Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Web Version: 1.0; 4.02; 06-09-11

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

1. Date of discharge: *(DISCHDT)* *(mm/dd/yyyy)*
2. Patient discharge status: *(DISCPTST)* ☐ 1 - Alive ☐ 2 - Dead
   If Dead, a Death Form must be submitted.
3. Record PRIMARY discharge diagnosis: *(PHSPREAS)*

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

   *Specify organ: *(ADM4SPEC)*
   **Specify other: *(ADM1SPEC)*
4. Record secondary discharge diagnoses:
   a. GVHD: *(REASGVHD)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   b. Relapse/progression: *(REASRLPS)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   c. Graft failure: *(REASGF)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   d. Infection: *(REASINF)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   e. Fever: *(REASFVR)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   f. Seizure: *(REASSZR)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   g. Bleeding/hemorrhage: *(REASGIBL)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   h. Diarrhea: *(REASDRH)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   i. Nausea/vomiting: *(REASNV)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   j. Organ failure: *(REASORGF)* ☐ 1 - Contributory ☐ 2 - Noncontributory
      Specify organ: *(ADM3SPEC)*
   k. Trauma: *(REASTRAM)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   l. Psychiatric: *(REASPSYC)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   m. Secondary malignancy: *(REASMALG)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   n. Scheduled procedure/treatment: *(REASPROC)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   o. Thrombosis/thrombus/embolism: *(REASTRMB)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   p. Other: *(REASOTHR)* ☐ 1 - Contributory ☐ 2 - Noncontributory
      Specify other: *(ADM2SPEC)*
5. Record re-admission institution: *(ADMCENTR)*

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

Comments: *(ADMCOMM1)*

Additional Selection Options for ADM

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

Blood and Marrow Transplant Clinical Trials Network

Unexpected, Grade 3-5 Adverse Event Form (AE1)

Web Version: 1.0; 3.06; 06-09-11

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

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

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

Comments: *(AE1COMM)*

Additional Selection Options for AE1

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

Blood and Marrow Transplant Clinical Trials Network

Summary Form - Unexpected, Grade 3-5 Adverse Event (AE2)

Web Version: 1.0; 3.06; 06-09-11

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

1. Report activation status: *(AVSTAT_A)*

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

Relevant Past Medical History

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

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

(SEMEDHX)

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

(SESUMM)

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

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

Blood and Marrow Transplant Clinical Trials Network

Therapy Form - Unexpected, Grade 3-5 Adverse Event (AE3)

Web Version: 1.0; 3.06; 06-09-11

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

1. Report activation status: *(AVSTAT_B)*

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

Medication	Start Date *(mm/dd/yyyy)*	Stop Date *(mm/dd/yyyy)*	Dose, Route, Schedule	Indication
(CONMED1)	*(CM1STDT)*	*(CM1SPDT)*	*(CM1DOSE)*	*(CM1INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED2)	*(CM2STDT)*	*(CM2SPDT)*	*(CM2DOSE)*	*(CM2INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED3)	*(CM3STDT)*	*(CM3SPDT)*	*(CM3DOSE)*	*(CM3INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED4)	*(CM4STDT)*	*(CM4SPDT)*	*(CM4DOSE)*	*(CM4INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED5)	*(CM5STDT)*	*(CM5SPDT)*	*(CM5DOSE)*	*(CM5INDIC)*

				1 - Treatment of adverse event 9 - Other
(CONMED6)	*(CM6STDT)*	*(CM6SPDT)*	*(CM6DOSE)*	*(CM6INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED7)	*(CM7STDT)*	*(CM7SPDT)*	*(CM7DOSE)*	*(CM7INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED8)	*(CM8STDT)*	*(CM8SPDT)*	*(CM8DOSE)*	*(CM8INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED9)	*(CM9STDT)*	*(CM9SPDT)*	*(CM9DOSE)*	*(CM9INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED10)	*(CM10STDT)*	*(CM10SPDT)*	*(CM10DOSE)*	*(CM10INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED11)	*(CM11STDT)*	*(CM11SPDT)*	*(CM11DOSE)*	*(CM11INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED12)	*(CM12STDT)*	*(CM12SPDT)*	*(CM12DOSE)*	*(CM12INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED13)	*(CM13STDT)*	*(CM13SPDT)*	*(CM13DOSE)*	*(CM13INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED14)	*(CM14STDT)*	*(CM14SPDT)*	*(CM14DOSE)*	*(CM14INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED15)	*(CM15STDT)*	*(CM15SPDT)*	*(CM15DOSE)*	*(CM15INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED16)	*(CM16STDT)*	*(CM16SPDT)*	*(CM16DOSE)*	*(CM16INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED17)	*(CM17STDT)*	*(CM17SPDT)*	*(CM17DOSE)*	*(CM17INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED18)	*(CM18STDT)*	*(CM18SPDT)*	*(CM18DOSE)*	*(CM18INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED19)	*(CM19STDT)*	*(CM19SPDT)*	*(CM19DOSE)*	*(CM19INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED20)	*(CM20STDT)*	*(CM20SPDT)*	*(CM20DOSE)*	*(CM20INDI)* 1 - Treatment of adverse event 9 - Other

(CONMED21)	*(CM21STDT)*	*(CM21SPDT)*	*(CM21DOSE)*	*(CM21INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED22)	*(CM22STDT)*	*(CM22SPDT)*	*(CM22DOSE)*	*(CM22INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED23)	*(CM23STDT)*	*(CM23SPDT)*	*(CM23DOSE)*	*(CM23INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED24)	*(CM24STDT)*	*(CM24SPDT)*	*(CM24DOSE)*	*(CM24INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED25)	*(CM25STDT)*	*(CM25SPDT)*	*(CM25DOSE)*	*(CM25INDI)* 1 - Treatment of adverse event 9 - Other

Comments: *(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

Laboratory/Diagnostics Form - Unexpected, Grade 3-5 Adverse Event (AE4)

Web Version: 1.0; 3.05; 06-09-11

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

1. Report activation status: *(AVSTAT_C)*

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

Laboratory Test Results

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

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

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

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

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

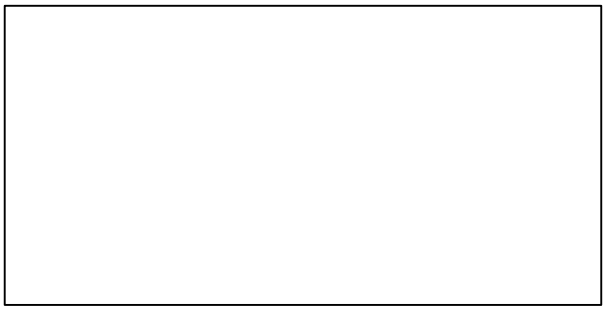
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

Test	Date Performed *(mm/dd/yyyy)*	Results/Comments

(ADDTS1)	*(AD1DTDAT)*	*(AD1DTRES)*
(ADDTS2)	*(AD2DTDAT)*	*(AD2DTRES)*
(ADDTS3)	*(AD3DTDAT)*	*(AD3DTRES)*
(ADDTS4)	*(AD4DTDAT)*	*(AD4DTRES)*
(ADDTS5)	*(AD5DTDAT)*	*(AD5DTRES)*

(ADDTS6)	*(AD6DTDAT)*	*(AD6DTRES)*
(ADDTS7)	*(AD7DTDAT)*	*(AD7DTRES)*
(ADDTS8)	*(AD8DTDAT)*	*(AD8DTRES)*
(ADDTS9)	*(AD9DTDAT)*	*(AD9DTRES)*
(ADDTS10)	*(AD10DTDT)*	*(AD10DTRS)*

Comments: *(AE4COMM)*



Blood and Marrow Transplant Clinical Trials Network

Review Form - Unexpected, Grade 3-5 Adverse Event (AE5)

Web Version: 1.0; 3.06; 06-09-11

Segment *(PROTSEG)*:
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

Medical Monitor Reviewer Form - Unexpected, Grade 3-5 Adverse Event (AE6)

Web Version: 1.0; 4.06; 06-09-11

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

1. Adverse event status: *(AVSTAT_E)*

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

2. Has this event been determined to be an unexpected, grade 3-5 adverse event? *(AMDETER)* ☐ 1 - Yes ☐ 2 - No
3. Does this require expedited reporting to the FDA? *(AMEXPFDA)* ☐ 1 - Yes ☐ 2 - No
4. Does this require expedited reporting to the DSMB? *(AMEXPDSM)* ☐ 1 - Yes ☐ 2 - No
5. Do you recommend the patient be withdrawn from further protocol therapy? *(AMWITHDR)* ☐ 1 - Yes ☐ 2 - No
6. Is the review complete? *(AMREVDNE)* ☐ 1 - Yes ☐ 2 - No
7. If **No**, what additional information is required: *(AMREVINF)*

8. Medical Monitor event description: *(AMMMEVDS)*

Comments: *(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Follow Up GVHD Form (CGV)

Web Version: 1.0; 7.03; 06-22-11

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

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

Answer questions 3-9 relating to acute GVHD.

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

Answer questions 10-20 relating to chronic GVHD.

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

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

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

16. Minimum platelet count at time of diagnosis: *(PLTLTCNT)* *(xxx.x)* x 10^9/L
17. Alkaline phosphatase at time of diagnosis: *(ALKPHOSP)* *(xxxx)* U/L
18. Weight at time of diagnosis: *(CGVWEIGH)* *(xxx.x)* kg
19. Total bilirubin at time of diagnosis: *(BILIRUBN)* *(xx.x)* mg/dL
20. Body surface area involved with rash at time of diagnosis: *(BSA)* *(xxx)* % ?

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

Skin/Hair

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

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

?

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

a. Lichenoid: *(RASHLICH)* ☐ 1 - Yes ☐ 2 - No
b. Maculopapular: *(RASHMACU)* ☐ 1 - Yes ☐ 2 - No
c. Sclerodermatous: *(RASHSCLR)* ☐ 1 - Yes ☐ 2 - No

Ocular

22. Xerophthalmia: *(DRYEYES)*

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

Oral

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

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

Pulmonary

24. Dyspnea: *(CGVDYSPN)*

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

25. Pulmonary fibrosis: *(PULMFIBR)*

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

26. Bronchiolitis obliterans: *(BRNCOBLT)*

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

27. FEV1: *(CGVFEV1)*

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

28. Oxygen saturation: *(O2SAT)*

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

Gastrointestinal

29. Esophagus: *(ESOPHAGS)*

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

30. Nausea and vomiting: *(NAUSVOMT)*

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

31. Diarrhea: *(CGVDIARH)*

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

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

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

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

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

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

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

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

35. Malabsorption: *(MALABSRP)*

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

Hepatic

36. Bilirubin level: *(LIVERBIL)*

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

Genitourinary

37. Vaginitis: *(VAGNITIS)*

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

Musculoskeletal

38. Contractures: *(CONTRCTR)*

0 - No Symptoms
2 - Mild Joint Contractures (Does not Affect ADL)
3 - Severe Joint Contractures (Interferes with ADL)

39. Myositis: *(MYOSITIS)*

☐ 1 - Yes ☐ 2 - No

Hematologic

40. Eosinophilia: *(EOSINPHL)*

☐ 1 - Yes ☐ 2 - No

Other

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

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

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

Specify other organ: *(ORGSPEC)* _____

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

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

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

Type of Biopsy:	If Other, Specify:	Date of Biopsy:	Result of Biopsy:
45. *(BIOTYP1)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP1OSPE)*	*(BIODT1)* _____ *(mm/dd/yyyy)*	*(BIORSLT1)* 1 - Positive 2 - Negative 3 - Equivocal
46. *(BIOTYP2)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP2OSPE)*	*(BIODT2)* _____ *(mm/dd/yyyy)*	*(BIORSLT2)* 1 - Positive 2 - Negative 3 - Equivocal
47. *(BIOTYP3)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP3OSPE)*	*(BIODT3)* _____ *(mm/dd/yyyy)*	*(BIORSLT3)* 1 - Positive 2 - Negative 3 - Equivocal
48. *(BIOTYP4)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP4OSPE)*	*(BIODT4)* _____ *(mm/dd/yyyy)*	*(BIORSLT4)* 1 - Positive 2 - Negative 3 - Equivocal
49. *(BIOTYP5)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP5OSPE)*	*(BIODT5)* _____ *(mm/dd/yyyy)*	*(BIORSLT5)* 1 - Positive 2 - Negative 3 - Equivocal
50. *(BIOTYP6)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(TYP6OSPE)*	*(BIODT6)* _____ *(mm/dd/yyyy)*	*(BIORSLT6)* 1 - Positive 2 - Negative 3 - Equivocal

Answer questions 51-54 relating to GVHD therapy.

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

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

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

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

b. Azathioprine: *(THRPYAZA)*

c. Cyclosporine: *(THRPYCYC)*

d. Systemic Corticosteroids: *(THRPYSCO)*

e. Topical Corticosteroids: *(THRPYTCO)*

f. Thalidomide: *(THRPYTHA)*

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

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

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

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

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

l. Etretinate: *(THRPYETR)*

m. Lamprene: *(THRPYLAM)*

n. Etanercept: *(THRPYETA)*

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

p. Chloroquine Phosphate: *(THRPYCPH)*

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

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

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

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

r. In Vivo Immunotoxin: *(THRPYIMM)*

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

Specify in vivo immunotoxin used: *(IMMAGNT)*

s. Other: *(THRPYOTH)*

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

Specify other agent used: *(OTHAGNT)*

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

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

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

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

?

Answer questions 55-58 relating to current patient status.

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

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

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

57. Current platelet count: *(CURPLTCT)* *(xxx.x)* x 10^9/L

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

Comments: *(CGVCOMM)*

Additional Selection Options for CGV

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 6.00; 06-22-11

1. Name Code: *(NAMECODE)*

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

3. CRID # (CIBMTR Recipient ID): *(CRIDNUM)* *(xxxxxxxxxx)*

Do NOT use IUBMID/UPN numbers in the CRID field.

4. Gender: *(GENDER)* ☐ 1 - Male ☐ 2 - Female

5. Date of Birth: *(DOB)* *(mm/dd/yyyy)*

6. Ethnicity: *(ETHNIC)*

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

7. 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)*

8. 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

Donor Toxicity Form (DTX)

Web Version: 1.0; 3.00; 04-26-11

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

For questions 1-28, record the highest grade of toxicity present after initation of mobilization, but prior to apheresis.
Record the grade of toxicity present at the time of contact with the donor, approximately 4 weeks after completion of apheresis.

Flu-Like Symptoms

1. Fever in absence of infections: *(DFLULIKE)*

1 - None (Grade 0)
2 - 38.0 - 39.0 degrees C (Grade 1)
3 - > 39.0 - 40.0 degrees C (Grade 2)
4 - > 40.0 degrees C for less than 24 hours (Grade 3)
5 - > 40.0 degrees C for more than 24 hours (Grade 4)

Constitutional Symptoms

2. Fatigue (lethargy, malaise, asthenia): *(DCONSTIT)*

1 - None (Grade 0)
2 - Mild fatigue over baseline (Grade 1)
3 - Moderate or causing difficulty performing some ADL (Grade 2)
4 - Severe fatigue interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

Ocular/Visual

3. Inflammation in the eyes: *(DOCVISIO)*

1 - None (Grade 0)
2 - Asymptomatic or minimally symptomatic but not interfering with function (Grade 1)
3 - Symptomatic, interfering with function but not w/ ADL; topical intervention indicated (Grade 2)
4 - Symptomatic, interfering with ADL; operative intervention indicated (Grade 3)

Dermatologic

4. Skin (rash): *(DSKIN)*

1 - None (Grade 0)
2 - Macular or papular eruption or erythema that is asymptomatic (Grade 1)
3 - Macular or papular eruption or erythema with pruritus or other associated symptoms (Grade 2)
4 - Severe, generalized erythroderma or macular, papular or vesicular eruption (Grade 3)
5 - Generalized exfoliative dermatitis or ulcerating dermatitis (Grade 4)

5. Local (site reaction): *(DLOCALDE)*

1 - None (Grade 0)
2 - Pain; itching; erythema (Grade 1)
3 - Pain and swelling with inflammation or phlebitis (Grade 2)
4 - Ulceration or necrosis that is severe; operative intervention indicated (Grade 3)

6. Ulceration: *(DULCERAT)*

1 - None (Grade 0)
2 - Superficial ulceration < 2 cm size; local wound care; medical intervention indicated (Grade 2)
3 - Ulceration at least 2 cm size; operative debridement, invasive intervention indicated (Grade 3)
4 - Life-threatening consequences; major invasive intervention indicated (Grade 4)

Cardiac

7. Hypotension (low blood pressure): *(DHYPOTEN)*

1 - Normal (Grade 0)
2 - Present, intervention not indicated (Grade 1)
3 - Brief (< 24 hours) fluid replacement or other therapy; no physiologic consequences (Grade 2)
4 - Sustained (at least 24 hours) therapy, resolved without physiologic consequences (Grade 3)
5 - Shock (Grade 4)

Pulmonary

8. Pneumothorax: *(DPULMONA)*

1 - Not present (Grade 0)
2 - Asymptomatic, radiographic findings only (Grade 1)
3 - Symptomatic; intervention indicated (Grade 2)
4 - Sclerosis and/or operative intervention indicated (Grade 3)
5 - Life-threatening, causing hemodynamic instability; ventilatory support indicated (Grade 4)

Gastrointestinal

9. Nausea: *(DNAUSEA)*

1 - None (Grade 0)
2 - Loss of appetite without alteration in eating habits (Grade 1)
3 - Oral intake decreased without significant weight loss, dehydration or malnutrition (Grade 2)
4 - Inadequate oral caloric or fluid intake (Grade 3)
5 - Life-threatening consequences (Grade 4)

10. Vomiting: *(DVOMITIN)*

1 - None (Grade 0)
2 - 1 episode in 24 hours (Grade 1)
3 - 2-5 episodes in 24 hours (Grade 2)
4 - At least 6 episodes in 24 hours (Grade 3)
5 - Life-threatening consequences (Grade 4)

11. Anorexia (loss of appetite): *(DANOREXI)*

1 - None (Grade 0)
2 - Loss of appetite without alteration in eating habits (Grade 1)
3 - Altered intake without significant weight loss or malnutrition (Grade 2)
4 - Significant weight loss or malnutrition (Grade 3)
5 - Life-threatening (Grade 4)

Vascular

12. Venous thrombosis/embolism: *(DEMBOLIS)*

1 - None (Grade 0)
2 - Deep vein thrombosis, or cardiac thrombosis; intervention not indicated (Grade 2)
3 - Deep vein thrombosis, or cardiac thrombosis; intervention indicated (Grade 3)
4 - Embolic event including pulmonary embolism or life-threatening thrombus (Grade 4)

Neurological

13. Insomnia (inability to sleep): *(DINSOMNI)*

1 - Normal (Grade 0)
2 - Occasional difficulty sleeping, not interfering with function (Grade 1)
3 - Difficulty sleeping, interfering with function but not interfering with ADL (Grade 2)
4 - Frequent difficulty sleeping, interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

14. Dizziness, vertigo, lightheadedness: *(DVERTIGO)*

1 - None (Grade 0)
2 - With head movements only; not interfering with function (Grade 1)
3 - Interfering with function, but not interfering with ADL (Grade 2)
4 - Interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

15. Syncope (fainting): *(DSYNCOPE)*

1 - None (Grade 0)
2 - Present (Grade 3)
3 - Life-threatening consequences (Grade 4)

Hematological

16. Low platelet count: *(DLOWPLAT)*

1 - Within normal limits (Grade 0)
2 - < LLN - 75.0 x 10^9/L (Grade 1)
3 - < 75.0 - 50.0 x 10^9/L (Grade 2)
4 - < 50.0 - 25.0 x 10^9/L (Grade 3)
5 - < 25.0 x 10^9/L (Grade 4)

Infection Sites

For each of the sites listed below, indicate the severity of infection present.

17. Peripheral IV site: *(DINFPERI)*

1 - None (Grade 0)
2 - Localized, local intervention indicated (Grade 2)
3 - IV antibiotic, antifungal, or antiviral intervention indicated (Grade 3)
4 - Life-threatening consequences (Grade 4)

18. Central catheter site: *(DINFCCS)*

1 - None (Grade 0)
2 - Localized, local intervention indicated (Grade 2)
3 - IV antibiotic, antifungal, or antiviral intervention indicated (Grade 3)
4 - Life-threatening consequences (Grade 4)

19. Other site: *(DINFOTHE)*

1 - None (Grade 0)
2 - Localized, local intervention indicated (Grade 2)
3 - IV antibiotic, antifungal, or antiviral intervention indicated (Grade 3)
4 - Life-threatening consequences (Grade 4)

Specify site: *(DINFSPEC)*

Pain Sites

For each of the sites listed below, indicate the severity of pain present.

20. Back: *(DPAIBACK)*

1 - None (Grade 0)
2 - Mild pain not interfering with function (Grade 1)
3 - Moderate pain interfering with function but not ADL (Grade 2)
4 - Severe pain severely interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

21. Bone: *(DPAIBONE)*

1 - None (Grade 0)
2 - Mild pain not interfering with function (Grade 1)
3 - Moderate pain interfering with function but not ADL (Grade 2)
4 - Severe pain severely interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

22. Limb (leg or arm): *(DPAILIMB)*

1 - None (Grade 0)
2 - Mild pain not interfering with function (Grade 1)
3 - Moderate pain interfering with function but not ADL (Grade 2)
4 - Severe pain severely interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

23. Joint: *(DPAIJOIN)*

1 - None (Grade 0)
2 - Mild pain not interfering with function (Grade 1)
3 - Moderate pain interfering with function but not ADL (Grade 2)
4 - Severe pain severely interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

24. Muscle: *(DPAIMUSC)*

1 - None (Grade 0)
2 - Mild pain not interfering with function (Grade 1)
3 - Moderate pain interfering with function but not ADL (Grade 2)
4 - Severe pain severely interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

25. Headache: *(DPAIHEAD)*

1 - None (Grade 0)
2 - Mild pain not interfering with function (Grade 1)
3 - Moderate pain interfering with function but not ADL (Grade 2)
4 - Severe pain severely interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

26. Neck: *(DPAINECK)*

1 - None (Grade 0)
2 - Mild pain not interfering with function (Grade 1)
3 - Moderate pain interfering with function but not ADL (Grade 2)
4 - Severe pain severely interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

27. IV site: *(DPAINIVS)*

1 - None (Grade 0)
2 - Mild pain not interfering with function (Grade 1)
3 - Moderate pain interfering with function but not ADL (Grade 2)
4 - Severe pain severely interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

28. Other site: *(DPAINOTH)*

1 - None (Grade 0)
2 - Mild pain not interfering with function (Grade 1)
3 - Moderate pain interfering with function but not ADL (Grade 2)
4 - Severe pain severely interfering with ADL (Grade 3)
5 - Disabling (Grade 4)

Specify site: *(DPAINSPE)*

Donor Pre-Apheresis Vital Signs

29. Pulse: *(DPULSE)* *(xxx)* beats per minute

30. Blood pressure: *(DBPSYSTO)* *(xxx)* mmHg (systolic)

(DBPDIAST) *(xxx)* mmHg (diastolic)

31. Temperature: *(DTEMPERA)* *(xx.x)* degrees C

Donor Pre-Apheresis Hematology

32. Date of sample collection: *(DDATESAM)* *(mm/dd/yyyy)*

33. WBC: *(DWBC)* *(xx.x)* x 10^9/L

34. Platelets: *(DPLATELE)* *(xxx)* x 10^9/L

35. Hematocrit: *(DHEMATOC)* *(xx.x)* %

36. Hemoglobin: *(DHEMOGLO)* *(xx.x)* g/dL

Apheresis Procedure

First Apheresis

37. Time procedure started: *(DTIMESTA)* _____ *(hh:mm)* (24-hour clock)
38. Time procedure ended: *(DTIMEEND)* _____ *(hh:mm)* (24-hour clock)
39. Does your center's blood cell separator calculate the time to complete the procedure? *(DBCSCALC)* ☐ 1 - Yes ☐ 2 - No
    Procedure time from the blood cell separator: *(DPROCTIM)* _____ *(hh:mm)*
40. Volume of whole blood processed: *(DVOLWBP)* _____ *(xx.x)* liters
41. Did the donor receive calcium replacement to treat or prevent symptoms of hypocalcemia? *(DCALREPL)* ☐ 1 - Yes ☐ 2 - No

    Specify therapy:

    a. Oral calcium for prevention: *(DOCAPREV)* ☐ 1 - Yes ☐ 2 - No
    b. IV calcium for prevention: *(DIVCAPRE)* ☐ 1 - Yes ☐ 2 - No
    c. Oral calcium for treatment: *(DOCATREA)* ☐ 1 - Yes ☐ 2 - No
    d. IV calcium for treatment: *(DIVCATRE)* ☐ 1 - Yes ☐ 2 - No

42. Did the donor experience symptoms of hypocalcemia? *(DHYPOCA)* ☐ 1 - Yes ☐ 2 - No
    Specify symptoms: *(DHCASYPT)*

    1 - Transient numbness or tingling
    2 - Persistent, moderate numbness or tingling
    3 - Severe numbness or tingling
    4 - Tetany

Second Apheresis

43. Was a second apheresis procedure performed? *(DSECONDA)* ☐ 1 - Yes ☐ 2 - No
44. Time procedure started: *(D2TIMSTA)* _____ *(hh:mm)* (24-hour clock)
45. Time procedure ended: *(D2TIMEEN)* _____ *(hh:mm)* (24-hour clock)
46. Does your center's blood cell separator calculate the time to complete the procedure? *(D2BCSCAL)* ☐ 1 - Yes ☐ 2 - No
    Procedure time from the blood cell separator: *(D2PROCTI)* _____ *(hh:mm)*
47. Volume of whole blood processed: *(D2VOLWBP)* _____ *(xx.x)* liters
48. Did the donor receive calcium replacement to treat or prevent symptoms of hypocalcemia? *(D2CALREP)* ☐ 1 - Yes ☐ 2 - No

    Specify therapy:

    a. Oral calcium for prevention: *(D2COAPRE)* ☐ 1 - Yes ☐ 2 - No
    b. IV calcium for prevention: *(D2IVCAPR)* ☐ 1 - Yes ☐ 2 - No
    c. Oral calcium for treatment: *(D2OCATRE)* ☐ 1 - Yes ☐ 2 - No
    d. IV calcium for treatment: *(D2IVCATR)* ☐ 1 - Yes ☐ 2 - No

49. Did the donor experience symptoms of hypocalcemia? *(D2HYPOCA)* ☐ 1 - Yes ☐ 2 - No
    a. Specify symptoms: *(D2HCASYP)*

    1 - Transient numbness or tingling
    2 - Persistent, moderate numbness or tingling
    3 - Severe numbness or tingling
    4 - Tetany

Third Apheresis

50. Was a third apheresis procedure performed? *(DTHIRDAP)* ☐ 1 - Yes ☐ 2 - No
51. Time procedure started: *(D3TIMSTA)* _____ *(hh:mm)* (24-hour clock)
52. Time procedure ended: *(D3TIMEEN)* _____ *(hh:mm)* (24-hour clock)
53. Does your center's cell separator calculate the time to complete the procedure? *(D3BCSCAL)* ☐ 1 - Yes ☐ 2 - No
    Procedure time from the blood cell separator: *(D3PROCTI)* _____ *(hh:mm)*
54. Volume of whole blood processed: *(D3VOLWBP)* _____ *(xx.x)* liters
55. Did the donor receive calcium replacement to treat or prevent symptoms of hypocalcemia? *(D3CALPRP)* ☐ 1 - Yes ☐ 2 - No

    Specify therapy:

    a. Oral calcium for prevention: *(D3OCAPRE)* ☐ 1 - Yes ☐ 2 - No
    b. IV calcium for prevention: *(D3IVCAPR)* ☐ 1 - Yes ☐ 2 - No
    c. Oral calcium for treatment: *(D3OCATRE)* ☐ 1 - Yes ☐ 2 - No
    d. IV calcium for treatment: *(D3IVCATR)* ☐ 1 - Yes ☐ 2 - No

56. Did the donor experience symptoms of hypocalcemia? *(D3HYPOCA)* ☐ 1 - Yes ☐ 2 - No

a. Specify symptoms: *(D3DCASYP)*

1 - Transient numbness or tingling
2 - Persistent, moderate numbness or tingling
3 - Severe numbness or tingling
4 - Tetany

Donor Post-Apheresis Hematology

57. Date of sample collection: *(DPAHEMDT)* *(mm/dd/yyyy)*
58. WBC: *(DPAWBC)* *(xx.x)* x 10^9/L
59. Platelets: *(DPAPLATE)* *(xxx)* x 10^9/L
60. Hematocrit: *(DPAHEMAT)* *(xx.x)* %
61. Hemoglobin: *(DPAHEMOG)* *(xx.x)* g/dL

Comments: *(DTXCOMM1)*

Blood and Marrow Transplant Clinical Trials Network

0102B (ENR)

Web Version: 1.0; 4.00; 08-20-09

Multiple Myeloma Enrollment Form - Segment B

1. Record the biologically assigned treatment arm: *(RXARMB)* ☐ 1 - Autologous/Allogeneic ☐ 2 - Tandem Autologous +/- Dex/Thal
2. Record the type of second transplant the patient will receive: *(TXPTYPE)*

```
1 - Allogeneic
2 - Autologous
3 - No Second Transplant
```

It is a protocol violation if the biological assignment does not match the second transplant type. Please contact the protocol coordinator before enrolling the patient.

3. Record the number of living siblings the patient has: *(NUMSIBS)* _____ *(xx)*
4. Record the number of living siblings that were HLA typed: *(SIBSTYPE)* _____ *(xx)*
5. Record the number of living HLA-identical siblings the patient has: *(ANYHLASB)* _____ *(xx)*

If the patient has been registered on the Autologous/Allogeneic arm, complete the following questions regarding donor eligibility.

Donor Inclusion Criteria

6. Record date donor informed consent form signed: *(CNSNTBDT)* _____ *(mm/dd/yyyy)*
7. Record the donor's birthdate: *(DNRBRTDT)* _____ *(mm/dd/yyyy)*

Donor Exclusion Criteria

8. Are the donor and patient identical twins? *(IDENTICL)* ☐ 1 - Yes ☐ 2 - No
9. Is the donor pregnant (positive β-HCG) or breastfeeding? *(DNRPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
10. Is the donor HIV seropositive? *(DNHIVPOS)* ☐ 1 - Yes ☐ 2 - No
11. Is the donor hepatitis B surface antigen positive? *(HEPBSAGP)* ☐ 1 - Yes ☐ 2 - No
12. Is the donor hepatitis C positive? *(DNRHEPCP)* ☐ 1 - Yes ☐ 2 - No
13. Does the donor have a known allergy to G-CSF? *(DALLGCSF)* ☐ 1 - Yes ☐ 2 - No
14. Does the donor currently have a serious systemic illness? *(DNRSYSIL)* ☐ 1 - Yes ☐ 2 - No
15. Does the donor have an uncontrolled viral, bacterial or fungal infection? *(DNRUNINF)* ☐ 1 - Yes ☐ 2 - No
16. Is the donor currently receiving experimental therapy or an investigational drug? *(DNREXTHR)* ☐ 1 - Yes ☐ 2 - No
17. Does the donor have a history of any malignant disease other than treated basal cell carcinoma or cervical carcinoma in situ? *(DNRCANCR)*

```
1 - Yes
2 - Yes, Approved by Study Chair/MM
3 - No
```

18. Date confirmed by study chair: *(DREVWDTB)* _____ *(mm/dd/yyyy)*

If the patient has been registered on the Autologous/Allogeneic arm, complete the following questions regarding DONOR consent for use of biological samples and RECIPIENT and DONOR HLA.

Consent for use of Biological Samples for Research - Donor

19. Did the donor give consent to provide blood stem cells for future research purposes? *(DCSTBLRS)* ☐ 1 - Yes ☐ 2 - No

HLA Typing

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

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

20. **Recipient HLA Typing**

HLA-A

Typing method: *(RHLAAMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided: *(RHLAANUM)*

1 - One
2 - Two

1st: *(RHLAA11X)* / *(RHLAA12X)* / *(RHLAA13X)* / *(RHLAA14X)* /

(RHLAA15X) / *(RHLAA16X)* / *(RHLAA17X)* / *(RHLAA18X)* /

2nd: *(RHLAA21X)* / *(RHLAA22X)* / *(RHLAA23X)* / *(RHLAA24X)* /

(RHLAA25X) / *(RHLAA26X)* / *(RHLAA27X)* / *(RHLAA28X)* /

HLA-B

Typing method: *(RHLABMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided: *(RHLABNUM)*

1 - One
2 - Two

1st: *(RHLAB11X)* / *(RHLAB12X)* / *(RHLAB13X)* / *(RHLAB14X)* /

(RHLAB15X) / *(RHLAB16X)* / *(RHLAB17X)* / *(RHLAB18X)* /

2nd: *(RHLAB21X)* / *(RHLAB22X)* / *(RHLAB23X)* / *(RHLAB24X)* /

(RHLAB25X) / *(RHLAB26X)* / *(RHLAB27X)* / *(RHLAB28X)* /

HLA-DRB1

Typing method: *(RHLADMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided: *(RHLADNUM)*

1 - One
2 - Two

1st: *(RHLAD11X)* / *(RHLAD12X)* / *(RHLAD13X)* / *(RHLAD14X)* /

(RHLAD15X) / *(RHLAD16X)* / *(RHLAD17X)* / *(RHLAD18X)* /

2nd: *(RHLAD21X)* / *(RHLAD22X)* / *(RHLAD23X)* / *(RHLAD24X)* /

(RHLAD25X) / *(RHLAD26X)* / *(RHLAD27X)* / *(RHLAD28X)* /

21. Donor HLA Typing

HLA-A

Typing method: *(DHLAAMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided: *(DHLAANUM)*

1 - One
2 - Two

1st: *(DHLAA11X)* / *(DHLAA12X)* / *(DHLAA13X)* / *(DHLAA14X)* /

(DHLAA15X) / *(DHLAA16X)* / *(DHLAA17X)* / *(DHLAA18X)* /

2nd: *(DHLAA21X)* / *(DHLAA22X)* / *(DHLAA23X)* / *(DHLAA24X)* /

(DHLAA25X) / *(DHLAA26X)* / *(DHLAA27X)* / *(DHLAA28X)* /

HLA-B

Typing method: *(DHLABMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided: *(DHLABNUM)*

1 - One
2 - Two

1st: *(DHLAB11X)* / *(DHLAB12X)* / *(DHLAB13X)* / *(DHLAB14X)* /

(DHLAB15X) / *(DHLAB16X)* / *(DHLAB17X)* / *(DHLAB18X)* /

2nd: *(DHLAB21X)* / *(DHLAB22X)* / *(DHLAB23X)* / *(DHLAB24X)* /

(DHLAB25X) | *(DHLAB26X)* / | *(DHLAB27X)* / | *(DHLAB28X)* /

HLA-DRB1

Typing method: *(DHLADMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided: *(DHLADNUM)*

1 - One
2 - Two

1st: *(DHLAD11X)* | *(DHLAD12X)* / | *(DHLAD13X)* / | *(DHLAD14X)* /

(DHLAD15X) | *(DHLAD16X)* / | *(DHLAD17X)* / | *(DHLAD18X)* /

2nd: *(DHLAD21X)* | *(DHLAD22X)* / | *(DHLAD23X)* / | *(DHLAD24X)* /

(DHLAD25X) | *(DHLAD26X)* / | *(DHLAD27X)* / | *(DHLAD28X)* /

Locus-A calculated HLA Match Score *(SCORE_A)*

Locus-B calculated HLA Match Score *(SCORE_B)*

Locus-DRB1 calculated HLA Match Score *(SCORE_D)*

Total calculated HLA Match Score *(HLASCORE)*

Do you agree with the calculated HLA Match Score? *(HLAAGREE)* ☐ 1 - Yes ☐ 2 - No

Indicate your institution's HLA Match Score for this participant: *(SITESCR)*

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

Comments *(COMMENTS)*

Additional Selection Options for ENR

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

Indicate your institution's HLA Match Score for this participant:
5/6
6/6
0/8
1/8
2/8
3/8
4/8
5/8
6/8
7/8
8/8

Blood and Marrow Transplant Clinical Trials Network

FACT-BMT (Version 4) (FCT)

Web Version: 1.0; 3.03; 06-09-11

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

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

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

Physical Well-Being

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

For each of the above:

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

Social/Family Well-Being

8. I feel close to my friends *(CLSFRNDS)*

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

9. I get emotional support from my family *(FAMSPPRT)*

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

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

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

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

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

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

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

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

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

Did the patient answer the following question? (CHECKBOX)

☐ 1 - Yes ☐ 2 - No

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

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

Emotional Well-Being

15. I feel sad *(FEELSAD)*

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

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

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

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

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

18. I feel nervous *(NERVOUS)*

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

19. I worry about dying *(WORRYDIE)*

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

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

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

Functional Well-Being

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

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

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

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

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

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

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

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

25. I am sleeping well *(SLEEPWEL)*

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

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

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

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

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

Additional Concerns

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

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

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

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

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

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

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

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

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

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

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

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

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

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

35. I get tired easily *(GETTIRED)*

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

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

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

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

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

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

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

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

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

40. I can remember things *(MEMORY)*

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

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

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

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

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

43. My eyesight is blurry *(EYESIGHT)*

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

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

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

45. I have tremors *(TREMORS)*

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

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

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

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

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

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

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

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

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

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

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

Additional Selection Options for FCT

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

Blood and Marrow Transplant Clinical Trials Network

Follow Up Status Form (FUS)

Web Version: 1.0; 12.01; 06-27-11

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

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

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

2. Has the patient died? *(DIED)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Death Form must be submitted.

3. Date of patient death: *(DEATHDT)* _____ *(mm/dd/yyyy)*

4. Has the patient relapsed or experienced disease progression? *(RELAPSE)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Progression/Relapse Form must be submitted.

5. Date of relapse or progression: *(RELAPSDT)* _____ *(mm/dd/yyyy)*

6. Has the patient experienced secondary graft failure? *(SECGRFAL)* ☐ 1 - Yes ☐ 2 - No

7. Has the patient experienced secondary graft failure? *(SECGRFAL)* ☐ 1 - Yes ☐ 2 - No

8. Date of secondary graft failure: *(SCGRFLDT)* _____ *(mm/dd/yyyy)*

9. Date of secondary graft failure: *(SCGRFLDT)* _____ *(mm/dd/yyyy)*

10. Has the patient initiated any non-protocol anti-myeloma therapy? *(ANTIMYEL)* ☐ 1 - Yes ☐ 2 - No

If yes, record the type of therapy

11.

	Receiving:	Start Date:	Has Treatment Been Discontinued?	Stop Date:
Dexamethesone:	*(DEXARECV)* ☐ 1 - Yes ☐ 2 - No	*(DEXASTDT)* _____ *(mm/dd/yyyy)*	*(DEXADISC)* ☐ 1 - Yes ☐ 2 - No	*(DEXASPDT)* _____ *(mm/dd/yyyy)*
Thalidomide:	*(THALRECV)* ☐ 1 - Yes ☐ 2 - No	*(THALSTDT)* _____ *(mm/dd/yyyy)*	*(THALDISC)* ☐ 1 - Yes ☐ 2 - No	*(THALSPDT)* _____ *(mm/dd/yyyy)*
Lenalidomide:	*(LENARECV)* ☐ 1 - Yes ☐ 2 - No	*(LENASTDT)* _____ *(mm/dd/yyyy)*	*(LENADISC)* ☐ 1 - Yes ☐ 2 - No	*(LENASPDT)* _____ *(mm/dd/yyyy)*
Bortezomib:	*(BORTRECV)* ☐ 1 - Yes ☐ 2 - No	*(BORTSTDT)* _____ *(mm/dd/yyyy)*	*(BORTDISC)* ☐ 1 - Yes ☐ 2 - No	*(BORTSPDT)* _____ *(mm/dd/yyyy)*
Other:	*(OTHRRECV)* ☐ 1 - Yes ☐ 2 - No	*(OTHRSTDT)* _____ *(mm/dd/yyyy)*	*(OTHRDISC)* ☐ 1 - Yes ☐ 2 - No	*(OTHRSPDT)* _____ *(mm/dd/yyyy)*

12. If other anti-myeloma therapy, specify: *(MYTHOTSP)* _____

13. Record the reason for initiation of non-protocol anti-myeloma therapy: *(ATMYREAS)*

14. Has the patient experienced any new clinically significant infections? *(NEWINFX)* ☐ 1 - Yes ☐ 2 - No
If Yes, an Infection Form must be submitted.

15. Date of infection: *(INFDT)* _____ *(mm/dd/yyyy)*

16. Has the patient been hospitalized? *(HOSPITAL)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Re-Admission Form must be submitted.

17. Date of hospitalization: *(HOSPTLDT)* _____ *(mm/dd/yyyy)*

18. Has the patient received a non-protocol specified transplant? *(TRANSTWO)* ☐ 1 - Yes ☐ 2 - No

19. Date of non-protocol specified transplant: *(DATRANSP)* *(mm/dd/yyyy)*

Comments: *(FUS1COMM)*

Blood and Marrow Transplant Clinical Trials Network

Acute GVHD Form (GVH)

Web Version: 1.0; 10.04; 06-09-11

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

1. Date of staging: *(STAGEDT)* _____ *(mm/dd/yyyy)*
   Start of GVHD Assessment Period: *(GVASSTDT)* _____ *(mm/dd/yyyy)*
   End of GVHD Assessment Period: *(GVASENDT)* _____ *(mm/dd/yyyy)*

   The assessment for which you are entering data must have taken place within the above dates. If the patient was not seen during the assessment period specified above, please exit the form and request an exception for this form.
2. Immunosuppressant (prophylaxis) received: *(IMMUNORC)*

   0 - Prednisone
   1 - Cyclosporine
   2 - Tacrolimus
   3 - Not taken during assessment
3. Record most recent blood level of immunosuppressant (prophylaxis): *(TROUGHLV)* _____ *(xxxx.x)* ng/mL
4. Record date blood sample obtained: *(TROUGHDT)* _____ *(mm/dd/yyyy)*

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

5. Skin abnormalities: *(GVHSKINA)*

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

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

   Specify other skin etiologies: *(GVHSKNSP)* _____

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

   1 - Positive
   2 - Negative
   3 - Equivocal
   4 - Not Done
8. Upper GI abnormalities: *(GVHUPGIA)*

   0 - No Protracted Nausea and Vomiting
   1 - Persistent Nausea, Vomiting or Anorexia
9. Upper intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(UGIETGVH) ☐ 1 - Yes ☐ 2 - No	*(UGIETDRG)* ☐ 1 - Yes ☐ 2 - No	*(UGIETCON)* ☐ 1 - Yes ☐ 2 - No
TPN	**Infection**	**Other**
(UGIETTPN) ☐ 1 - Yes ☐ 2 - No	*(UGIETINF)* ☐ 1 - Yes ☐ 2 - No	*(UGIETOTH)* ☐ 1 - Yes ☐ 2 - No

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

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

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

11. Lower GI abnormalities: *(GVHINTA)*

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

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

12. Lower intestinal tract etiologies:

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

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

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

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

14. Liver abnormalities: *(GVHLIVRA)*

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

15. Liver etiologies:

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

Specify other liver etiologies: *(GVHLIVRS)*

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

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

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

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

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

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

Specify other agent: *(GVHAGNSP)*

19. Indicate treatment modification: *(GVHTRMOD)*

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

Comments: *(GVHCOMM)*

Additional Selection Options for GVH

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

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

Blood and Marrow Transplant Clinical Trials Network

Infection Form (INF)

Web Version: 1.0; 3.04; 04-26-11

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

INFECTION I

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

2. Organism I: *(ORGN01)*
   - B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
   - B02 - Agrobacterium radiobacter
   - B03 - Alcaligenes xylosoxidans
   - B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
   - B05 - Bacillus (cereus, other species)
   - *Additional Options Listed Below

   If other specify: *(INFSPEC1)*

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

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

INFECTION II

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

6. Organism II: *(ORGN02)*
   - B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
   - B02 - Agrobacterium radiobacter
   - B03 - Alcaligenes xylosoxidans
   - B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
   - B05 - Bacillus (cereus, other species)
   - *Additional Options Listed Below

   If other specify: *(INFSPEC2)*

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

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

INFECTION III

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

10. Organism III: *(ORGN03)*

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

If other specify: *(INFSPEC3)*

11. Record the level of certainty of the fungal infection diagnosis: *(CERTNTY3)*

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

12. Severity of infection: *(SVRTY03)*

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

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

☐ 1 - Yes ☐ 2 - No

Provide agent(s) administered for this infectious period:

14. 1st agent: *(AGENT1)*

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

15. 2nd agent: *(AGENT2)*

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

16. 3rd agent: *(AGENT3)*

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

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

☐ 1 - Yes ☐ 2 - No

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

Comments: *(INFCOM)*

Additional Selection Options for INF

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

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Medication Form (MMD)

Web Version: 1.0; 6.00; 05-28-09

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

1. Record start date of assessment period: *(MMDASTDT)* *(mm/dd/yyyy)*
2. Record end date of assessment period: *(MMDAEDDT)* *(mm/dd/yyyy)*

3. How many days during this assessment period has the patient received dexamethasone? *(DAYSDEX)* *(xx)*
4. Record total dose of dexamethasone during this assessment period: *(DEXDOSE)* *(xxx)* mg
5. Was administration of dexamethasone terminated during this assessment period? *(DEXDISCT)* ☐ 1 - Yes ☐ 2 - No
   6. Record reason dexamethasone was terminated: *(REASDXDS)*

   1 - Therapy Completed
   2 - Patient Refused
   9 - Other

   Specify other reason dexamethasone was terminated: *(RDXDSPEC)*
   7. Record date administration of dexamethasone terminated: *(DEXDISDT)* *(mm/dd/yyyy)*
   8. Record date administration of dexamethasone terminated: *(DEXDISDT)* *(mm/dd/yyyy)*

9. Record daily dose of thalidomide at the start of the assessment period: *(THALDOSE)* *(xxx)* mg/day
10. Record daily dose of thalidomide at the end of the assessment period: *(CRTHLDOS)* *(xxx)* mg/day

11. Was administration of thalidomide withheld or reduced at any time during this assessment period? *(THALWHLD)* ☐ 1 - Yes ☐ 2 - No
    12. Was thalidomide withheld or reduced due to toxicity? *(THLWHLDT)* ☐ 1 - Yes ☐ 2 - No
        13. Was the toxicity grade 3 or higher? *(THLTXGRD)* ☐ 1 - Yes ☐ 2 - No
        14. Did toxicity resolve within 72 hours? *(THLTXRSL)* ☐ 1 - Yes ☐ 2 - No
        15. Was toxicity considered life-threatening? *(THLTOXLT)* ☐ 1 - Yes ☐ 2 - No

16. Record the start date, end date and dose modifications for the time period(s) thalidomide was withheld or reduced **beginning** during this assessment period. **If thalidomide was withheld, record '0' in the 'Dose' column.**

Modification #	Start Date Thalidomide Withdrawn or Reduced	End Date Thalidomide Withdrawn or Reduced	Dose (mg/day)
#1	*(STREDCD1)* *(mm/dd/yyyy)*	*(ENDRDCD1)* *(mm/dd/yyyy)*	*(THLDOSE1)* *(xxx)*
#2	*(STREDCD2)* *(mm/dd/yyyy)*	*(ENDRDCD2)* *(mm/dd/yyyy)*	*(THLDOSE2)* *(xxx)*
#3	*(STREDCD3)* *(mm/dd/yyyy)*	*(ENDRDCD3)* *(mm/dd/yyyy)*	*(THLDOSE3)* *(xxx)*
#4	*(STREDCD4)* *(mm/dd/yyyy)*	*(ENDRDCD4)* *(mm/dd/yyyy)*	*(THLDOSE4)* *(xxx)*
#5	*(STREDCD5)* *(mm/dd/yyyy)*	*(ENDRDCD5)* *(mm/dd/yyyy)*	*(THLDOSE5)* *(xxx)*
#6	*(STREDCD6)* *(mm/dd/yyyy)*	*(ENDRDCD6)* *(mm/dd/yyyy)*	*(THLDOSE6)* *(xxx)*

17. Was administration of thalidomide terminated during this assessment period? *(THALTERM)* ☐ 1 - Yes ☐ 2 - No
    18. Record reason thalidomide was terminated: *(REASDCTD)*

    1 - Recurrence of Grade 3 or 4 Toxicity Despite Dose Reduction
    2 - Therapy Completed
    3 - Patient Refused
    9 - Other

    Specify other reason thalidomide was terminated: *(RTHDSPEC)*
    19. Record date administration of thalidomide terminated: *(THLDISDT)* *(mm/dd/yyyy)*
    20. Record date administration of thalidomide terminated: *(THLDISDT)* *(mm/dd/yyyy)*

21. Was coumadin administered during this assessment period? *(COUMADIN)* ☐ 1 - Yes ☐ 2 - No

22. Was coumadin administered for deep vein thrombosis (DVT) prophylaxis? *(DVTPROPH)*
☐ 1 - Yes ☐ 2 - No

23. Record date administration of coumadin was initiated: *(CMDNSTDT)*
(mm/dd/yyyy)

24. Was coumadin given to target the therapeutic INR? *(CMDDLYDS)*
☐ 1 - Yes ☐ 2 - No

25. Is patient currently receiving coumadin: *(CRECVCMD)*
☐ 1 - Yes ☐ 2 - No

26. Record date coumadin administration ended: *(CMDENDDT)*
(mm/dd/yyyy)

27. Will the patient receive maintenance therapy per protocol? *(MAINTST)*
☐ 1 - Yes ☐ 2 - No

28. If no, indicate the reason for not receiving maintenance therapy per protocol: *(MAINTSPR)*
1 - Patient/Physician Refused
2 - Other

29. Specify other reason: *(MSPOTHER)*

30. Date treatment with dexamethasone and thalidomide began: *(DXTHLSTD)*
(mm/dd/yyyy)

Comments: *(MMDCOMM1)*

Blood and Marrow Transplant Clinical Trials Network

Myeloma Status Form (MST)

Web Version: 1.0; 7.00; 06-10-09

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

1. Record start of assessment period: *(STASSMST)* *(mm/dd/yyyy)*
2. Record end of assessment period: *(ENDASMST)* *(mm/dd/yyyy)*
3. Indicate the patient's best disease response in this assessment period: *(BESTDZR)*
   - 1 - Complete Remission
   - 2 - Continuing Complete Remission
   - 3 - Partial Response
   - 4 - Minimal Response
   - 5 - Stable Disease
   - *Additional Options Listed Below
4. Record date best disease response established: *(BESTDXDT)* *(mm/dd/yyyy)*
5. Indicate the patient's current disease response: *(CURRDXR)*
   - 1 - Complete Remission
   - 2 - Continuing Complete Remission
   - 3 - Partial Response
   - 4 - Minimal Response
   - 5 - Stable Disease
   - *Additional Options Listed Below
6. Record date current disease response established: *(CURDXRDT)* *(mm/dd/yyyy)*

If patient's current disease status is progression or relapse, please save and exit this form and complete the Progression/Relapse Form

7. Is m-protein present in urine but not quantifiable? *(CUPEPQFB)* ☐ 1 - Yes ☐ 2 - No

If the value is 0, answer question as "2 - No" and enter "0.00" below.

8. Record most recent m-protein level in urine: *(MPROTURN)* *(xxx.xx)* g/dL
9. Record date urine m-protein level obtained: *(UMPRTDT)* *(mm/dd/yyyy)*
10. Record result of immunofixation to detect the presence of m-protein in urine: *(IMMNOURN)*
    - 1 - Positive
    - 2 - Negative
    - 3 - Not Done
11. Baseline urinary light chain excretion: *(MSTBLULC)* *(xxx.xx)* g/24h
12. Is 24-hour urinary light chain excretion present but not quantifiable? *(CURLIQFB)* ☐ 1 - Yes ☐ 2 - No

If the value is 0, answer question as "2 - No" and enter "0.00" below.

13. Record most recent urinary light chain excretion: *(URLGTLVL)* *(xxx.xx)* g/24h
14. Record date urinary light chain excretion level obtained: *(ULCEXDT)* *(mm/dd/yyyy)*
15. Has there been a reduction in the 24-hour urinary light chain excretion? *(LTCHNRED)* ☐ 1 - Yes ☐ 2 - No
16. Percent reduction of urinary light chain excretion: *(PRCRDULC)* *(xxxx)* %
17. Baseline m-protein level in serum: *(MSTBSLSR)* *(xxx.xx)* g/dL
18. Is m-protein present in serum but not quantifiable? *(CSPEPQFB)* ☐ 1 - Yes ☐ 2 - No

If value is 0, answer question as "2 - No" and enter "0.00" below.

19. Record most recent m-protein level in serum: *(SPROTLVL)* *(xxx.xx)* g/dL
20. Record date serum m-protein level obtained: *(SMPRTDT)* *(mm/dd/yyyy)*
21. Record result of immunofixation to detect m-protein in serum: *(IMMNOSRM)*
    - 1 - Positive
    - 2 - Negative
    - 3 - Not Done
22. Has there been a reduction in the m-protein serum level? *(SERMRDCT)* ☐ 1 - Yes ☐ 2 - No
23. Percent reduction in serum level of m-protein: *(PRCREDLS)* *(xxxx)* %
24. Was a bone marrow aspirate performed during this assessment period? *(BMADONE)* ☐ 1 - Yes ☐ 2 - No
25. Are plasma cells present in bone marrow aspirate, but not quantifiable? *(BMASPNQF)* ☐ 1 - Yes ☐ 2 - No

If the value is 0, answer question as "2 - No" and enter "0.00" below.

26. Record most recent percentage of plasma cells in bone marrow (aspirate): *(BMAMST)* _____ *(xxx)* %

27. Was a bone marrow biopsy performed during this assessment period? *(BMBDONE)* ☐ 1 - Yes ☐ 2 - No

28. Are plasma cells present in bone marrow biopsy, but not quantifiable? *(BMBONQFB)* ☐ 1 - Yes ☐ 2 - No

If the value is 0, answer the question as "2 - No" and enter "0.00" below.

29. Record most recent percentage of plasma cells in bone marrow (biopsy): *(BMBMST)* _____ *(xxx)* %

30. Record date bone marrow aspirate and biopsy obtained: *(BMBRDT)* _____ *(mm/dd/yyyy)*

31. Were cytogenetics performed during this assessment period? *(CYTOGENT)* ☐ 1 - Yes ☐ 2 - No

32. Record result of cytogenetic testing: *(CYTORSLT)*
1 - Normal
2 - Abnormal
3 - Test Failed

33. Was standard metaphase karyotype cytogenetic testing performed during this assessment period? *(STKARPER)* ☐ 1 - Yes ☐ 2 - No

34. Record result of standard cytogenetic testing for chromosome 13 abnormalities: *(STKARRLT)*
1 - Normal
2 - Abnormal
3 - Test Failed

35. Was FISH cytogenetic testing performed during this assessment period? *(FISHDONE)* ☐ 1 - Yes ☐ 2 - No

36. Record result of FISH cytogenetic testing for chromosome 13 abnormalities: *(FISHRSLT)*
1 - Normal
2 - Abnormal
3 - Test Failed

If results of the cytogenetic tests are abnormal, submit a copy of the report to the Data Coordinating Center at 301-251-1355. Be sure to remove the patient's name and write in the patient ID before faxing.

37. Have soft tissue plasmacytomas disappeared/resolved? *(PLSMADSP)*
1 - Yes
2 - No
3 - Not Applicable

38. Has there been a reduction in soft tissue plasmacytomas? *(PLSMARED)* ☐ 1 - Yes ☐ 2 - No

39. Record most recent percent reduction in soft tissue plasmacytomas: *(PRCNTRED)* _____ *(xxx)* %

40. Record the most current laboratory values:

	Laboratory Value	Laboratory Value Units	Date Value Obtained
Serum B2-microglobulin:	*(SRMBMGLB)* _____ *(xxxxx.xxxxx)*	*(SBMUNITS)* g/dL, mg/L	*(BSRMDT)* _____ *(mm/dd/yyyy)*
Quantitative IgG:	*(IGGMST)* _____ *(xxxxx.xxxxx)*	*(IGGUNITS)* g/dL, mg/L, mg/dL	*(IGGDT)* _____ *(mm/dd/yyyy)*
Quantitative IgA:	*(IGAMST)* _____ *(xxxxx.xxxxx)*	*(IGAUNITS)* g/dL, mg/L, mg/dL	*(IGADT)* _____ *(mm/dd/yyyy)*
Quantitative IgM:	*(IGMMST)* _____ *(xxxxx.xxxxx)*	*(IGMUNITS)* g/dL, mg/L, mg/dL	*(IGMDT)* _____ *(mm/dd/yyyy)*

Comments: *(COMMMST1)*

Additional Selection Options for MST

Indicate the patient's best disease response in this assessment period:
6 - Relapse
7 - Progression

Blood and Marrow Transplant Clinical Trials Network

NST Hematopoiesis Form (NHM)

Web Version: 1.0; 7.00; 05-24-11

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

1. Did the patient's ANC drop below 500/mm^3 after the initiation of the conditioning regimen? *(ANCDROP)* ☐ 1 - Yes ☐ 2 - No
   2. Record date ANC dropped below 500/mm^3: *(ANCDRPDT)* _____ *(mm/dd/yyyy)*
3. Did the patient's ANC recover to ≥500/mm^3? *(MDNRPRCN)* ☐ 1 - Yes ☐ 2 - No
   4. Record first day ANC ≥500/mm^3: *(ANC500DT)* _____ *(mm/dd/yyyy)*
   5. Record ANC: *(ANC500LV)* _____ *(xxxx)* /mm^3

Record Chimerism Assay Data for Marrow and/or Blood

Please upload source documents for all chimerism results during the assessment period.

Marrow:

6. Was a chimerism assay performed on a marrow sample during this assessment period? *(MRWCHMRS)* ☐ 1 - Yes ☐ 2 - No
   7. Record date specimen collected: *(MRWCOLDT)* _____ *(mm/dd/yyyy)*
   8. Record method of evaluation: *(MRWEVALM)*
      1 - Standard Cytogenetics
      2 - Fluorescent In Situ Hybridization (FISH)
      3 - Restriction Fragment-Length Polymorphisms (RFLP)
      4 - Polymerase Chain Reaction (PCR)
      5 - HLA Serotyping
      *Additional Options Listed Below
      Specify other method of evaluation: *(NHMSPEC1)* _____
   9. Record marrow chimerism cell type: *(CELLTYPE)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes
   10. Record marrow assay results: *(ASSYRSLT)*
      1 - All Host Cells
      2 - All Donor Cells
      3 - Host and Donor
      %
   11. Record % donor: *(MDNRPRCT)* _____ *(xx)* %

Blood:

12. Was a chimerism assay performed on a blood sample during this assessment period? *(BLDCHMRS)* ☐ 1 - Yes ☐ 2 - No
   13. Record date specimen collected: *(BLDCHMDT)* _____ *(mm/dd/yyyy)*
   14. Record method of evaluation: *(BLDEVALM)*
      1 - Standard Cytogenetics
      2 - Fluorescent In Situ Hybridization (FISH)
      3 - Restriction Fragment-Length Polymorphisms (RFLP)
      4 - Polymerase Chain Reaction (PCR)
      5 - HLA Serotyping
      *Additional Options Listed Below
      Specify other method of evaluation: *(NHMSPEC2)* _____
   15. Record blood chimerism cell type: *(BLDCLTYP)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes
   16. Record blood assay results: *(BLDARSLT)*
      1 - All Host Cells
      2 - All Donor Cells
      3 - Host and Donor
   17. Record % donor: *(BDNRPRCT)* _____ *(xx)*

T Cell:

18. Was a chimerism assay performed on a T cell sample during this assessment period? *(TCLCHRSM)* ☐ 1 - Yes ☐ 2 - No
   19. Record the type of T cell sample: *(SMPLTYPE)* ☐ 1 - Blood ☐ 2 - Marrow
   20. Record date specimen collected: *(TCLSPCDT)* _____ *(mm/dd/yyyy)*

21. Record method of evaluation: *(TCLEVALM)*

1 - Standard Cytogenetics
2 - Fluorescent In Situ Hybridization (FISH)
3 - Restriction Fragment-Length Polymorphisms (RFLP)
4 - Polymerase Chain Reaction (PCR)
5 - HLA Serotyping
*Additional Options Listed Below

Specify other method of evaluation: *(NHMSPEC3)*

22. Record T cell assay results: *(TCLRSLTS)*

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

23. Record % donor: *(TCLDNRPC)*

(xx)

Comments: *(NHMCOMM1)*

Additional Selection Options for NHM

Record method of evaluation:
9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Post 1st Autologous Transplant Checklist (PAC)

Web Version: 1.0; 6.00; 04-20-09

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

1. Treatment arm: *(RXBARM)* ☐ 1 - Autologous/Allogeneic ☐ 2 - Tandem Autologous +/- Dex/Thal
2. Record proposed date of initiation of conditioning regimen: *(PRPCNDDT)* _____ *(mm/dd/yyyy)*
3. Record proposed date of allogeneic or tandem autologous transplant: *(PRPTXDTB)* _____ *(mm/dd/yyyy)*

Inclusion Criteria

4. Has mucositis resolved? *(MUCORESL)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
5. Is the patient currently receiving hyperalimentation? *(RCVHYPRL)* ☐ 1 - Yes ☐ 2 - No
6. Is the patient currently receiving intravenous hydration? *(RCVHYDRT)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value	ULN for your Institution	Date Sample Obtained
7. Bilirubin:	*(BILIRBNB)* _____ *(xx.x)* mg/dL	*(BILIULNC)* _____ *(xx.x)* mg/dL	*(BILIDTB)* _____ *(mm/dd/yyyy)*
8. ALT:	*(ALTB)* _____ *(xxx)* Units/L	*(ALTULNB)* _____ *(xxx)* Units/L	*(ALTDTB)* _____ *(mm/dd/yyyy)*
9. AST:	*(ASTB)* _____ *(xxx)* Units/L	*(ASTULNB)* _____ *(xxx)* Units/L	*(ASTDTB)* _____ *(mm/dd/yyyy)*

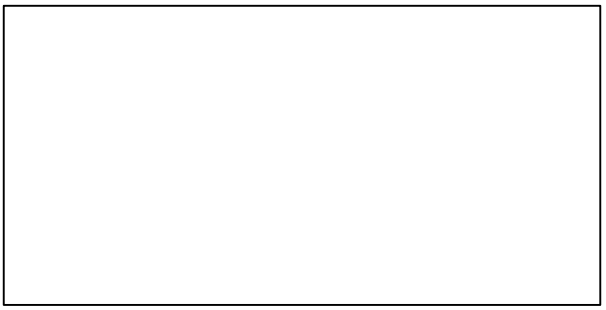
10. Record creatinine clearance: *(CREATCLB)* _____ *(xxx)* ml/min
11. Record date creatinine clearance sample obtained: *(CRCLDTB)* _____ *(mm/dd/yyyy)*
12. Is the patient currently taking intravenous antibiotics? *(IVANTCRT)* ☐ 1 - Yes ☐ 2 - No
13. Is the patient currently taking any amphotericin B formulations or voriconazole for possible, probable, or proven fungal infections? *(AMPHOCRT)* ☐ 1 - Yes ☐ 2 - No
14. Did the patient receive radiation therapy post-autologous transplant? *(RDIATION)* ☐ 1 - Yes ☐ 2 - No
    15. Record date radiation therapy ended: *(RADENDDT)* _____ *(mm/dd/yyyy)*

16. Were Pulmonary Function Tests performed? *(PLMNFUNC)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value Corrected for Hemoglobin:	Date Sample Obtained
17. DLCO:	*(DLCOC)* _____ *(xxx)* % of predicted value	*(DLCODTB)* _____ *(mm/dd/yyyy)*
18. FEV1:	*(FEV1C)* _____ *(xxx)* % of predicted value	*(FEV1DTB)* _____ *(mm/dd/yyyy)*
19. FVC:	*(FVCC)* _____ *(xxx)* % of predicted value	*(FVCDTB)* _____ *(mm/dd/yyyy)*

20. O_2 saturation on room air: *(O2SATUR)* _____ *(xxx)* Date O_2 saturation was obtained: *(O2SADT)* _____ *(mm/dd/yyyy)*
21. Did the patient develop symptoms of cardiac insufficiency post-autologous transplant? *(CARDIACB)* ☐ 1 - Yes ☐ 2 - No
    22. Record the left ventricular ejection fraction at rest: *(VENTEFB)* _____ *(xxx)* %
    23. Record date ejection fraction performed: *(EJFRCDTB)* _____ *(mm/dd/yyyy)*
24. Is the patient pregnant (positive β-HCG) or breastfeeding? *(PACPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

Comments: *(COMMPAC)*



Blood and Marrow Transplant Clinical Trials Network

Progression/Relapse Form - 0102 (PRG)

Web Version: 1.0; 7.00; 04-20-09

Segment *(PROTSEG)*:
Date of Progress/Relapse *(PRGRLPDT)*:

1. Record reason for form completion: *(DXSTPRG)* ☐ 1 - Progression ☐ 2 - Relapse

2. Record the following values from the patient's BEST disease response obtained post-transplant:

	Are Protein/Plasma Cells Present But Not Quantifiable? *(If the value is 0, answer as "2 - No" and enter "0.00" as the value.)*	Laboratory Value
Serum m-protein (g/dL):	*(SRMQFBLE)* ☐ 1 - Yes ☐ 2 - No	*(SRMRCNTV)* _____ *(xxx.xx)*
Urinary light chain excretion (g/24h):	*(URNQFBLE)* ☐ 1 - Yes ☐ 2 - No	*(URNRCNTV)* _____ *(xxx.xx)*
Urine m-protein (g/dL):	*(URMQFBLE)* ☐ 1 - Yes ☐ 2 - No	*(URNMPROT)* _____ *(xxx.xx)*
Percent plasma cells (%):	*(PLSQFBLE)* ☐ 1 - Yes ☐ 2 - No	*(PLSMRCTV)* _____ *(xxx)*

Questions 4-23 relate ONLY to patients who have relapsed

3. Was there a re-appearance of serum m-protein? *(SRMRAPP)* ☐ 1 - Yes ☐ 2 - No
4. Was the re-appearance of serum m-protein seen on two consecutive investigations? *(SRMRTWO)* ☐ 1 - Yes ☐ 2 - No
5. Was the re-appearance of serum m-protein diagnosed by immunofixation? *(SRMRIMMN)* ☐ 1 - Yes ☐ 2 - No
6. Was the re-appearance of serum m-protein diagnosed by routine electrophoresis? *(SERMRELE)* ☐ 1 - Yes ☐ 2 - No
7. Record date initial test indicating relapse was performed: *(SERMR1DT)* _____ *(mm/dd/yyyy)*
8. Is m-protein present in serum but not quantifiable? *(SM1DTQFB)* ☐ 1 - Yes ☐ 2 - No

If value is 0, answer question as "2 - No" and enter "0.00" below.

9. Record initial serum m-protein value indicating relapse: *(SERMR1RS)* _____ *(xxx.xx)* g/dL
10. Record date confirmatory test indicating relapse was performed: *(SERMR2DT)* _____ *(mm/dd/yyyy)*
11. Is m-protein present in serum but not quantifiable in confirmatory test? *(SM2DTQFB)* ☐ 1 - Yes ☐ 2 - No

If value is 0, answer question as "2 - No" and enter "0.00" below.

12. Record confirmatory serum m-protein value indicating relapse: *(SERMR2RS)* _____ *(xxx.xx)* g/dL

13. Was there a re-appearance of urine m-protein? *(URNRAPP)* ☐ 1 - Yes ☐ 2 - No
14. Was the re-appearance of urine m-protein seen on two consecutive investigations? *(URNRTWO)* ☐ 1 - Yes ☐ 2 - No
15. Was the re-appearance of urine m-protein diagnosed by immunofixation? *(URNRIMMN)* ☐ 1 - Yes ☐ 2 - No
16. Was the re-appearance of urine m-protein diagnosed by routine electrophoresis? *(URNRELEC)* ☐ 1 - Yes ☐ 2 - No
17. Record date initial test indicating relapse was performed: *(URINR1DT)* _____ *(mm/dd/yyyy)*
18. Is m-protein present in urine but not quantifiable? *(UR1DTQFB)* ☐ 1 - Yes ☐ 2 - No

If value is 0, answer question as "2 - No" and enter "0.00" below.

19. Record initial urine m-protein value indicating relapse: *(URINR1RS)* _____ *(xxx.xx)* g/dL
20. Record date confirmatory test indicating relapse was performed: *(URINR2DT)* _____ *(mm/dd/yyyy)*
21. Is m-protein present in urine but not quantifiable in confirmatory test? *(UR2DTQFB)* ☐ 1 - Yes ☐ 2 - No

If value is 0, answer question as "2 - No" and enter "0.00" below.

22. Record confirmatory urine m-protein value indicating relapse: *(URINR2RS)* _____ *(xxx.xx)* g/dL

Questions 24-39 relate ONLY to patients who have progressed

23. Has the level of the serum m-protein increased by >25% from the BEST disease response post-transplant? *(SERMPROT)* ☐ 1 - Yes ☐ 2 - No

24. Was the increase in serum m-protein seen on two consecutive investigations? *(SRMPTWO)* ☐ 1 - Yes ☐ 2 - No

25. Record date initial test indicating progression was performed: *(SERMP1DT)* _____ *(mm/dd/yyyy)*

26. Record initial serum m-protein value indicating progression: *(SERMP1RS)* _____ *(xxx.xx)* g/dL

27. Record date confirmatory test indicating progression was performed: *(SERMP2DT)* _____ *(mm/dd/yyyy)*

28. Record confirmatory serum m-protein value indicating progression: *(SERMP2RS)* _____ *(xxx.xx)* g/dL

29. Percent increase: *(SSPRCPIN)* _____ *(xxxx)* %

30. Absolute increase: *(SSABSPIN)* _____ *(xxx.xx)* g/dL

31. Has the 24 hour urinary light chain excretion increased by >25% from the BEST disease response post-transplant? *(URINLCHP)* ☐ 1 - Yes ☐ 2 - No

32. Was the increase in urinary light chain excretion seen on two consecutive investigations? *(URNPTWO)* ☐ 1 - Yes ☐ 2 - No

33. Record date initial test indicating progression was performed: *(URINP1DT)* _____ *(mm/dd/yyyy)*

34. Record initial urinary light chain excretion value indicating progression: *(URINP1RS)* _____ *(xxx.xx)* g/24h

35. Record date confirmatory test indicating progression was performed: *(URINP2DT)* _____ *(mm/dd/yyyy)*

36. Record confirmatory urinary light chain excretion value indicating progression: *(URINP2RS)* _____ *(xxx.xx)* g/24h

37. Percent increase: *(SUPRCPIN)* _____ *(xxxx)* %

38. Absolute increase: *(SUABSPIN)* _____ *(xxx.xx)* g/24 hours

Questions 40-51 relate to patients who have relapsed or progressed

39. Have the plasma cells in a bone marrow aspirate or on a biopsy increased? *(PLASMAIN)* ☐ 1 - Yes ☐ 2 - No

40. Was the increase in plasma cells seen on two consecutive investigations? *(PLSMATWO)* ☐ 1 - Yes ☐ 2 - No

41. Record date initial test indicating progression/relapse was performed: *(PLSMR1DT)* _____ *(mm/dd/yyyy)*

42. Record initial percentage of plasma cells indicating progression/relapse: *(PLSM1RST)* _____ *(xxx)* %

43. Record date confirmatory test indicating progression/relapse was performed: *(PLSMR2DT)* _____ *(mm/dd/yyyy)*

44. Record confirmatory percentage of plasma cells indicating progression/relapse: *(PLSM2RST)* _____ *(xxx)* %

45. Percent increase: *(SPPRCNIN)* _____ *(xxxx)* %

46. Absolute increase: *(SPABSIN)* _____ *(xxx)* %

47. Record most recent information regarding lytic bone lesions: *(BONELESN)*

1 - No Change
2 - New Lytic Bone Lesions
3 - Definite Size Increase of Existing Lytic Bone Lesions
4 - Both, New and Definite Size Increase

48. Record most recent information regarding soft tissue plasmacytomas: *(PLASMACY)*

1 - No Change
2 - New Plasmacytomas
3 - Definite Size Increase of Existing Plasmacytomas
4 - Both, New and Definite Size Increase

49. Record most recent corrected serum calcium value: *(SERUMCLC)* _____ *(xx.x)* *(SRMCLUNT)* ☐ 1 - mg/dL ☐ 2 - mmol/L

50. Record date corrected serum calcium sample obtained: *(SERMCLDT)* _____ *(mm/dd/yyyy)*

Treatment for Progression/Relapse

51. Has the patient been treated for progression/relapse? *(TRTPRGRL)* ☐ 1 - Yes ☐ 2 - No

52. Date treatment administered: *(TRTADMDT)* _____ *(mm/dd/yyyy)*

53. Indicate type of treatment: *(TYPTREAT)*

1 - DLI
2 - PBSCs
3 - Chemotherapy
4 - Radiation
5 - Second Transplant
*Additional Options Listed Below

Specify other treatment: *(OTHTREAT)* _____

Comments: *(PRG1COMM)*

Additional Selection Options for PRG

Indicate type of treatment:
6 - Other Cellular Therapy
7 - Other

Blood and Marrow Transplant Clinical Trials Network

Post Tandem Autologous Transplant Checklist (PTC)

Web Version: 1.0; 3.00; 06-10-09

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

Patients assigned to the Autologous/Allogeneic Transplant Arm are NOT required to complete this form. Please exit the form without saving.

Answer the following questions regarding patient recovery from the tandem autologous transplant.

1. Has mucositis resolved? *(MUCRSPTC)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
2. Is the patient currently receiving hyperalimentation? *(RVHYPPTC)* ☐ 1 - Yes ☐ 2 - No
3. Is the patient currently receiving intravenous hydration? *(RVHYDPTC)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value	ULN for your Institution	Date Sample Obtained
4. Bilirubin:	*(BILIPTC)* *(xx.x)* mg/dL	*(BILULPTC)* *(xx.x)* mg/dL	*(BILDTPTC)* *(mm/dd/yyyy)*
5. ALT:	*(ALTPTC)* *(xxx)* Units/L	*(ALTULPTC)* *(xxx)* Units/L	*(ALTDTPTC)* *(mm/dd/yyyy)*
6. AST:	*(ASTPTC)* *(xxx)* Units/L	*(ASTULPTC)* *(xxx)* Units/L	*(ASTDTPTC)* *(mm/dd/yyyy)*

7. Record creatinine clearance: *(CRCLPTC)* *(xxx)* ml/min
8. Record date creatinine clearance sample obtained: *(CCLDTPTC)* *(mm/dd/yyyy)*
9. Is the patient currently taking intravenous antibiotics? *(IVANTPTC)* ☐ 1 - Yes ☐ 2 - No
10. Is the patient currently taking any amphotericin B formulations or voriconazole for possible, probable, or proven fungal infections? *(AMPHOPTC)* ☐ 1 - Yes ☐ 2 - No
11. Did the patient receive radiation therapy post-tandem autologous transplant? *(RADPTC)* ☐ 1 - Yes ☐ 2 - No
    12. Record date radiation therapy ended: *(RDEDTPTC)* *(mm/dd/yyyy)*
13. Is the patient pregnant (positive β-HCG) or breastfeeding? *(PTCPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

Comments: *(PTCCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Specimen Acquisition Form - 0102 (SAM)

Web Version: 1.0; 3.00; 04-20-09

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

Disease Assessment Samples for Future Testing - Serum and Peripheral Blood Mononuclear Cells (PBMCs)

1. Was a serum sample drawn for future testing during this assessment period? *(SERUMCOL)* ☐ 1 - Yes ☐ 2 - No
2. If yes, record the date the serum sample was obtained: *(SRMCOLDT)* _____ *(mm/dd/yyyy)*

3. Was a PBMC sample drawn for future testing during this assessment period? *(NUCCLCOL)* ☐ 1 - Yes ☐ 2 - No
4. If yes, record the date the PBMC sample was collected: *(NCSCLCDT)* _____ *(mm/dd/yyyy)*

Donor Allograft Peripheral Blood Stem Cell (PBSC) Sample

5. Was a PBSC sample taken from the allogeneic stem cell product for future testing? *(DNCSCLCT)* ☐ 1 - Yes ☐ 2 - No
6. If yes, record the date the PBSC sample was collected: *(DNRNCSDT)* _____ *(mm/dd/yyyy)*

Comments: *(SAMCOMM1)*

Blood and Marrow Transplant Clinical Trials Network

SF36 Quality of Life (SFH)

Web Version: 1.0; 3.03; 08-16-10

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

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

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

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

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

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

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

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

Activities	Amount of Limitation
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	*(VIGOROUS)* 1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all; 9 - Subject did not complete
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	*(MODERATE)* 1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all; 9 - Subject did not complete
c. Lifting or carrying groceries	*(LIFTING)* 1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all; 9 - Subject did not complete
d. Climbing several flights of stairs	*(CLINBSEV)* 1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all; 9 - Subject did not complete
e. Climbing one flight of stairs	*(CLIMBONE)* 1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all; 9 - Subject did not complete
f. Bending, kneeling, or stooping	*(BENDING)* 1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all; 9 - Subject did not complete

g. Walking more than one mile

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

h. Walking several hundred yards

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

i. Walking one hundred yards

(WALK1BLK)
1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

j. Bathing or dressing yourself

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

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

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

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

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

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

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

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

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

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

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

a. Cut down on the amount of time you spent on work or other activities

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

b. Accomplished less than you would like

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

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

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

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

(PRFMDIFF)

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

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

a. Cut down on the amount of time you spent on work or other activities

(ECUTTIME)

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

b. Accomplished less than you would like

(ELESSACC)

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

c. Did work or other activities less carefully than usual

(ECARELES)

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

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

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

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

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

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

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

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

a. Did you feel full of pep?

(FULLPEP)

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

b. Have you been a very nervous person?

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

(NERVOUS)

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

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

(DUMPS)

d. Have you felt calm and peaceful?

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

(CALM)

e. Did you have a lot of energy?

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

(LOTSNRG)

f. Have you felt downhearted and blue?

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

(BLUE)

g. Did you feel worn out?

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

(WORNOUT)

h. Have you been a happy person?

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

(HAPPY)

i. Did you feel tired?

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

(TIRED)

j. Did you feel full of life?

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

(FULLLIFE)

k. Have you been very nervous?

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

(FEELNERV)

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

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

(FEELDOWN)

m. Have you felt calm and peaceful?

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

(FEELCALM)

n. Did you have a lot of energy?

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

(FLENERGY)

o. Have you felt downhearted and depressed?

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

(FEELDEPR)

p. Did you feel worn out?

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

(FEELWORN)

q. Have you been happy?

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

(FEELHAP)

r. Did you feel tired?

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

(FEELTIR)

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

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

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

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

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

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

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

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

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

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

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

d. My health is excellent *(EXCLNT)*

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

Additional Selection Options for SFH

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

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

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

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Secondary Graft Failure Form (SGF)

Web Version: 1.0; 3.01; 05-10-11

Segment *(PROTSEG)*:

1. Did the patient achieve engraftment, defined as >5% donor chimerism by Day 56 post HSCT? *(PREVENGR)* ☐ 1 - Yes ☐ 2 - No
2. Did the patient subsequently experience secondary graft failure, defined as <5% donor chimerism? *(LOSTGRFT)* ☐ 1 - Yes ☐ 2 - No
3. Record date of collection of the sample indicating secondary graft failure: *(TCCHIMDT)* _____ *(mm/dd/yyyy)*
4. Record type of sample: *(CHSAMTYP)* ☐ 1 - Blood ☐ 2 - Marrow
5. Record method of evaluation: *(TCMETSFG)*

   1 - Standard Cytogenetics
   2 - Fluorescent In Situ Hybridization (FISH)
   3 - Restriction Fragment-Length Polymorphisms (RFLP)
   4 - Polymerase Chain Reaction (PCR)
   5 - HLA Serotyping
   *Additional Options Listed Below
6. Specify other method of evaluation: *(TCMETSPE)* _____
7. Record percent donor cell: *(TCPERDNR)* _____ *(x)* %

Comments: *(SGFCOMM)*

Additional Selection Options for SGF

Record method of evaluation:
9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Sibling Information Form (SIB)

Web Version: 1.0; 3.00; 04-20-09

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

1. Number of living siblings patient has: *(LIVSIBS)* ☐☐ *(xx)*
2. Number of living siblings that were HLA typed: *(SIBTYPED)* ☐☐ *(xx)*
3. Number of living HLA-identical siblings patient has: *(ANYHLAS1)* ☐☐ *(xx)*

For each living sibling who was NOT HLA typed, indicate the reason why:

4. 1st sibling that was not HLA typed: *(RNOTYPE1)*

01 - Sibling Refused
02 - Sibling Did Not Fall Within the Age Limits
03 - Sibling and Patient are Identical Twins
04 - Sibling is Pregnant or Breastfeeding
05 - Sibling Has History of Infectious Disease as Listed in Protocol Exclusion Criteria
*Additional Options Listed Below

Specify other reason: *(SIB1SPEC)*

5. 2nd sibling that was not HLA typed: *(RNOTYPE2)*

01 - Sibling Refused
02 - Sibling Did Not Fall Within the Age Limits
03 - Sibling and Patient are Identical Twins
04 - Sibling is Pregnant or Breastfeeding
05 - Sibling Has History of Infectious Disease as Listed in Protocol Exclusion Criteria
*Additional Options Listed Below

Specify other reason: *(SIB2SPEC)*

6. 3rd sibling that was not HLA typed: *(RNOTYPE3)*

01 - Sibling Refused
02 - Sibling Did Not Fall Within the Age Limits
03 - Sibling and Patient are Identical Twins
04 - Sibling is Pregnant or Breastfeeding
05 - Sibling Has History of Infectious Disease as Listed in Protocol Exclusion Criteria
*Additional Options Listed Below

Specify other reason: *(SIB3SPEC)*

For each HLA-identical sibling who did NOT donate peripheral blood stem cells to the patient, answer the following questions:

1st HLA-identical sibling:

7. Did the sibling consent to take part in the study? *(SIB1CONS)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Approached
8. Record the sibling's birthdate: *(SIB1BDAY)* ☐☐☐☐☐☐☐☐ *(mm/dd/yyyy)*
9. Are the sibling and patient identical twins? *(IDENT1TW)* ☐ 1 - Yes ☐ 2 - No
10. Is the sibling pregnant (positive β-HCG) or breastfeeding? *(SIB1PREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
11. Is the sibling HIV seropositive? *(SIB1HIVP)* ☐ 1 - Yes ☐ 2 - No
12. Is the sibling hepatitis B surface antigen positive? *(SIB1HEPB)* ☐ 1 - Yes ☐ 2 - No
13. Is the sibling hepatitis C positive? *(SIB1HEPC)* ☐ 1 - Yes ☐ 2 - No
14. Does the sibling have a known allergy to G-CSF? *(SIB1GCSF)* ☐ 1 - Yes ☐ 2 - No
15. Does the sibling currently have a serious systemic illness? *(SIB1SYS)* ☐ 1 - Yes ☐ 2 - No
16. Does the sibling have an uncontrolled viral, bacterial or fungal infection? *(SIB1UINF)* ☐ 1 - Yes ☐ 2 - No
17. Is the sibling currently receiving experimental therapy or an investigational drug? *(SIB1EXTH)* ☐ 1 - Yes ☐ 2 - No
18. Does the sibling have a history of any malignant disease other than treated basal cell carcinoma or cervical carcinoma in situ? *(SIB1CNCR)*

1 - Yes
2 - Yes, Approved by Study Chair/MM
3 - No

19. Record reason sibling did not donate peripheral blood stem cells to patient? *(SIB1NSTD)*

2nd HLA-identical sibling:

20. Did the sibling consent to take part in the study? *(SIB2CONS)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Approached
21. Record the sibling's birthdate: *(SIB2BDAY)* _____ *(mm/dd/yyyy)*
22. Are the sibling and patient identical twins? *(IDENT2TW)* ☐ 1 - Yes ☐ 2 - No
23. Is the sibling pregnant (positive β-HCG) or breastfeeding? *(SIB2PREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
24. Is the sibling HIV seropositive? *(SIB2HIVP)* ☐ 1 - Yes ☐ 2 - No
25. Is the sibling hepatitis B surface antigen positive? *(SIB2HEPB)* ☐ 1 - Yes ☐ 2 - No
26. Is the sibling hepatitis C positive? *(SIB2HEPC)* ☐ 1 - Yes ☐ 2 - No
27. Does the sibling have a known allergy to G-CSF? *(SIB2GCSF)* ☐ 1 - Yes ☐ 2 - No
28. Does the sibling currently have a serious systemic illness? *(SIB2SYSI)* ☐ 1 - Yes ☐ 2 - No
29. Does the sibling have an uncontrolled viral, bacterial or fungal infection? *(SIB2UINF)* ☐ 1 - Yes ☐ 2 - No
30. Is the sibling currently receiving experimental therapy or an investigational drug? *(SIB2EXTH)* ☐ 1 - Yes ☐ 2 - No
31. Does the sibling have a history of any malignant disease other than treated basal cell carcinoma or cervical carcinoma in situ? *(SIB2CNCR)*

```
1 - Yes
2 - Yes, Approved by Study Chair/MM
3 - No
```

32. Record reason sibling did not donate peripheral blood stem cells to patient? *(SIB2NSTD)* _____

3rd HLA-identical sibling:

33. Did the sibling consent to take part in the study? *(SIB3CONS)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Approached
34. Record sibling's birthdate: *(SIB3BDAY)* _____ *(mm/dd/yyyy)*
35. Are the sibling and patient identical twins? *(IDENT3TW)* ☐ 1 - Yes ☐ 2 - No
36. Is the sibling pregnant (positive β-HCG) or breastfeeding? *(SIB3PREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
37. Is the sibling HIV seropositive? *(SIB3HIV)* ☐ 1 - Yes ☐ 2 - No
38. Is the sibling hepatitis B surface antigen positive? *(SIB3HEPB)* ☐ 1 - Yes ☐ 2 - No
39. Is the sibling hepatitis C positive? *(SIB3HEPC)* ☐ 1 - Yes ☐ 2 - No
40. Does the sibling have a known allergy to G-CSF? *(SIB3GCSF)* ☐ 1 - Yes ☐ 2 - No
41. Does the sibling currently have a serious systemic illness? *(SIB3SYSI)* ☐ 1 - Yes ☐ 2 - No
42. Does the sibling have an uncontrolled viral, bacterial or fungal infection? *(SIB3UINF)* ☐ 1 - Yes ☐ 2 - No
43. Is the sibling currently receiving experimental therapy or an investigational drug? *(SIB3EXTH)* ☐ 1 - Yes ☐ 2 - No
44. Does the sibling have a history of any malignant disease other than treated basal cell carcinoma or cervical carcinoma in situ? *(SIB3CNCR)*

```
1 - Yes
2 - Yes, Approved by Study Chair/MM
3 - No
```

45. Record reason sibling did not donate peripheral blood stem cells to patient? *(SIB3NSTD)* _____

Comments: *(SIB1COMM)*

Additional Selection Options for SIB

1st sibling that was not HLA typed:
06 - Sibling Has a Known Allergy to G-CSF
07 - Sibling Currently Has a Systemic Illness
08 - Sibling Has an Uncontrolled Infection
09 - Sibling is Currently Receiving an Experimental Therapy
10 - Sibling Has a History of Malignant Disease
99 - Other

Blood and Marrow Transplant Clinical Trials Network

Single Transplant Follow Up Form (STF)

Web Version: 1.0; 2.00; 04-20-09

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

1. Has the patient died? *(STFDIED)* ☐ 1 - Yes ☐ 2 - No
   If Yes, a Death Form must be submitted.
   2. Date of patient death: *(STFDTHDT)* _____ *(mm/dd/yyyy)*
3. Has the patient relapsed or experienced disease progression? *(STFRLPSE)* ☐ 1 - Yes ☐ 2 - No
   If Yes, a Progression/Relapse Form must be submitted.
   4. Date of relapse or progression: *(STFRLPDT)* _____ *(mm/dd/yyyy)*
5. Indicate the patient's current disease status: *(STFDISST)*
   1 - Complete Remission
   2 - Continuing Complete Remission
   3 - Partial Response
   4 - Minimal Response
   5 - Stable Disease
   *Additional Options Listed Below
6. Did the patient receive therapy during this assessment period? *(STFTHRPY)* ☐ 1 - Yes ☐ 2 - No
   7. Indicate type of therapy: *(STFTHTYP)*
   1 - Thalidomide
   2 - Dexamethasone
   3 - Dex And Thal
   9 - Other
   8. If other, specify: *(STFOTHSP)* _____
   9. Start date of therapy: *(STFTHSDT)* _____ *(mm/dd/yyyy)*
   10. Is the patient currently receiving therapy? *(STFCRTTH)* ☐ 1 - Yes ☐ 2 - No
   11. End date of therapy: *(STFETHDT)* _____ *(mm/dd/yyyy)*

Reminder: Adverse events must be reported for patients who do not receive a second transplant.

Comments: *(STFCMMTS)*

Additional Selection Options for STF

Indicate the patient's current disease status:
6 - Relapse
7 - Progression

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0102 (TX1)

Web Version: 1.0; 3.00; 04-20-09

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

1. Record date of evaluation: *(TX1ASSDT)* _____ *(mm/dd/yyyy)*

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

Neurologic Toxicity

2. Tremors: *(TX1NTRMS)*
   - 0 - Grades 0-2
   - 3 - Severe Tremor Interfering with ADL
   - 4 - Disabling

3. Ataxia: *(TX1ATXIA)*
   - 0 - Grades 0-2
   - 3 - Symptomatic, Interfering with ADL; Mechanical Assistance Indicated
   - 4 - Disabling
   - 5 - Death

4. Somnolence: *(TX1SMNLN)*
   - 0 - Grades 0-2
   - 3 - Obtundation or Stupor; Difficult to Arouse; Interfering with ADL
   - 4 - Coma
   - 5 - Death

5. Neuropathy - motor: *(TX1MOTOR)*
   - 0 - Grades 0-2
   - 3 - Weakness Interfering with ADL; Bracing or Assistance to Walk Indicated
   - 4 - Life-Threatening; Disabling (e.g., Paralysis)
   - 5 - Death

6. Neuropathy - sensory: *(TX1SENSR)*
   - 0 - Grades 0-2
   - 3 - Sensory Alteration or Paresthesia Interfering with ADL
   - 4 - Disabling
   - 5 - Death

7. Did the patient experience any seizures during this assessment period? *(TX1SEIZR)*
   - ☐ 1 - Yes
   - ☐ 2 - No

   8. Record seizure toxicity grade: *(TX1SZGRD)*
      - 2 - One Brief Generalized Seizure; Seizure(s) Well Controlled by Anticonvulsants
      - 3 - Seizures in Which Consciousness is Altered; Poorly Controlled Seizure Disorder
      - 4 - Seizures of Any Kind Which are Prolonged, Repetitive or Difficult to Control
      - 5 - Death

Cardiovascular Toxicity

9. Hypertension: *(TX1HYPRC)*
   - 0 - Grades 0-2
   - 3 - Requiring More than One Drug or More Intensive Therapy than Previously
   - 4 - Life-Threatening Consequences (e.g., Hypertensive Crisis)
   - 5 - Death

10. Hypotension: *(TX1HYPO1)*
    - 0 - Grades 0-2
    - 3 - Sustained (> or = 24 Hours) Therapy, Resolves Without Persisting Physiologic Consequences
    - 4 - Shock (e.g., Acidemia; Impairment of Vital Organ Function)
    - 5 - Death

11. Left ventricular systolic dysfunction: *(TX1LVSD)*
    - 0 - Grades 0-2
    - 3 - Symptomatic CHF Responsive to Intervention
    - 4 - Refractory CHF or Poorly Controlled; Intervention with Ventricular Assist Device
    - 5 - Death

12. Cardiac arrhythmia: *(TX1CRDAR)*
    - 0 - Grades 0-2
    - 3 - Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
    - 4 - Life-Threatening; Disabling (e.g., Arrhythmia Associated with CHF, Syncope, Shock)
    - 5 - Death

GI Toxicity

13. Constipation: *(TX1CNSTP)*

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

14. Ulcers: *(TX1ULCER)*

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

15. Mucositis/stomatitis (clinical exam): *(TX1MUCOS)*

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

Renal Toxicity

16. Did the patient experience renal failure severe enough to warrant dialysis? *(TX1RNLFL)* ☐ 1 - Yes ☐ 2 - No

17. Did the patient receive dialysis? *(TX1DIALY)* ☐ 1 - Yes ☐ 2 - No

18. Hemorrhagic cystitis: *(TX1CYSTI)*

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

	Peak Value During Interval	ULN for your Institution	Date Sample Obtained
19. Creatinine:	*(TX1CREAT)* *(xx.x)* mg/dL	*(TX1ULNCR)* *(xx.x)* mg/dL	*(TX1CRTDT)* *(mm/dd/yyyy)*

Coagulation Toxicity

20. HUS/TTP/thrombotic microangiopathy: *(TX1DCTTP)*

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

Metabolic Toxicity

21. Hyperglycemia: *(TX1HYPGL)*

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

Hepatobiliary/Pancreas Toxicity

22. Pancreatitis: *(TX1PANCR)*

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

Hemorrhagic Toxicity

23. Hemorrhage: *(TX1HEMRH)*

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

Vascular Toxicity

24. Vascular leak syndrome: *(TX1VASCL)*

0 - Grades 0-3
4 - Life-Threatening; Pressor Support or Ventilatory Support Indicated
5 - Death

25. Thrombosis/thrombus/embolism: *(TX1THRMB)*

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

Pulmonary Toxicity

26. Hypoxia (for more than 24 hours): *(TX1HYPX1)*

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

27. Dyspnea: *(TX1DYSPN)*

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

28. During this assessment period, was an FEV1 performed? *(TX1FEVDN)* ☐ 1 - Yes ☐ 2 - No

29. Record FEV1 value obtained: *(TX1FEVLV)* _____ *(xxx)* % of predicted value

30. During this assessment period, was an FVC performed? *(TX1FVCDN)* ☐ 1 - Yes ☐ 2 - No

31. Record the FVC value obtained: *(TX1FVCLV)* _____ *(xxx)* % of predicted value

Hepatic Toxicity

32. Bilirubin: *(TX1BILIR)*

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

33. Alkaline phosphatase: *(TX1ALKPH)*

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

34. Did the patient develop abnormal liver function during this assessment period? *(TX1LVRTX)* ☐ 1 - Yes ☐ 2 - No

Did the patient develop any of the following clinical signs/symptoms of abnormal liver function during this assessment period?

35. Jaundice: *(TX1JANDC)* ☐ 1 - Yes ☐ 2 - No

36. Hepatomegaly: *(TX1HEPTM)* ☐ 1 - Yes ☐ 2 - No

37. Right upper quadrant pain: *(TX1QUADP)* ☐ 1 - Yes ☐ 2 - No

38. Weight gain (>5%) from baseline: *(TX1WGTGN)* ☐ 1 - Yes ☐ 2 - No

39. Other clinical signs/symptoms of abnormal liver function: *(TX1OTHSS)* ☐ 1 - Yes ☐ 2 - No

Specify other clinical signs/symptoms: *(TX1SPEC1)* _____

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

	Etiology	Biopsy Results	Doppler Ultrasound Results
VOD:	*(TX1VODET)* 1 - Yes 2 - No	*(TX1VODBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX1VODDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
GVHD:	*(TX1GVHET)* 1 - Yes 2 - No	*(TX1GVHBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX1GVHDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
Infection:	*(TX1INFET)* 1 - Yes 2 - No	*(TX1INFBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX1INFDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
Other:	*(TX1OTHET)* 1 - Yes 2 - No	*(TX1OTHBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX1OTHDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
Unknown:	*(TX1UNKET)* 1 - Yes 2 - No	*(TX1UNKBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX1UNKDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done

Specify other etiology: *(TX1SPEC2)*

Stem Cell Infusional Toxicity (Within 24 Hours of Infusion)

41. Allergic reaction/hypersensitivity: *(TX1ALRGY)*

0 - Grades 0-2
3 - Symptomatic Bronchospasm, with or without Urticaria; Parenteral Med(s) Indicated
4 - Anaphylaxis
5 - Death

42. Cardiac arrhythmia: *(TX1CARDC)*

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

43. Hypertension: *(TX1HYPRT)*

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

44. Hypotension: *(TX1HYPO2)*

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

45. Fever: *(TX1FEVER)*

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

46. Rigors, chills: *(TX1RIGOR)*

0 - Grades 0-2
3 - Severe or Prolonged, not Responsive to Narcotics

47. Vomiting: *(TX1VOMT)*

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

48. Hypoxia: *(TX1HYPX2)*

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

Comments: *(TX1COMM1)*

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

Web Version: 1.0; 10.00; 06-22-11

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

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

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

   1 - Adverse Event (grades 3-5), Specify
   2 - Death
   3 - Myeloma Progression/Relapse
   4 - Insurance Coverage Denied
   5 - Inadequate Physical Recovery From First Transplant
   *Additional Options Listed Below

   If reason is Adverse event (grades 3-5) **or** Other, specify: *(SECTXPOT)*

   *If reason is **Death**, a Death form must be submitted.*
   *If reason is **Myeloma progression**, a Progression/Relapse form must be submitted.*

2. Record date of initiation of conditioning regimen: *(CONDNGDT)* *(mm/dd/yyyy)*
3. Record date of hematopoietic stem cell infusion: *(TXDTTXP)* *(mm/dd/yyyy)*
4. Record patient weight: *(PTWGTTB)* *(xxx.x)* kg
5. Record the number of $CD34^+$ cells (or $CD34^+$ cells/kg) in the graft (autologous or allogeneic): *(CELLSTB)*

   1 - x10^6 CD34+ Cells
   2 - x10^6 CD34+ Cells/Kg

   (xxxx.x) Unit: *(CDUNIT)*

6. IUBMID for this patient (if available): *(T_IUBMID)*
7. CRID # (CIBMTR Recipient ID): *(TXPCRID)* *(xxxxxxxxxx)*

Do NOT use IUBMID/UPN numbers in the CRID field.

Comments: *(COMMTXP1)*

Additional Selection Options for TXP

If no, indicate the reason for not receiving a second transplant:
6 - Patient Refused/Withdrew consent
9 - Other, Specify