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

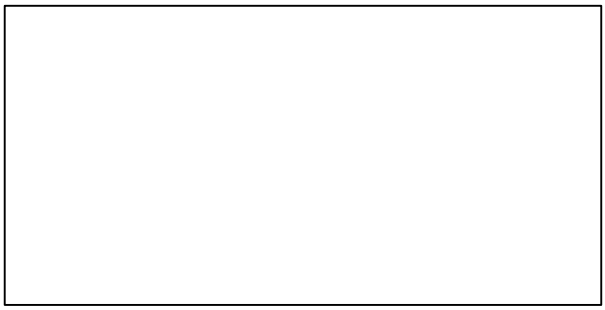
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

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

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

Death Form (DTH)

Web Version: 1.0; 4.06; 06-22-11

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

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

If yes, submit autopsy report to DCC

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

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

10 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
11 - Autologous Recovery
12 - Rejection
21 - Bacterial
*Additional Options Listed Below

?

Specify other: *(DTHSPEC1)*

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

10 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
11 - Autologous Recovery
12 - Rejection
21 - Bacterial
*Additional Options Listed Below

Specify other: *(DTHSPEC2)*

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

10 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
11 - Autologous Recovery
12 - Rejection
21 - Bacterial
*Additional Options Listed Below

Specify other: *(DTHSPEC3)*

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

10 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
11 - Autologous Recovery
12 - Rejection
21 - Bacterial
*Additional Options Listed Below

Specify other: *(DTHSPEC4)*

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

10 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
11 - Autologous Recovery
12 - Rejection
21 - Bacterial
*Additional Options Listed Below

Specify other: *(DTHSPEC5)*

Comments: *(DTCMMNTS)*

Additional Selection Options for DTH

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

Blood and Marrow Transplant Clinical Trials Network

0102A (ENR)

Web Version: 1.0; 5.00; 06-26-09

Multiple Myeloma Enrollment Form - Segment A

1. Record date informed consent form signed: *(CNSNTDT)* _____ *(mm/dd/yyyy)*
2. Does the patient have a consenting, eligible HLA-matched sibling donor? *(ELHLASIB)* ☐ 1 - Yes ☐ 2 - No

Inclusion Criteria

3. Does the patient meet the Durie and Salmon criteria for initial diagnosis of multiple myeloma (MM)? *(MYLYESNO)* ☐ 1 - Yes ☐ 2 - No
4. Record patient's most advanced stage of MM at diagnosis or anytime thereafter: *(MMSTAGE)*
   1 - Stage I
   2 - Stage II
   3 - Stage III
5. Does the patient have symptomatic MM requiring treatment at diagnosis or anytime thereafter? *(MMSYMPTM)* ☐ 1 - Yes ☐ 2 - No
6. What is the patient's current disease status (prior to conditioning)? *(DXSTATUS)*
   1 - Complete Remission
   2 - Continuing Complete Remission
   3 - Partial Response
   4 - Minimal Response
   5 - Stable Disease
   *Additional Options Listed Below
7. Patient's birthdate: *(PTBRTHDT)* 07/05/1971 *(mm/dd/yyyy)*
8. Has the patient received at least three cycles of initial systemic therapy? *(TMSYSTRX)* ☐ 1 - Yes ☐ 2 - No
   9. Date conventional therapy began: *(SYSBEGDT)* _____ *(mm/dd/yyyy)*
   10. Date conventional therapy ended: *(SYSENDDT)* _____ *(mm/dd/yyyy)*
11. Record start date of mobilization therapy: *(MOBLSTDT)* _____ *(mm/dd/yyyy)*
12. Record proposed start date of conditioning (administration of melphalan): *(CONDITDT)* _____ *(mm/dd/yyyy)*
13. Record left ventricular ejection fraction at rest: *(EJCTFRCT)* _____ *(xxx)* %
14. Date ejection fraction performed: *(EJCFRDTA)* _____ *(mm/dd/yyyy)*

	Most Recent Value	ULN For Your Institution	Date Sample Obtained
15. Bilirubin:	*(TOTBILIB)* _____ *(xx.x)* mg/dL	*(BILIULNB)* _____ *(xx.x)* mg/dL	*(BILITSDT)* _____ *(mm/dd/yyyy)*
16. ALT:	*(ALT)* _____ *(xxx)* Units/L	*(ALT1ULN)* _____ *(xxx)* Units/L	*(ALTTSTDT)* _____ *(mm/dd/yyyy)*
17. AST:	*(AST)* _____ *(xxx)* Units/L	*(AST1ULN)* _____ *(xxx)* Units/L	*(ASTTSTDT)* _____ *(mm/dd/yyyy)*

18. Record creatinine clearance: *(CRCL)* _____ *(xxx)* ml/min
19. Date creatinine clearance sample obtained: *(CRCLTSDT)* _____ *(mm/dd/yyyy)*
20. Were Pulmonary Function Tests performed? *(PFTPERFM)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value Corrected for Hemoglobin	Date Sample Obtained
21. DLCO:	*(DLCOB)* _____ *(xxx)* %	*(DLCOBTDT)* _____ *(mm/dd/yyyy)*
22. FEV1:	*(FEV1B)* _____ *(xxx)* %	*(FEV1BTDT)* _____ *(mm/dd/yyyy)*
23. FVC:	*(FECB)* _____ *(xxx)* %	*(FECBTDT)* _____ *(mm/dd/yyyy)*

24. O_2 saturation on room air: *(O2SATMM)* _____ *(xxx)* Date O_2 saturation was obtained: *(O2SATMDT)* _____ *(mm/dd/yyyy)*

25. Record patient's weight: *(ENTRYWT)* _____ *(xxx.x)* kg

26. Date patient's weight assessed: *(PTWTDT)* _____ *(mm/dd/yyyy)*

27. Record the total number of $CD34^+$ cells ($CD34^+$ cells/kg) in the autograft: *(CD34POS)*

_____ *(xxxx.x)* Unit: *(CDENRUNT)*

1 - x 10^6 CD34+ Cells
2 - x 10^6 CD34+ Cells/Kg

Exclusion Criteria

28. Does the patient have non-secretory multiple myeloma? *(NONSECMM)* ☐ 1 - Yes ☐ 2 - No

29. Does the patient have plasma cell leukemia? *(PLASMACL)* ☐ 1 - Yes ☐ 2 - No

30. What is the patient's Karnofsky/Lansky (for patients < 16 years old) performance score? *(PSB)*

01 - 100 (Normal; No Complaints/Fully Active)
02 - 90 (Normal Activity/Minor Restrictions 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

31. Does the patient have uncontrolled hypertension? *(HYPERTNS)* ☐ 1 - Yes ☐ 2 - No

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

33. Does the patient have a history of any malignant diseases other than multiple myeloma, basal cell carcinoma or cervical carcinoma in situ? *(MALIGHX)*

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

34. Date confirmed by study chair: *(MALAPPDT)* _____ *(mm/dd/yyyy)*

35. Was the malignancy treated with curative intent > 5 years previously? *(MAL5YRS)* ☐ 1 - Yes ☐ 2 - No

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

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

38. Is the patient willing to use contraceptive techniques during and for 12 months following treatment? *(CONTRAB)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

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

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

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

Consent for Use of Biological Samples for Research - Patient

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

Risk Status

43. Record serum beta 2 microglobulin value: *(BSLSBM)* _____ *(xxxxx.xxxxx)* *(BSLUNITS)* ☐ g/dL ☐ mg/L

44. Date serum beta 2 microglobulin obtained: *(BSLSBMDT)* _____ *(mm/dd/yyyy)*

45. Was standard metaphase karyotype cytogenetic testing performed prior to conditioning? *(BSLSMKCD)* ☐ 1 - Yes ☐ 2 - No

46. Record result of standard cytogenetic testing for chromosome 13 abnormalities: *(BSLSMDCR)*

1 - Normal
2 - Abnormal
3 - Test Failed

47. Was FISH cytogenetic testing performed prior to conditioning? *(BSLFISHD)* ☐ 1 - Yes ☐ 2 - No

48. Record result of FISH cytogenetic testing for chromosome 13 abnormalities: *(BSLFISHR)*

1 - Normal
2 - Abnormal
3 - Test Failed

If the 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 number before faxing.

Comments: *(ENRBCOMM)*

Additional Selection Options for ENR

What is the patient's current disease status (prior to conditioning)?
6 - Relapse
7 - Progression

What is the patient's Karnofsky/Lansky (for patients < 16 years old) performance score?
06 - 50 (Requires Considerable Assistance/No Active Play)
07 - 40 (Disabled/Able to Initiate Quiet Activities)
08 - 30 (Severely Disabled/Needs Assistance for Quiet Play)
09 - 20 (Very Sick/Limited to Very Passive Activity)
10 - 10 (Moribund; Completely Disabled)
99 - Karnofsky or Lansky <70% with Approval by Study Chair/MM

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, other than for a protocol-specified transplant? *(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

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

Myeloma Status Form (MST)

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

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

1. Record baseline assessment date: *(BSLASSDT)* _____ *(mm/dd/yyyy)*

2. Record the following laboratory values prior to the initiation of conditioning:

	Is Paraprotein Present But Not Quantifiable? *(If the value is 0, answer as "2 - No" and enter "0.00" as the value.)*	Laboratory Value	Date Value Obtained	Immunofixation Result
Serum m-protein (g/dL):	*(BSPEPQFB)* ☐ 1 - Yes ☐ 2 - No	*(SRMPTBSL)* _____ *(xxx.xx)*	*(SRMBSLDT)* _____ *(mm/dd/yyyy)*	*(BSRMIMMR)* 1 - Positive 2 - Negative 3 - Not Done
Urine m-protein (g/dL):	*(BUPEPQFB)* ☐ 1 - Yes ☐ 2 - No	*(URNMPBSL)* _____ *(xxx.xx)*	*(URNMPBDT)* _____ *(mm/dd/yyyy)*	*(BURNIMMR)* 1 - Positive 2 - Negative 3 - Not Done
24-hour urinary light chain excretion (g/24h):	*(BURLIQFB)* ☐ 1 - Yes ☐ 2 - No	*(URNPTBSL)* _____ *(xxx.xx)*	*(URNBSLDT)* _____ *(mm/dd/yyyy)*	

3. Was a bone marrow aspirate performed during this assessment period? *(BMADONE)* ☐ 1 - Yes ☐ 2 - No
4. 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.

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

6. Was a bone marrow biopsy performed during this assessment period? *(BMBDONE)* ☐ 1 - Yes ☐ 2 - No
7. 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.

8. Record most recent percentage of plasma cells in bone marrow (biopsy): *(BMBMST)* _____ *(xxx)* %
9. Record date bone marrow aspirate and biopsy obtained: *(BMBRDT)* _____ *(mm/dd/yyyy)*

10. Were cytogenetics performed during this assessment period? *(CYTOGENT)* ☐ 1 - Yes ☐ 2 - No
11. Record result of cytogenetic testing: *(CYTORSLT)*
    1 - Normal
    2 - Abnormal
    3 - Test Failed

12. Was standard metaphase karyotype cytogenetic testing performed during this assessment period? *(STKARPER)* ☐ 1 - Yes ☐ 2 - No
13. Record result of standard cytogenetic testing for chromosome 13 abnormalities: *(STKARRLT)*
    1 - Normal
    2 - Abnormal
    3 - Test Failed

14. Was FISH cytogenetic testing performed during this assessment period? *(FISHDONE)* ☐ 1 - Yes ☐ 2 - No
15. Record result of FISH cytogenetic testing for chromosome 13 abnormalities: *(FISHRSLT)*
    1 - Normal
    2 - Abnormal
    3 - Test Failed

16. Has the size or number of lytic bone lesions increased since the last skeletal survey? *(BNLSINMS)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

17. Record the most current laboratory values:

	Laboratory Value	Laboratory Value Units	Date Value Obtained
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)*

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

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)*

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

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

1 - x 10^6 CD34+ Cells
2 - x 10^6 CD34+ Cells/Kg

3. Record the patient's pre-transplant CMV status: *(CMVSTAT)* ☐ 1 - Positive ☐ 2 - Negative
4. IUBMID for this patient (if available): *(T_IUBMID)* _____
5. CRID # (CIBMTR Recipient ID): *(TXPCRID)* _____ *(xxxxxxxxx)*

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

Comments: *(COMMTXP1)*