

	0	1	2	3
1. Eye Score	(GP4YESC) <input type="checkbox"/> No symptoms	<input type="checkbox"/> Mild dry eye not affecting ADL OR asymptomatic signs of kerato- conjunctivitis sicca	<input type="checkbox"/> Moderate dry eye partially affecting ADL WITHOUT vision impairment	<input type="checkbox"/> Severe dry eye symptoms significantly affecting ADL OR unable to work OR loss of vision
2. Joints and Fascia Score	(GP4JOINT) <input type="checkbox"/> No Symptoms	<input type="checkbox"/> Mild tightness of arms or legs, normal range of motion	<input type="checkbox"/> Tightness of arms or legs OR joint contractures, erythema due to fasciitis, decrease in ROM	<input type="checkbox"/> Contractures with significant decrease in ROM and significant limitation of ADL
3. Genital Tract Score(GP4GTSNA) <input type="checkbox"/> No GYN Exam or N/A (males)	(GP4GENTT) <input type="checkbox"/> No symptoms	<input type="checkbox"/> Symptomatic, mild distinct signs on exam and no effect on coitus, minimal discomfort w/ GYN exam	<input type="checkbox"/> Symptomatic, distinct signs on exam and mild dyspareunia or discomfort w/ GYN exam	<input type="checkbox"/> Symptomatic, advanced signs, severe pain with coitus or inability to insert vaginal spectrum
4. Lung Score	(GP4LUNGS) <input type="checkbox"/> No symptoms	<input type="checkbox"/> Mild symptoms (shortness of breath after climbing one flight of steps)	<input type="checkbox"/> Moderate symptoms (shortness of breath after walking on flat ground)	<input type="checkbox"/> Severe symptoms (shortness of breath at rest; requiring oxygen)
5. Other Organ Score (specify organ)(GP410 OSP) <input type="text"/>	(GP4OR1 OT) <input type="checkbox"/> No effect on ADL	<input type="checkbox"/> Mild effect on ADL	<input type="checkbox"/> Moderate effect on ADL	<input type="checkbox"/> Severe effect on ADL
6. Other Organ Score (specify organ)(GP420 OSP) <input type="text"/>	(GP4OR2 OT) <input type="checkbox"/> No effect on ADL	<input type="checkbox"/> Mild effect on ADL	<input type="checkbox"/> Moderate effect on ADL	<input type="checkbox"/> Severe effect on ADL

Comments:(GP4COMM)



c. Eyes	(GP5EYECH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Joints	(GP5JNTCH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Chronic GVHD overall		(GP5CGVCH) <input type="checkbox"/>	<input type="checkbox"/>						

f. What are your reasons for how you rated "chronic GVHD overall"? (GP5CGVRS)

6. Sentinel Organ

Indicate which organ system will guide your treatment decisions. (If more than one, please rank with 1 being first and 4 being last).

a. Skin	(GP5TDSKN) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
b. Joints	(GP5TDJNT) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
c. Fascia	(GP5TDFAS) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
d. Lung	(GP5TDLNG) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
e. Urogenital	(GP5TDURO) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
f. Liver	(GP5TDLIV) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
g. Mouth	(GP5TDMTH) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
h. Esophagus	(GP5TDESP) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
i. Lower GI	(GP5TDLGI) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
j. Other	(GP5TDO TH) <input type="checkbox"/> 0 - No, will not guide	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
k. Specify other:	(GP5TDO SP) <input type="text"/>				

Comments:(GP5COMM)

## Blood and Marrow Transplant Clinical Trials Network

### Section 6 - Provider cGVHD Survey (GP6)

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

Segment (PROTSEG): A

Visit Number (VISNO):

### Section 6: Other indicators, clinical manifestations or severe complications related to chronic GVHD

Other indicators, clinical manifestations or severe complications related to chronic GVHD

	Never (0)	Past, not now (1)	Mild (2)	Moderate (3)	Severe (4)
1. Pleural Effusion(s)	(GP6OIPLE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Bronchiolitis obliterans	(GP6OIBO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Bronchiolitis obliterans organizing pneumonia	(GP6OIBOP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Nephrotic syndrome	(GP6OINS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Malabsorption	(GP6OIMAL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Esophageal stricture or web	(GP6OIESW) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Ascites (serositis)	(GP6OIASC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Myasthenia Gravis	(GP6OIMG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Peripheral Neuropathy	(GP6OIPN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Polymyositis	(GP6OIPM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Pericardial Effusion	(GP6OIPCE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Cardiomyopathy	(GP6OICAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Cardiac conduction defects	(GP6OICCD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Coronary artery involvement	(GP6OICAI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Other 1, please specify:(GP6O T1SP) <input type="text"/>	(GP6O I1OT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other 2, please specify:(GP6O T2SP) <input type="text"/>	(GP6O I2OT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other 3, please specify:(GP6O T3SP) <input type="text"/>	(GP6O I3OT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	0	1	2	3	4
16. Infection	(GP6INF) <input type="checkbox"/> 0 - None	<input type="checkbox"/> 1 - Mild, topical or no therapy required	<input type="checkbox"/> 2 - Moderate, localized, requiring oral treatment	<input type="checkbox"/> 3 - Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospital	<input type="checkbox"/> 4 - Life-threatening infection
	If 2, 3, or 4, then select one:	(GP6INFSP) <input type="checkbox"/> Pending Lab Report	<input type="checkbox"/> Unidentified organism	<input type="checkbox"/> Identified organism	

Specify organism:(GP6ORGSP)

17. Peripheral Edema?	(GP6PERED) <input type="checkbox"/> 0 - None	<input type="checkbox"/> 9- Trace	<input type="checkbox"/> 1+	<input type="checkbox"/> 2+	<input type="checkbox"/> 3+	<input type="checkbox"/> 4+
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Comments:(GP6COMM)

# Blood and Marrow Transplant Clinical Trials Network

## Section 1 - Pediatric cGVHD Survey (GV1)

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

Segment (PROTSEG): A

Visit Number (VISNO):

### Section 1: Your Chronic Graft vs. Host Disease (GVHD) Symptoms

Date of assessment:(GV1ASDT)  (mm/dd/yyyy)

Please select the number that shows how severe your symptoms have been **in the last week** with 0 representing 'Not Present' and 10 representing 'As Bad As You Can Imagine':

	0	1	2	3	4	5	6	7	8	9	10	Not Answered
1. Your chronic GVHD symptoms <b>overall</b> ? <small>(GV1CGVHD)</small>	<input type="checkbox"/>											
2. Your <b>skin itching</b> at its WORST? <small>(GV1SKIN)</small>	<input type="checkbox"/>											
3. Your <b>mouth dryness</b> at its WORST? <small>(GV1MTDRY)</small>	<input type="checkbox"/>											
4. Your <b>mouth pain</b> at its WORST? <small>(GV1MTPN)</small>	<input type="checkbox"/>											
5. Your <b>mouth sensitivity</b> at its WORST? <small>(GV1MTSEN)</small>	<input type="checkbox"/>											
6. Your <b>eye problem</b> at its WORST? <small>(GV1EYE)</small>	<input type="checkbox"/>											

7. What is your main complaint with regard to your eyes?(GV1EYECO)

8. Overall, how would you rate the severity of your chronic graft vs host disease?  
(GV1SGVHD)

- 0 - None
- 1 - Mild
- 2 - Moderate
- 3 - Severe
- 4 - Not Answered

9. Do you think your chronic GVHD symptoms are in good enough control to decrease your immunosuppressive medications?(GV1DMED)

- 1 - Yes   
  2 - No   
  3 - N/A   
  4 - Not Answered

	0- Not involved with GVHD	1- Completely gone	2- Very much better	3- Moderately better	4- A little better	5- About the same	6- A little worse	7- Moderately worse	8- Very much worse	Not Answered
10. GVHD Symptoms Overall:	--	<small>(GV1OGVHD)</small> <input type="checkbox"/>	<input type="checkbox"/>							
11. Mouth:	<small>(GV1MOUTH)</small> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Skin:	<small>(GV1SKN)</small> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Eye:	<small>(GV1EYESX)</small> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Joints:	<small>(GV1JNTS)</small> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(GV1COMM)



19. Vomiting	(GV2VOMIT) <input type="checkbox"/>	<input type="checkbox"/>				
20. Weight loss	(GV2WTLS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**MUSCLES AND JOINTS:**

	0 - Not At All	1 - Slightly	2 - Moderately	3 - Quite A Bit	4 - Extremely	Not Answered
21. Joint and muscle aches	(GV2JIONT) <input type="checkbox"/>	<input type="checkbox"/>				
22. Limited joint movement	(GV2LTJTM) <input type="checkbox"/>	<input type="checkbox"/>				
23. Muscle cramps	(GV2MUSCR) <input type="checkbox"/>	<input type="checkbox"/>				
24. Weak Muscles	(GV2WKMUS) <input type="checkbox"/>	<input type="checkbox"/>				

**ENERGY:**

	0 - Not At All	1 - Slightly	2 - Moderately	3 - Quite A Bit	4 - Extremely	Not Answered
25. Loss of energy	(GV2LSERG) <input type="checkbox"/>	<input type="checkbox"/>				
26. Need to sleep more/take naps	(GV2SLEEP) <input type="checkbox"/>	<input type="checkbox"/>				
27. Fevers	(GV2FEVER) <input type="checkbox"/>	<input type="checkbox"/>				

**MENTAL AND EMOTIONAL:**

	0 - Not At All	1 - Slightly	2 - Moderately	3 - Quite A Bit	4 - Extremely	Not Answered
28. Depression	(GV2DEPRS) <input type="checkbox"/>	<input type="checkbox"/>				
29. Anxiety	(GV2ANXY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Difficulty sleeping	(GV2DFSLP) <input type="checkbox"/>	<input type="checkbox"/>				

Comments:(GV2COMM)

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Section 3 - Pediatric cGVHD Survey (GV3)

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

Segment (PROTSEG): A

Visit Number (VISNO):

Section 3: Your Health and Well-Being

1. Which statement describes how you feel most of the time? (please check one)(GV3FLMST)

- 1 - Fully active, normal
  - 2 - Minor restrictions in physically strenuous activity
  - 3 - Active, but tires more quickly
  - 4 - Both greater restriction of and less time spent in play activity
  - 5 - Up and around, but minimal active play; keeps busy with quieter activities
- \*Additional Options Listed Below

Comments:(GV3COMM)

### **Additional Selection Options for GV3**

**Which statement describes how you feel most of the time? (please check one)**

- 6 - Gets dressed but lie around much of day, no active play but able to take part in quiet play
- 7 - Mostly in bed; participates in quiet activities
- 8 - In bed; needs assistance even for quiet play
- 9 - Often sleeping; play entirely limited to very passive activities

Blood and Marrow Transplant Clinical  
Trials Network

Section 4 - Pediatric cGVHD Survey (GV4)

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

Segment (PROTSEG): A

Visit Number (VISNO):

Section 4: Activities Scale

Last week...

1. I put toothpaste on my toothbrush then brushed my teeth by myself...(GV4BRTTH)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

2. I used the toilet at home by myself... (includes getting on and off the toilet) (GV4TOILT)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

3. I washed my whole body by myself... (GV4WSHWB)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

4. I put my shirt on by myself...(GV4SHIRT)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

5. I put my pants on by myself...(GV4PANTS)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

6. I fastened my clothes by myself... (fastened means doing up buttons and zippers)(GV4FSCLT)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOFST) Or  I did not need to because none of my clothes have fasteners

7. I put my shoes on and did them up by myself...(G V4SHOES)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOSHE)

Or  I did not need to wear shoes last week

(GV4NSHEX)

Explain:

8. I made a snack by myself (or prepared breakfast or lunch)... (GV4SNACK)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOSNK)

Or  I was not allowed to snack or make my own meals

9. I did my usual job or chores...

(Examples: paper route, babysitting, doing the dishes)  
(GV4USLJB)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOJOB)

Or  I don't have a job or chores

10. I took care of my medical needs...

(Examples: put on splints or took medication)  
(GV4MEDCL)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOMED)

Or  I did not have special medical needs last week

11. I did my printing (or script writing) by myself...

(Examples: to do my school work)(GV4PRINT)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

12. I did the same sports that I usually enjoy by myself...

(Examples: Gymnastics, jungle gym, dance, bicycling, swimming)  
(GV4SPORT)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

13. I walked without any support...(No crutches or canes)

(GV4NOSUP)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

14. To get around INSIDE I usually used...

(please choose as many of these as you use)

no special support:  1 - Yes  2 - No  3 - Not Answered  
(GV4ISPLS)

an artificial leg (or legs):(GV4IARLG)  1 - Yes  2 - No  3 - Not Answered

one cane:(GV41CAN)  1 - Yes  2 - No  3 - Not Answered

two canes:  1 - Yes  2 - No  3 - Not Answered

(GV42CAN)

crutches:  1 - Yes  2 - No  3 - Not Answered

(GV4ICRUT)

my hands and  1 - Yes  2 - No  3 - Not Answered

knees:(GV4IHDKN)

a walker:  1 - Yes  2 - No  3 - Not Answered

(GV4IWLKR)

a wheelchair:  1 - Yes  2 - No  3 - Not Answered

(GV4IWLCH)

a scooter:  1 - Yes  2 - No  3 - Not Answered

(GV4ISCOT)

brace, splint or  1 - Yes  2 - No  3 - Not Answered

orthosis:

(GV4IBRCE)

other:(GV4INSOT)  1 - Yes  2 - No  3 - Not Answered

please describe

other:

(GV4INSOS)

15. I got around inside

my home without anyone to help me...

(Examples: walked or wheeled to the bathroom, to the dinner table, or to the kitchen for a drink)

(GV4INOHP)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

16. I walked (or wheeled)

in crowded areas...

(Examples: school hallways between classes or at a busy shopping mall)(GV4CROWD)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4AWCRW)

Or  I tried to stay away from crowds

17. To get around OUTSIDE I usually used...

(please choose as many of these as you use)

no special support:  1 - Yes  2 - No  3 - Not Answered

(GV4OSPLS)

an artificial leg (or  1 - Yes  2 - No  3 - Not Answered

legs):(GV4OARLG)

one  1 - Yes  2 - No  3 - Not Answered

cane:(GV4O1CAN)

two canes:  1 - Yes  2 - No  3 - Not Answered

(GV4O2CAN)

crutches:  1 - Yes  2 - No  3 - Not Answered

(GV4OCRUT)

my hands and  1 - Yes  2 - No  3 - Not Answered

knees:

(GV4OHDKN)

a walker:  1 - Yes  2 - No  3 - Not Answered

(GV4OWLKR)

a wheelchair:  1 - Yes  2 - No  3 - Not Answered

(GV4OWLCH)

a scooter:  1 - Yes  2 - No  3 - Not Answered

(GV4OSCOT)

brace, splint or  1 - Yes  2 - No  3 - Not Answered

orthosis:

(GV4OBRCE)

other:(GV4OUTOT)  1 - Yes  2 - No  3 - Not Answered

please describe

other:

(GV4OUTOS)

18. I got around outside without anyone to help me...  
(Examples: walked or wheeled to a friend's house, to school, or to the park)(GV4NOHLP)

- All of the time
- Most of the time
- Sometimes
- Once in a while
- None of the time
- \*Additional Options Listed Below

(GV4NO OUT)

Or  I never had the chance to go outside last week

(GV4NO OTE)

Explain:

19. I walked (or wheeled) up a gentle hill or slope by myself...  
(GV4GHILL)

- All of the time
- Most of the time
- Sometimes
- Once in a while
- None of the time
- \*Additional Options Listed Below

(GV4AWHIL)

Or  I always tried to stay away from hills

20. I walked (or wheeled) on rough or slippery surfaces...  
(Examples: gravel driveways, or wet sidewalks)  
(GV4RGHSP)

- All of the time
- Most of the time
- Sometimes
- Once in a while
- None of the time, or I stay away from rough and slippery surfaces
- \*Additional Options Listed Below

(GV4NORGH)

Or  I did not need to, I did not come across a rough or slippery surface

21. When I ran (or wheeled) a round outside, I kept up with my friends...  
(GV4KPTUP)

- All of the time
- Most of the time
- Sometimes
- Once in a while
- None of the time
- \*Additional Options Listed Below

(GV4NOFRD)

Or  I did not have a chance to be outside with friends

(GV4NOFRE)

Explain:

How much help have you had so far?(GV4HELP)

- I have done the questions all by myself.
- Someone has read the questions to me.
- Someone has helped me with some of the answers.
- Someone has helped me with most of the answers.
- Other
- \*Additional Options Listed Below

Please describe:  
(GV4HLPDS)

22. I carried a drink or food to the table by myself without spilling...  
(GV4CRDRK)

- All of the time
- Most of the time
- Sometimes
- Once in a while
- None of the time
- \*Additional Options Listed Below

(GV4NODRK)

Or  I am not allowed to do this

23. I carried things in 2 hands by myself...  
(Examples: big or heavy things like stuffed animals, family pet)(GV4CRDTH)

- All of the time
- Most of the time
- Sometimes
- Once in a while
- None of the time
- \*Additional Options Listed Below

(GV4NOCRD)

Or  I had no reason to carry anything in 2 hands last week

24. I **stood still for 10 minutes** without resting...  
(Examples: waiting in line at the store)  
(GV4STSTL)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

25. I **stretched to reach** a high shelf (or to see over the person in front of me)...  
(GV4REACH)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NORCH) Or  I did not need to stretch for anything

26. I **got through heavy doors** by myself...  
(Examples: the front door at home or at school)(GV4HVDOR)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

27. I **walked up and down a flight of stairs** (even when other people were using them)...  
(Note: one flight is about 14 stairs)  
(GV4STAIR)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOSTR) Or  I did not need to, because I did not come across a flight of stairs

28. I **got in and out of an automobile** by myself...  
(opened the door, got in, closed the door, and got out again)  
(GV4AUTMB)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOAUT) Or  I didn't need to go anywhere by automobile last week

29. I **got in and out of a chair** (or wheelchair) by myself...  
(GV4CHAIR)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

30. I **sat on the floor**...  
(Examples: at a school assembly or watching TV)(GV4STFLR)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOFLR) Or  I did not have any reason to sit on the floor

31. I **got in and out of my bed** by myself...  
(GV4IOBED)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

32. **I got down onto the ground from standing**, and got back up again by myself...(G V4GRSTD)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOGRD)

Or  *I did not need to get onto the floor or ground*

(GV4GRDEX)

Explain:

33. **I did climbing activities...**

(Examples: climbing trees, rocks, or climbing over a fence)  
(GV4CLIMB)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOCLM)

Or  *I did not do climbing activities*

34. **I played team sports** with others in my class...

(Examples: basketball, baseball, soccer, hockey)  
(GV4TMSPT)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOSPT)

Or  *I did not play sports in class*

35. **I played some sports by myself or with a few friends...**

(Examples: dribbling and shooting a basketball)  
(GV4SPTMS)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOSMS)

Or  *I did not play sports*

36. I played some **sports in competitive leagues...**

(Examples: with a local basketball, baseball, soccer, or hockey team)(GV4SPTCL)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOSCL)

Or  *I did not play sports in competitive leagues*

37. **I kept my balance** while playing rough games...

(Examples: tag, wrestling, karate, judo)(GV4BALNC)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOGMS)

Or  *I did not play rough games*

38. **I did activities** I usually enjoy for a long time without getting tired out...

(Examples: swimming, jogging, tennis, badminton, rowing, skiing)  
(GV4NO TRD)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOACT)

Or  *I did not do these activities*

39. I ran in a race...  
(Examples: 100 meter dash)(GV4RACE)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NORAC)

Or  I did not run in races

40. I worked carefully with my hands...  
(Examples: building with Lego, making models, sewing, making bead necklaces)  
(GV4WRKHD)

All of the time  
Most of the time  
Sometimes  
Once in a while  
None of the time  
\*Additional Options Listed Below

(GV4NOWRK)

Or  I did not work with my hands

Comments:  
(GV4COMM)

## Additional Selection Options for GV4

I put toothpaste on my toothbrush then brushed my teeth by myself...

Not answered

I walked (or wheeled) on rough or slippery surfaces...

*(Examples: gravel driveways, or wet sidewalks)*

Not answered

How much help have you had so far?

Not answered

Blood and Marrow Transplant Clinical  
Trials Network

Section 5: Pediatric cGVHD Survey (GV5)

Web Version: 1.0; 1.00; 12-11-15

Segment (PROTSEG): A

Visit Number (VISNO):

Section 5: About Yourself

Describe your current work status by checking one box per line.

- 1. In school full time(GV5SCHFT)  1 - Yes  2 - No
- 2. In school part time(GV5SCHPT)  1 - Yes  2 - No
- 3. Working full time(GV5WKFT)  1 - Yes  2 - No
- 4. Working part time(GV5WKPT)  1 - Yes  2 - No
- 5. Not going to school or working due to work status(GV5NOSW)  1 - Yes  2 - No
- 6. Other(GV5OTH)  1 - Yes  2 - No
- 7. Specify other:(GV5OTHSP)

Comments:(GV5COMM)

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:(ORG N01)

- B01 - Acinetobacter (baumanii, calcoaceticus, lwoffii, 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:(ORG N02)

- B01 - Acinetobacter (baumanii, calcoaceticus, lwoffii, 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, lwoffii, 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. 1<sup>st</sup> agent:(*AGENT1*)

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

If other specify:(*AGTSPEC1*)

15. 2<sup>nd</sup> agent:(*AGENT2*)

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

If other specify:(*AGTSPEC2*)

16. 3<sup>rd</sup> 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 - Wound site
- 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 - Branhamella 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-diphtheria 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, bovis, haemophilum, intercellulare)
- B39 - Mycoplasma
- B40 - Neisseria (gonorrhoea, meningitidis, other species)
- B41 - Nocardia
- B42 - Pharyngeal/Respiratory Flora
- B43 - Propionibacterium (acnes, avidum,

granulorum, 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 mucilaginosus  
 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, HTLV-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 - Pneumocystis (PCP)  
 P2 - Toxoplasma  
 P3 - Giardia  
 P4 - Cryptosporidium  
 P5 - Amebiasis  
 P6 - Echinococcal cyst  
 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 Parasitosis  
 F04 - Candida Tropicalis  
 F05 - Torulopsis Galbrata (a subspecies of Candida)  
 F06 - Candida (NOS)  
 F07 - Aspergillus Flavus  
 F08 - Aspergillus Fumigatus  
 F09 - Aspergillus Niger  
 F10 - Aspergillus (NOS)  
 F11 - Cryptococcus Species  
 F12 - Fusarium Species  
 F13 - Mucormycosis (Zygomycetes, Rhizopus)  
 F14 - Yeast (NOS)  
 F15 - Other Fungus

**1<sup>st</sup> agent:**

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

cefoxitin (Mefoxin)  
cefepime (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)  
clotrimazole / betamethasone (Lotrisone)  
co-trimoxazole (Bactrim, Septra, Sulfamethoprim)  
dapsone (DDS)  
dicloxacillin (Dycill, Dynapen, Pathocil)  
didanosine (Videx, ddl)  
doxycycline (Vibramycin)  
efavirenz (Sustiva)  
erythromycin (Ery-Tab, Ilosone, Pediamycin)  
erythromycin ethylsuccinate (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 (Crivivan)  
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 (Lariam)  
meropenem (Merrem I.V.)  
metronidazole (Flagyl, Protostat)  
minocycline (Arestin)  
moxifloxacin hydrochloride (Avelox)  
mupirocin (Bactroban)  
nafcillin (Nallpen, Unipen)  
nelfinavir (Viracept)  
neomycin (Mycifradin, Myciguent)  
neomycin / polymyxin / 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, Cardioquin)  
quinupristin/dalfopristin (Synercid)  
respiratory syncytial immune globulin (Respigam)  
ribavirin (Virazole)  
rifampin (Rifadin, Rimactane)  
rifampin/isoniazid (Rifamate, Rimactan e/INH)  
rifampin/isoniazid/pyrazinamide (Rifater)  
rimantadine (Flumadine)  
ritonavir (Norvir)  
saquinavir mesylate (Fortovase, Invirase)  
stavudine (d4T, Zerit)

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

## Blood and Marrow Transplant Clinical Trials Network

### Laboratory Assessment Form - 0801 (LA6)

Web Version: 1.0; 5.00; 10-16-15

Segment (PROTSEG): A

Visit Number (VISNO):

#### Laboratory Assessments

1. Start of Assessment Period: (LA6APST)  (mm/dd/yyyy)
2. Target Assessment Date: (LA6APEND)  (mm/dd/yyyy)
3. End of Assessment Period: (LA6APEND)  (mm/dd/yyyy)
4. Patient's body weight: (LA6WGTKG)  (xxx.x) kg (LA6WGTLB)  (xxx.x) lb

#### CBC

	Most Recent Value	Date of Sample	Date of Sample
5. Hematocrit	(LA6HCT) <input type="text"/> (xx.x) %	(LA6HCTDT) <input type="text"/> (mm/dd/yyyy)	(LA6HCTDT) <input type="text"/> (mm/dd/yyyy)
6. Hemoglobin	(LA6HGB) <input type="text"/> (xx.x) g/dL	(LA6HGBDT) <input type="text"/> (mm/dd/yyyy)	(LA6HGBDT) <input type="text"/> (mm/dd/yyyy)
7. WBC	(LA6WBC) <input type="text"/> (xxxxx) /mCL	(LA6WBCDT) <input type="text"/> (mm/dd/yyyy)	(LA6WBCDT) <input type="text"/> (mm/dd/yyyy)
8. Platelet Count	(LA6PLAT) <input type="text"/> (xxxxx) /mCL	(LA6PLADT) <input type="text"/> (mm/dd/yyyy)	(LA6PLADT) <input type="text"/> (mm/dd/yyyy)
9. Neutrophils	(LA6NEUT) <input type="text"/> (xxxx) /mCL	(LA6NEUDT) <input type="text"/> (mm/dd/yyyy)	(LA6NEUDT) <input type="text"/> (mm/dd/yyyy)
10. Lymphocytes	(LA6LYMP) <input type="text"/> (xxxx) /mCL	(LA6LYMDT) <input type="text"/> (mm/dd/yyyy)	(LA6LYMDT) <input type="text"/> (mm/dd/yyyy)
11. Eosinophils	(LA6EOS) <input type="text"/> (xx.x) %	(LA6EOSDT) <input type="text"/> (mm/dd/yyyy)	(LA6EOSDT) <input type="text"/> (mm/dd/yyyy)

#### Chemistry and LFT's

	Most Recent Value	ULN For Your Institution	Date of Sample	Date of Sample
12. Creatinine	(LA6CREAT) <input type="text"/> (x.x) mg/dL		(LA6CREDT) <input type="text"/> (mm/dd/yyyy)	(LA6CREDT) <input type="text"/> (mm/dd/yyyy)
13. Total Bilirubin	(LA6BILI) <input type="text"/> (xx.x) mg/dL	(LA6BILUN) <input type="text"/> (xx.x) mg/dL	(LA6BILD) <input type="text"/> (mm/dd/yyyy)	(LA6BILD) <input type="text"/> (mm/dd/yyyy)
14. Alkaline Phosphatase	(LA6ALKPH) <input type="text"/> (xxx) IU/L	(LA6ALKUN) <input type="text"/> (xxx) IU/L	(LA6APDT) <input type="text"/> (mm/dd/yyyy)	(LA6APDT) <input type="text"/> (mm/dd/yyyy)
15. AST	(LA6AST) <input type="text"/> (xxx) IU/L	(LA6ASTUN) <input type="text"/> (xxx) IU/L	(LA6ASTDT) <input type="text"/> (mm/dd/yyyy)	(LA6ASTDT) <input type="text"/> (mm/dd/yyyy)
16. ALT	(LA6ALT) <input type="text"/> (xxx) IU/L	(LA6ALTUN) <input type="text"/> (xxx) IU/L	(LA6ALTD) <input type="text"/> (mm/dd/yyyy)	(LA6ALTD) <input type="text"/> (mm/dd/yyyy)
17. Cholesterol	(LA6CHOL) <input type="text"/> (xxx) mg/dL		(LA6CHODT) <input type="text"/> (mm/dd/yyyy)	(LA6CHODT) <input type="text"/> (mm/dd/yyyy)
18. Triglycerides	(LA6TRIG) <input type="text"/> (xxxx) mg/dL		(LA6TRIDT) <input type="text"/> (mm/dd/yyyy)	(LA6TRIDT) <input type="text"/> (mm/dd/yyyy)

#### Pulmonary Function Tests

	Most Recent Value	Date of Sample	Date of Sample
19. FEV1	(LA6FEV) <input type="text"/> (xxx) % of predicted value	(LA6FEVDT) <input type="text"/> (mm/dd/yyyy)	(LA6FEVDT) <input type="text"/> (mm/dd/yyyy)

20. FVC1	(LA6FVC) <input type="text"/> (xxx) % of predicted value	(LA6FVCDT) <input type="text"/> (mm/dd/yyyy)	(LA6FVCDT) <input type="text"/> (mm/dd/yyyy)
21. DLCO	(LA6DLCO) <input type="text"/> (xxx) % of predicted value	(LA6DLCDT) <input type="text"/> (mm/dd/yyyy)	(LA6DLCDT) <input type="text"/> (mm/dd/yyyy)

Comments:(LA6CMNTS)

## Blood and Marrow Transplant Clinical Trials Network

### Medication Form - 0801 (MD6)

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

Segment (PROTSEG): A

Visit Number (VISNO):

1. Assessment start date: (MD6STDT)  (mm/dd/yyyy)

2. Target assessment date: (MD6ENDDT)  (mm/dd/yyyy)

3. Assessment end date: (MD6ENDDT)  (mm/dd/yyyy)

4. Has the patient ever received a steroid dose of >2mg/kg/day during the assessment period? (MD6STRD)  1 - Yes  2 - No

If Yes, a Secondary Therapy Form must be submitted.

5. Indicate date patient received steroid dose of >2mg/kg/day. (MD6STRDT)  (mm/dd/yyyy)

6. STUDY THERAPY the patient is receiving: (MD6THPRC)

- 1 - Sirolimus + Prednisone
  - 2 - Sirolimus + Extracorporeal Photopheresis + Prednisone
  - 3 - Sirolimus + Calcineurin Inhibitor + Prednisone

STUDY THERAPY	Steroid	CNI	Sirolimus
	<div style="border: 1px solid black; padding: 2px;">                     1 - Prednisone                      2 - Methylprednisolone                      3 - Prednisolone                 </div> (MD6MTPD)	<div style="border: 1px solid black; padding: 2px;">                     1 - Cyclosporine                      2 - Tacrolimus                 </div> (MD6CNI)	
<b>Currently Receiving</b>	(MD6PRDCT) <div style="border: 1px solid black; padding: 2px;">                     1 - Yes, Still Receiving Therapy                      2 - No, Temporarily Withheld                      3 - No, Permanently Discontinued                 </div>	<div style="border: 1px solid black; padding: 2px;">                     1 - Yes, Still Receiving Therapy                      2 - No, Temporarily Withheld                      3 - No, Permanently Discontinued                 </div> (MD6CNICT)	<div style="border: 1px solid black; padding: 2px;">                     1 - Yes, Still Rec                      2 - No, Tempora                      3 - No, Permane                 </div> (MD6SIRCT)
<b>Dose Schedule</b>	(MD6PRDHO) <div style="border: 1px solid black; padding: 2px;">                     1 - Daily                      2 - Alternating Days                 </div>		
<b>Dose 1</b>	(MD6PR1D) <input type="text"/> (xxx.x)		
<b>Dose 2</b>	(MD6PR2D) <input type="text"/> (xxx.x)		
<b>Dose Units</b>	(MD6DSUNT) <div style="border: 1px solid black; padding: 2px;">                     1 - mg                      2 - mg/kg                 </div>		
<b>Date Withheld</b>	(MD6PRDDT) <input type="text"/> (mm/dd/yyyy)	(MD6CNIDT) <input type="text"/> (mm/dd/yyyy)	(MD6SIRDT) <input type="text"/> (n
<b>Date Withheld</b>	(MD6PRDDT) <input type="text"/> (mm/dd/yyyy)	(MD6CNIDT) <input type="text"/> (mm/dd/yyyy)	(MD6SIRDT) <input type="text"/> (n
<b>Date Discontinued</b>	(MD6PRWDT) <input type="text"/> (mm/dd/yyyy)	(MD6CNWDT) <input type="text"/> (mm/dd/yyyy)	(MD6SRWDT) <input type="text"/>
<b>Date Discontinued</b>	(MD6PRWDT) <input type="text"/> (mm/dd/yyyy)	(MD6CNWDT) <input type="text"/> (mm/dd/yyyy)	(MD6SRWDT) <input type="text"/>
<b>Reason Withheld/Discontinued</b>	(MD6PRDRD) <div style="border: 1px solid black; padding: 2px;">                     1 - Toxicity                      2 - cGVHD Progression/Flare                      3 - Underlying Malignancy Progression/Relapse                      4 - Infection                      5 - Physician Decision                      *Additional Options Listed Below                 </div>	(MD6CNIRD) <div style="border: 1px solid black; padding: 2px;">                     1 - Toxicity                      2 - cGVHD Progression/Flare                      3 - Underlying Malignancy Progression/Relapse                      4 - Infection                      5 - Physician Decision                      *Additional Options Listed Below                 </div>	(MD6SIRRD) <div style="border: 1px solid black; padding: 2px;">                     1 - Toxicity                      2 - cGVHD Progression/Flare                      3 - Underlying Malignancy Pro                      4 - Infection                      5 - Physician Decision                      *Additional Options Listed Bel                 </div>

<b>If physician decision or other, specify</b>	(MD6OT1SP) _____	(MD6OT2SP) _____	(MD6OT3SP) _____
--	------------------	------------------	------------------

7. Were Cyclosporine and Tacrolimus interchanged this assessment period? (MD6CNIXG)  1 - Yes  2 - No

8. Indicate reason for switch between Cyclosporine and Tacrolimus: (MD6CYTAS)

- 1 - Toxicity
- 2 - cGVHD Progression/Flare
- 3 - Underlying Malignancy Progression/Relapse
- 4 - Physician Decision
- 5 - Other

9. If physician decision or other, specify: (MD6CNISW) \_\_\_\_\_

10. Has the patient received any of the following agents since cGVHD diagnosis?  1 - Yes  2 - No

(MD6AGTSD)

If Yes, indicate which agents were received and the start and stop dates (when applicable).

	Agent Received	Start Date	Stop Date
11. ECP	(MD6ECPD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6ECPDT) _____ (mm/dd/yyyy)	(MD6ECSDT) _____ (mm/dd/yyyy)
12. Cyclosporine	(MD6CYCSD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6CYCDT) _____ (mm/dd/yyyy)	(MD6CYSDT) _____ (mm/dd/yyyy)
13. Tacrolimus	(MD6TACSD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6TACDT) _____ (mm/dd/yyyy)	(MD6TASDT) _____ (mm/dd/yyyy)
14. MMF	(MD6MMFSD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6MMFDT) _____ (mm/dd/yyyy)	(MD6MMSDT) _____ (mm/dd/yyyy)
15. Azathioprine	(MD6AZASD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6AZADT) _____ (mm/dd/yyyy)	(MD6AZSDT) _____ (mm/dd/yyyy)
16. Rituximab	(MD6RITSD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6RITDT) _____ (mm/dd/yyyy)	(MD6RISDT) _____ (mm/dd/yyyy)
17. Infliximab	(MD6INFSD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6INFDT) _____ (mm/dd/yyyy)	(MD6INSDT) _____ (mm/dd/yyyy)
18. Thalidomide	(MD6THASD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6THADT) _____ (mm/dd/yyyy)	(MD6THSDT) _____ (mm/dd/yyyy)
19. ATG	(MD6ATGSD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6ATGDT) _____ (mm/dd/yyyy)	(MD6ATSDT) _____ (mm/dd/yyyy)
20. Pentostatin	(MD6PTSSD) <input type="checkbox"/> 1 - Yes, Agent Received, Still Taking <input type="checkbox"/> 2 - Yes, Agent Received, Not Still Taking <input type="checkbox"/> 3 - No, Agent Not Received	(MD6PTSDT) _____ (mm/dd/yyyy)	(MD6PTDT) _____ (mm/dd/yyyy)

21. Etanercept	<div style="border: 1px solid black; padding: 2px;"> 1 - Yes, Agent Received, Still Taking  2 - Yes, Agent Received, Not Still Taking  3 - No, Agent Not Received </div> (MD6ETNSD)	(MD6ETNDT) <input type="text"/> (mm/dd/yyyy)	(MD6ENSdT) <input type="text"/> (mm/
22. Methotrexate	<div style="border: 1px solid black; padding: 2px;"> 1 - Yes, Agent Received, Still Taking  2 - Yes, Agent Received, Not Still Taking  3 - No, Agent Not Received </div> (MD6MTXSD)	(MD6MTXDT) <input type="text"/> (mm/dd/yyyy)	(MD6MXSDT) <input type="text"/> (mm/
23. Other	<div style="border: 1px solid black; padding: 2px;"> 1 - Yes, Agent Received, Still Taking  2 - Yes, Agent Received, Not Still Taking  3 - No, Agent Not Received </div> (MD6OTHSD)	(MD6OTHDT) <input type="text"/> (mm/dd/yyyy)	(MD6OTSdT) <input type="text"/> (mm/

24. If other agent, specify: (MD6OSDSP)

Comments: (MD6COMM)

## Additional Selection Options for MD6

Pred Disc/With Rsn  
6 - Other

## Blood and Marrow Transplant Clinical Trials Network

### Endpoint Review Query Form - 0801 (Q06)

Web Version: 1.0; 2.00; 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) <input type="text"/> (mm/dd/yyyy)	(QDESC01) <input type="text"/>	(QRSPDT01) <input type="text"/> (mm/dd/yyyy)	(QRSPNS01) <input type="text"/>

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) <input type="text"/> (mm/dd/yyyy)	(QDESC02) <input type="text"/>	(QRSPDT02) <input type="text"/> (mm/dd/yyyy)	(QRSPNS02) <input type="text"/>

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) <input type="text"/> (mm/dd/yyyy)	(QDESC03) <input type="text"/>	(QRSPDT03) <input type="text"/> (mm/dd/yyyy)	(QRSPNS03) <input type="text"/>

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) <input type="text"/> (mm/dd/yyyy)	(QDESC04) <input type="text"/>	(QRSPDT04) <input type="text"/> (mm/dd/yyyy)	(QRSPNS04) <input type="text"/>

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT05)	(QSNTDT05) <input type="text"/> (mm/dd/yyyy)	(QDESC05) <input type="text"/>	(QRSPDT05) <input type="text"/> (mm/dd/yyyy)	(QRSPNS05) <input type="text"/>

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

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTA T06) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	(QSNTDT06) <input type="text"/> (mm/dd/yyyy)	(QDESC06) <input type="text"/>	(QRSPDT06) <input type="text"/> (mm/dd/yyyy)	(QRSPNS06) <input type="text"/>

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTA T07) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	(QSNTDT07) <input type="text"/> (mm/dd/yyyy)	(QDESC07) <input type="text"/>	(QRSPDT07) <input type="text"/> (mm/dd/yyyy)	(QRSPNS07) <input type="text"/>

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTA T08) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	(QSNTDT08) <input type="text"/> (mm/dd/yyyy)	(QDESC08) <input type="text"/>	(QRSPDT08) <input type="text"/> (mm/dd/yyyy)	(QRSPNS08) <input type="text"/>

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTA T09) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	(QSNTDT09) <input type="text"/> (mm/dd/yyyy)	(QDESC09) <input type="text"/>	(QRSPDT09) <input type="text"/> (mm/dd/yyyy)	(QRSPNS09) <input type="text"/>

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTA T10) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	(QSNTDT10) <input type="text"/> (mm/dd/yyyy)	(QDESC10) <input type="text"/>	(QRSPDT10) <input type="text"/> (mm/dd/yyyy)	(QRSPNS10) <input type="text"/>

Blood and Marrow Transplant Clinical  
Trials Network

Specimen Acquisition Form - 0801 (SA3)

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

Segment (PROTSEG): A

Visit Number (VISNO):

Be sure to enter the collection and shipment of specimens into GlobalTrace as soon as possible.

1. Were blood samples for BAFF levels by ELISA collected? (BAFFLVLS)  1 - Yes  2 - No  
If yes, record the date the blood samples were collected: (BAFFDT)  (mm/dd/yyyy)
2. Were blood samples for Regulatory T-cell and B-cell Immunophenotyping collected? (IMMUNOPH)  1 - Yes  2 - No  
If yes, record the date the blood samples were collected: (IMMUNODT)  (mm/dd/yyyy)
3. Were buccal swabs collected? (BUCCSWAB)  1 - Yes  2 - No  
If yes, record the date the buccal swabs were collected: (BUCSWBDT)  (mm/dd/yyyy)
4. Were blood samples collected for future research? (SA3PLSMA)  1 - Yes  2 - No  
If yes, record the date the blood samples were collected: (SA3PLSDT)  (mm/dd/yyyy)

Comments: (SA3CMMNT)

## Blood and Marrow Transplant Clinical Trials Network

### Secondary Therapy Form (SCT)

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

**Secondary Therapy Date (SCTDT):**

Secondary immunosuppressive systemic therapy includes any intervention intended to control chronic GVHD through an immunosuppressive effect from oral or parenteral administration of any systemic medication not originally given under the auspices of this protocol for treatment of chronic GVHD. See Section 3.3.2 of the protocol for examples.

*Record secondary systemic immunosuppressive therapy agents administered:*

1. 1st agent: (SCTAGNT1)

01 - ECP  
02 - Cyclosporine  
03 - Tacrolimus  
04 - MMF  
05 - Azathioprine  
\*Additional Options Listed Below

Specify other 1st agent: (SCTOT1SP)

2. Start date: (SCTAT1DT)

(mm/dd/yyyy)

3. 2nd agent: (SCTAGNT2)

01 - ECP  
02 - Cyclosporine  
03 - Tacrolimus  
04 - MMF  
05 - Azathioprine  
\*Additional Options Listed Below

Specify other 2nd agent: (SCTOT2SP)

4. Start date: (SCTAT2DT)

(mm/dd/yyyy)

5. 3rd agent: (SCTAGNT3)

01 - ECP  
02 - Cyclosporine  
03 - Tacrolimus  
04 - MMF  
05 - Azathioprine  
\*Additional Options Listed Below

Specify other 3rd agent: (SCTOT3SP)

6. Start date: (SCTAT3DT)

(mm/dd/yyyy)

7. Was secondary therapy given due to progression of cGVHD? (SCTCGVHD)  1 - Yes  2 - No

*Indicate which organ system(s) have progressed that lead to the start of secondary therapy.*

8. Skin	(SCTSKIN) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
9. Joints	(SCTJNT) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
10. Fascia	(SCTFSC) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
11. Lung	(SCTLUNG) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
12. Urogenital	(SCTUGNTL) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
13. Liver	(SCTLIVER) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
14. Mouth	(SCTMOUTH) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
15. Esophagus	(SCTESPH) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
16. Lower GI	(SCTLGI) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No

17. Other

(SCTOOT)  1 - Yes  2 - No

If Other, specify:(SCTOOSP)

Comments:(SCTCOMM)

## Additional Selection Options for SCT

### 1st agent:

- 06 - Rituximab
- 07 - Infliximab
- 08 - Thalidomide
- 09 - Antithymocyte Globulin
- 10 - Pentostatin
- 11 - Etanercept
- 12 - Methotrexate
- 99 - Other

# Blood and Marrow Transplant Clinical Trials Network

## Toxicity Form - 0801 (T16)

Web Version: 1.0; 5.01; 10-16-15

Segment (PROTSEG): A

Visit Number (VISNO):

1. Record date of evaluation:(T16X7EVL)  (mm/dd/yyyy)

Record the highest grade of toxicity diagnosed since the previous evaluation. If this is the first evaluation, record the highest toxicity diagnosed since enrollment on the BMT 0801 study. The toxicity grades are based on the NCI CTCAE Version 3.0.

### Renal Toxicity

2. Did the patient experience renal failure severe enough to warrant dialysis? (T16RENAL)  1 - Yes  2 - No

3. Did the patient receive dialysis?(T16DIALS)  1 - Yes  2 - No

4. Creatinine:(T16CREAT)

0 - Grades 0-2  
3 - > 3.0 - 6.0 x ULN  
4 - > 6.0 x ULN  
5 - Death

### Hemorrhagic Toxicity

5. Hemorrhage:(T16HEM RG)

0 - Grades 0-3  
4 - Catastrophic Bleeding; Requiring Major Non-Elective Intervention  
5 - Death

### Cardiovascular Toxicity

6. Hypertension:(T16HYPER)

0 - Normal  
1 - Asymptomatic, Transient Increase by >20mmHg; Intervention not Indicated  
2 - Recurrent or Persistent or Symptomatic Increase by >20mmHg; Monotherapy may be Indicated  
3 - Requiring More than One Drug or More Intensive Therapy than Previously  
4 - Life-Threatening Consequences (e.g., Hypertensive Crisis)  
\*Additional Options Listed Below

### Neurologic Toxicity

7. Did the patient experience any seizures during this assessment period?(T16SEIZR)  1 - Yes  2 - No

8. Record seizure toxicity grade:(T16SZGRD)

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

### Musculoskeletal and Connective Tissue Toxicity

9. Avascular necrosis:(T16NECRO)

0 - Grades 0 - 1  
2 - Symptomatic; limiting instrumental ADL  
3 - Severe symptoms; limiting self care ADL; elective operative intervention indicated  
4 - Life-threatening consequences; urgent intervention indicated  
5 - Death

10. Osteoporosis:(T16OSTEO)

0 - Grade 0  
1 - T-score (Z-score) -1 to -2.5 (osteopenia); no loss of height or intervention indicated  
2 - T-score(Z-score)<-2.5; loss of ht<2cm; anti-osteoporotic thpy indicated; limiting inst ADL  
3 - Loss of height >=2cm; hospitalization indicated; limiting self care ADL

### Endocrine Toxicity

11. Glucose intolerance/Diabetes:(T16DIAB)

0 - Grades 0 - 2  
3 - Symptoms interfering with ADL; insulin indicated  
4 - Life-threatening consequences  
5 - Death

**Coagulation Toxicity**

12. HUS/TTP/thrombotic microangiopathy:(T16DIC)

0 - Grades 0 - 2  
3 - Laboratory Findings Present with Clinical Consequences  
4 - Laboratory Findings and Life-threatening or Disabling Consequences  
5 - Death

13. Thrombocytopenia:(T16THROM)

0 - Grades 0 - 2  
3 -  $<50,000 - 25,000/\text{mm}^3$  or  $<50.0 - 25.0 \times 10^9/\text{L}$   
4 -  $<25,000/\text{mm}^3$  or  $<25.0 \times 10^9/\text{L}$   
5 - Death

14. Anemia:(T16ANEM)

0 - Grades 0-2  
3 -  $< 8.0 - 6.5 \text{ g/dL}$   
4 -  $< 6.5 \text{ g/dL}$   
5 - Death

**Dermatology/Skin Toxicity**

15. Photosensitivity:(T16PHOTO)

0 - Grades 0 - 2  
3 - Erythema with Desquamation  
4 - Life-threatening; Disabling  
5 - Death

**Vascular Toxicity**

16. Serious Catheter Associated Complications (SCAC):  
(T16SCAC)

0 - Grades 0 - 1  
2 - Pain or Swelling with Inflammation or Phlebitis at Catheter Site  
3 - Ulceration or Necrosis That Is Severe; Operative Intervention Indicated

**Pulmonary Toxicity**

17. Pneumonitis (NIP):(T16NIP)

0 - Grades 0-2  
3 - Severe pain; limiting self care ADL  
4 - Life-threatening respiratory compromise; urgent intervention indicate (e.g., trach/intubation)  
5 - Death

18. Hypoxia (for more than 24 hours):(T16HYPXI)

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

**Chemistry**

*Only the most abnormal interim value should be recorded.*

19. Cholesterol:(T16CHOLE)

0 - Grade 0-2  
3 - 400-500 mg/dL or  $>10.34-12.92 \text{ mmol/L}$   
4 - 500 mg/dL or  $>12.92 \text{ mmol/L}$   
5 - Death

20. Triglycerides:(T16TRIGL)

0 - Grade 0-2  
3 -  $>5.0 - 10.0 \times \text{ULN}$   
4 -  $> 10.0 \times \text{ULN}$   
5 - Death

21. Hypocalcemia:(T16HCAL)

0 - Grades 0 - 2  
3 -  $<7.0 - 6.0 \text{ mg/ml}$  or  $<1.75 - 1.50 \text{ mmol/L}$   
4 -  $< 6.0 \text{ mg/dL}$  or  $<1.5 \text{ mmol/L}$   
5 - Death

**Hepatic Toxicity**

22. ALT: (T16ALT)

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

23. AST: (T16AST)

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

24. Bilirubin: (T16BILIR)

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

25. Alkaline Phosphatase: (T16ALKPH)

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:

26. Jaundice: (T16JANDC)  1 - Yes  2 - No
27. Hepatomegaly: (T16HP TMG)  1 - Yes  2 - No
28. Right upper quadrant pain: (T16QUADP)  1 - Yes  2 - No
29. Weight gain (>5%) from baseline: (T16WGHTG)  1 - Yes  2 - No

30. Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
VOD:	<input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No (T16VODET)	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done (T16VODBI)	<input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done (T16VODDP)
GVHD:	<input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No (T16GVHET)	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done (T16GVHBI)	<input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done (T16GVHDP)
Infection:	<input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No (T16INFET)	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done (T16INFBI)	<input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done (T16INFDP)
Other:	<input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No (T16OTHET)	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done (T16OTHBI)	<input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done (T16OTHDP)
Unknown:	<input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No (T16UNKET)		

Specify other etiology: (T162SPEC)

Comments: (T16COMM)

## Additional Selection Options for T16

Hypertension:  
5 - Death