

## 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)

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



\*Specify organ: (ADM4SPEC)

\*\*Specify other: (ADM1SPEC)

4. Record secondary discharge diagnoses:

a. GVHD: (REAGVHD)

1 - Contributory  2 - Non contributory



b. Relapse/progression: (REASRLPS)

1 - Contributory  2 - Non contributory

c. Graft failure: (REASGF)

1 - Contributory  2 - Non contributory

d. Infection: (REASINF)

1 - Contributory  2 - Non contributory

e. Fever: (REASFVR)

1 - Contributory  2 - Non contributory

f. Seizure: (REASSZR)

1 - Contributory  2 - Non contributory

g. Bleeding/hemorrhage: (REASGIBL)

1 - Contributory  2 - Non contributory

h. Diarrhea: (REASDRH)

1 - Contributory  2 - Non contributory

i. Nausea/vomiting: (REASNV)

1 - Contributory  2 - Non contributory

j. Organ failure: (REASORGF)

1 - Contributory  2 - Non contributory

Specify organ: (ADM3SPEC)

k. Trauma: (REASTRAM)

1 - Contributory  2 - Non contributory

l. Psychiatric: (REASPSYC)

1 - Contributory  2 - Non contributory

m. Secondary malignancy: (REASMALG)

1 - Contributory  2 - Non contributory

n. Scheduled procedure/treatment: (REASPROC)

1 - Contributory  2 - Non contributory

o. Thrombosis/thrombus/embolism: (REASTRMB)

1 - Contributory  2 - Non contributory

p. Other: (REASOTHR)

1 - Contributory  2 - Non contributory

Specify other: (ADM2SPEC)

5. Record re-admission institution: (ADMCENTR)

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

Comments: (ADMCOMM1)

## **Additional Selection Options for ADM**

### **Record PRIMARY discharge diagnosis:**

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

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

- 1-1 - Mild
- 2-2 - Moderate
- 3-3 - Severe
- 4-4 - Life Threatening
- 5-5 - Fatal



6. What is the relationship to study therapy/intervention: (AVRELAT)

- 1-1 - Unrelated
- 2-2 - Unlikely
- 3-3 - Possible
- 4-4 - Probable
- 5-5 - Definite

7. Is there an alternative etiology: (AVETIOL)

- 0-0 - None Apparent
- 1-1 - Study Disease
- 2-2 - Other Pre-Existing Disease or Condition
- 3-3 - Accident, Trauma, or External Factors
- 4-4 - Concurrent Illness/Condition (Not Pre-Existing)

8. What is the effect on study therapy/intervention schedule: (AVEFFECT)

- 1-1 - No Change - Completed
- 2-2 - No Change - Ongoing
- 3-3 - Dose Modified
- 4-4 - Temporarily Stopped
- 5-5 - Permanently Stopped

9. Record the most severe outcome of the event: (AVOUTCOM)

- 1-1 - Resolved, No Residual Effects
- 2-2 - Resolved with Sequelae
- 3-3 - Persistent Condition
- 4-4 - Resolved by Death



10. Record the date of resolution: (AVRESDT)

(mm/dd/yyyy)

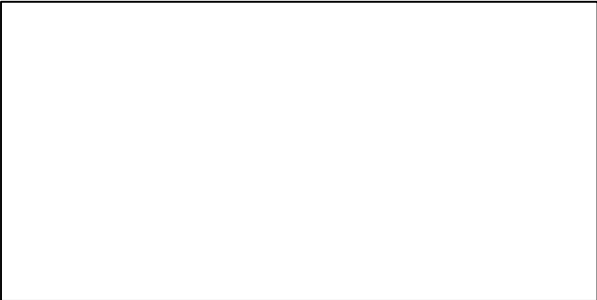


11. Was this event associated with: (AVASSOCI)

- 0-0 - None of the Following
- 1-1 - Death
- 2-2 - Life-Threatening Event
- 3-3 - Disability
- 4-4 - Congenital Anomaly
- \*Additional Options Listed Below



Comments: (AE 1COMM)



## **Additional Selection Options for AE1**

**Was this event associated with:**

5-5 - Required Intervention to Prevent Permanent Impairment or Damage

6-6 - Hospitalization (Initial or Prolonged)

9-9 - Other SAE

**Blood and Marrow Transplant Clinical  
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**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)

1-1 - Keep report active
2-2 - Deactivate - Report filed in error
3-3 - Deactivate - Key field error
9-9 - 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  
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**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)

1-1 - Keep report active 2-2 - Deactivate - Report filed in error 3-3 - Deactivate - Key field error 9-9 - Deactivate - Other reason
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**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) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED2)	(CM2STDT)	(CM2SPDT)	(CM2DOSE)	(CM2INDIC) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED3)	(CM3STDT)	(CM3SPDT)	(CM3DOSE)	(CM3INDIC) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED4)	(CM4STDT)	(CM4SPDT)	(CM4DOSE)	(CM4INDIC) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED5)	(CM5STDT)	(CM5SPDT)	(CM5DOSE)	(CM5INDIC)

				1-1 - Treatment of adverse event 9-9 - Other
(CONMED6)	(CM6STDY)	(CM6SPDY)	(CM6DOSE)	(CM6INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED7)	(CM7STDY)	(CM7SPDY)	(CM7DOSE)	(CM7INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED8)	(CM8STDY)	(CM8SPDY)	(CM8DOSE)	(CM8INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED9)	(CM9STDY)	(CM9SPDY)	(CM9DOSE)	(CM9INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED10)	(CM10STDY)	(CM10SPDY)	(CM10DOSE)	(CM10INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED11)	(CM11STDY)	(CM11SPDY)	(CM11DOSE)	(CM11INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED12)	(CM12STDY)	(CM12SPDY)	(CM12DOSE)	(CM12INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED13)	(CM13STDY)	(CM13SPDY)	(CM13DOSE)	(CM13INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED14)	(CM14STDY)	(CM14SPDY)	(CM14DOSE)	(CM14INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED15)	(CM15STDY)	(CM15SPDY)	(CM15DOSE)	(CM15INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED16)	(CM16STDY)	(CM16SPDY)	(CM16DOSE)	(CM16INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED17)	(CM17STDY)	(CM17SPDY)	(CM17DOSE)	(CM17INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED18)	(CM18STDY)	(CM18SPDY)	(CM18DOSE)	(CM18INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED19)	(CM19STDY)	(CM19SPDY)	(CM19DOSE)	(CM19INDY) 1-1 - Treatment of adverse event 9-9 - Other
(CONMED20)	(CM20STDY)	(CM20SPDY)	(CM20DOSE)	(CM20INDY) 1-1 - Treatment of adverse event 9-9 - Other



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

1-1 - Keep report active 2-2 - Deactivated - Report filed in error 3-3 - Deactivated - Key field error 9-9 - Deactivated - Other reason
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**Laboratory Test Results**

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

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

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

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

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

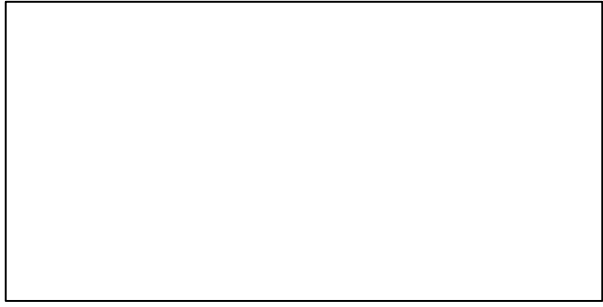
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

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

(ADDTS1) <input type="text"/>	(AD1DTDAT) <input type="text"/>	(AD1DTRES) <input type="text"/>
(ADDTS2) <input type="text"/>	(AD2DTDAT) <input type="text"/>	(AD2DTRES) <input type="text"/>
(ADDTS3) <input type="text"/>	(AD3DTDAT) <input type="text"/>	(AD3DTRES) <input type="text"/>
(ADDTS4) <input type="text"/>	(AD4DTDAT) <input type="text"/>	(AD4DTRES) <input type="text"/>
(ADDTS5) <input type="text"/>	(AD5DTDAT) <input type="text"/>	(AD5DTRES) <input type="text"/>

(ADDTS6) <input type="text"/>	(AD6DTDAT) <input type="text"/>	(AD6DTRES) <input type="text"/>
(ADDTS7) <input type="text"/>	(AD7DTDAT) <input type="text"/>	(AD7DTRES) <input type="text"/>
(ADDTS8) <input type="text"/>	(AD8DTDAT) <input type="text"/>	(AD8DTRES) <input type="text"/>
(ADDTS9) <input type="text"/>	(AD9DTDAT) <input type="text"/>	(AD9DTRES) <input type="text"/>
(ADDTS10) <input type="text"/>	(AD10TDT) <input type="text"/>	(AD10DTRS) <input type="text"/>

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)

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

2. Reviewed: (AEREVIEW)

1 - Yes     2 - No

3. Reviewed by: (ARFREVB Y)

4. Review date: (ARFREVD T)

(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; 5.00; 10-14-11

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

1. Adverse event status: (AVSTAT\_E)

1-1 - Keep report active  
2-2 - Deactivate - Report filed in error  
3-3 - Deactivate - Key field error  
9-9 - 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: (AMMEVDS)

Comments: (AE6COMM)

**Blood and Marrow Transplant Clinical  
Trials Network**

**Baseline Form - Prior to Conditioning (BSL)**

Web Version: 1.0; 6.01; 08-20-09

Segment (PROTSEG):

Visit Number (VISNO):

1. Is patient pregnant (positive -HCG) or breastfeeding? (PREGNANT)       1 - Yes     2 - No     3 - Not Applicable
2. Does patient have cardiac insufficiency or coronary artery disease requiring treatment? (CARDIAC)       1 - Yes     2 - No
3. Does patient have an active infection requiring therapy with antibiotic, antiviral, or antifungal medication? (INFECT)       1 - Yes     2 - No
4. Is patient enrolled in a Phase I study? (PHASE1)       1 - Yes     2 - No
5. Is the patient HIV positive? (HIVPOS)       1 - Yes     2 - No
6. Has a CBC with differential and platelet count been collected? (CBC)       1 - Yes     2 - No
7. Record percent leukemic blasts at time of enrollment: (PRCLEUBL)       (xxx) %
8. Record source of blasts at time of enrollment: (SRCEBLST)       1 - Blood     2 - Marrow
9. Record percent promyelocytes at time of enrollment: (PRCPROMY)       (xxx) %
10. Record source of promyelocytes at time of enrollment: (SRCEPROM)       1 - Blood     2 - Marrow
11. Were pulmonary function tests performed? (PFTYN)       1 - Yes     2 - No

If PFT's were not performed, then an O<sub>2</sub> saturation must be obtained.

	Most Recent Value Corrected for Hemoglobin	Date Sample Obtained
12. DLCO:	(PERDLCO) <input type="text"/> (xxx) % of predicted value	(DTDLCO) <input type="text"/> (mm/dd/yyyy)
13. FEV1:	(PERFEV1) <input type="text"/> (xxx) % of predicted value	(DTFEV1) <input type="text"/> (mm/dd/yyyy)
14. FVC:	(PERFEC) <input type="text"/> (xxx) % of predicted value	(DTFEC) <input type="text"/> (mm/dd/yyyy)

15. O<sub>2</sub> saturation on room air: (OXYS TRN)       (xxx) % Date O<sub>2</sub> saturation was obtained: (D TOXY,  (mm/dd/yyyy)

**Renal/Liver Function Test Results:**

	Most Recent Value	LLN for your Institution	ULN for your Institution	Date Sample Obtained
16. Creatinine (mg/dL):	(CREATMRV) <input type="text"/> (x.x)	(CREATLLN) <input type="text"/> (x.x)	(CREATULN) <input type="text"/> (x.x)	(CREATDAT) <input type="text"/> (mm/dd/yyyy)
17. ALT (Units/L):	(ALTMRV) <input type="text"/> (xxx)		(ALTULN) <input type="text"/> (xxx)	(ALTDATE) <input type="text"/> (mm/dd/yyyy)
18. AST (Units/L):	(ASTMRV) <input type="text"/> (xxx)		(ASTULN) <input type="text"/> (xxx)	(ASTDATE) <input type="text"/> (mm/dd/yyyy)
19. Bilirubin (mg/dL):	(BILIMRV) <input type="text"/> (x.x)		(BILIULN) <input type="text"/> (xx.x)	(BILIDATE) <input type="text"/> (mm/dd/yyyy)

Comments: (COMMTXM1)



**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)
- 0-0 - No Symptoms of Acute GVHD  
1-1 - I  
2-2 - II  
3-3 - III  
4-4 - IV

4. Did clinical signs and/or symptoms of acute GVHD develop during this assessment period? (AGVDLVP)  1 - Yes  2 - No

5. Record method used to diagnose acute GVHD: (DGNSAGVH)
- 1-1 - Histologic Evidence  
2-2 - Clinical Evidence  
3-3 - Both

6. Date of diagnosis of acute GVHD: (DTDGNA GV)  (mm/dd/yyyy)

7. Was prophylaxis for GVHD given during this assessment period? (PROPHIMM)
- 1-1 - Yes  
2-2 - No  
3-3 - Discontinued During This Assessment Period

8. If yes, specify all immunosuppressants used for GVHD prophylaxis:
- a. Cyclosporine: (PROPHCY)  1 - Yes  2 - No
  - b. Tacrolimus: (PROPH TAC)  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)
- 0-0 - No Symptoms of Chronic GVHD  
1-1 - Mild  
2-2 - Moderate  
3-3 - 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? (CGVDLVP)  1 - Yes  2 - No

13. Record method used to diagnose chronic GVHD: (DGNSCGVH)
- 1-1 - Histologic Evidence  
2-2 - Clinical Evidence  
3-3 - Both

14. Date of diagnosis of chronic GVHD: (DTDGNCGV)  (mm/dd/yyyy)

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

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

16. Minimum platelet count at time of diagnosis: (PLTLTCNT)

(xxx.x) x 10<sup>9</sup>/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)

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

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

**Oral**

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

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

**Pulmonary**

24. Dyspnea: (CGVDYSPN)

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

25. Pulmonary fibrosis: (PULMFIBR)

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

26. Bronchiolitis obliterans: (BRNCOBLT)

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

27. FEV1: (CGVFEV1)

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

28. Oxygen saturation: (O2SAT)

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

**Gastrointestinal**

29. Esophagus: (ESOPHAGS)

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

30. Nausea and vomiting: (NAUSVOMT)

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

31. Diarrhea: (CGVDIARRH)

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

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

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

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

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

Use mL/day for adult recipients and mL/m<sup>2</sup> for pediatric recipients.

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

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

35. Malabsorption: (MALABSRP)

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

**Hepatic**

36. Bilirubin level: (LIVERBIL)

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

**Genitourinary**

37. Vaginitis: (VAGNITIS)

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

**Musculoskeletal**

38. Contractures: (CONTRACTR)

0-0 - No Symptoms  
2-2 - Mild Joint Contractures (Does not Affect ADL)  
3-3 - 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. Fasciitis: (*FASCITIS*)  1 - Yes  2 - No
43. Was there other organ involvement? (*ORGNOTH*)  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. ( <i>BIOTYP1</i> ) 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	( <i>TYP1OSPE</i> ) <input type="text"/>	( <i>BIODT1</i> ) <input type="text"/> (mm/dd /yyy) <input type="text"/>	( <i>BIORSLT1</i> ) 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
46. ( <i>BIOTYP2</i> ) 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	( <i>TYP2OSPE</i> ) <input type="text"/>	( <i>BIODT2</i> ) <input type="text"/> (mm/dd /yyy) <input type="text"/>	( <i>BIORSLT2</i> ) 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
47. ( <i>BIOTYP3</i> ) 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	( <i>TYP3OSPE</i> ) <input type="text"/>	( <i>BIODT3</i> ) <input type="text"/> (mm/dd /yyy) <input type="text"/>	( <i>BIORSLT3</i> ) 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
48. ( <i>BIOTYP4</i> ) 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	( <i>TYP4OSPE</i> ) <input type="text"/>	( <i>BIODT4</i> ) <input type="text"/> (mm/dd /yyy) <input type="text"/>	( <i>BIORSLT4</i> ) 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
49. ( <i>BIOTYP5</i> ) 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	( <i>TYP5OSPE</i> ) <input type="text"/>	( <i>BIODT5</i> ) <input type="text"/> (mm/dd /yyy) <input type="text"/>	( <i>BIORSLT5</i> ) 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
50. ( <i>BIOTYP6</i> ) 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	( <i>TYP6OSPE</i> ) <input type="text"/>	( <i>BIODT6</i> ) <input type="text"/> (mm/dd /yyy) <input type="text"/>	( <i>BIORSLT6</i> ) 1-1 - Positive 2-2 - Negative 3-3 - Equivocal

**Answer questions 51-54 relating to GVHD therapy.**

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

1-1 - Yes, Initiated this Assessment Period
2-2 - Yes, Continuing from Previous Assessment Period
3-3 - 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*)

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

b. Azathioprine: (*THRPYAZA*)

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

c. Cyclosporine: (*THRPYCYC*)

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

d. Systemic Corticosteroids: (*THRPYSCO*)

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

e. Topical Corticosteroids: (*THRPYTCO*)

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

f. Thalidomide: (*THRPYTHA*)

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

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

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

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

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

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

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

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

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

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

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

l. Etretnate: (*THRPPYETR*)

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

m. Lamprone: (*THRPPYLAM*)

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

n. Etanercept: (*THRPPYETA*)

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

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

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

p. Chloroquine Phosphate: (*THRPPYCPH*)

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

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

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

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

r. In Vivo Immunotoxin: (THRPIYIMM)

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

Specify in vivo immunotoxin used: (IMMAGNT)

s. Other: (THRPIYOTH)

- 1-1 - Yes, Still Taking Drug
- 2-2 - Yes, No Longer Taking Drug
- 3-3 - 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)

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

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

57. Current platelet count: (CURPLTCT)

(xxx.x) x 10<sup>9</sup>/L

58. Current weight: (CURWGHT)

(xxx.x) kg

Comments: (GVVCOMM)

## **Additional Selection Options for CGV**

### **Minimum Karnofsky/Lansky Score at time of diagnosis:**

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

### **Biopsy Type 1**

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

### **Current Karnofsky/Lansky Score:**

06-06 - 50 (Requires Considerable Assistance/No Active Play)  
07-07 - 40 (Disabled/Able to Initiate Quiet Activities)  
08-08 - 30 (Severely Disabled/Needs Assistance for Quiet Play)  
09-09 - 20 (Very Sick/Limited to Very Passive Activity)  
10-10 - 10 (Moribund; Completely Disabled)  
11-11 - 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 # (CIBMT R Recipient ID): (CRIDNUM)

	(xxxxxxxxxx)

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

- 4. Gender: (GENDER)
- 5. Date of Birth: (DOB)
- 6. Ethnicity: (ETHNIC)

<input type="checkbox"/> 1 - Male	<input type="checkbox"/> 2 - Female
(mm/dd/yyyy)	

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

- 7. Race: (RACE)

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

Specify race: (RACESP)

- 8. Secondary Race: (RACE2)

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

Specify secondary race: (RACE2SP)

Comments: (DEMCOMM1)



## Additional Selection Options for DEM

### Race:

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

**Blood and Marrow Transplant Clinical  
Trials Network**

**Donor Assessment (DNR)**

Web Version: 1.0; 4.00; 05-28-09

**Donor ID (DNRID):**

1. Enter Donor ID: *(DNMDPNUM)*
  2. Enter Recipient ID: *(DRCNMDPN)*
  3. Date donor Informed Consent Form was signed: *(DCNSTDT)*
  4. Donor age: *(DAGE)*
  5. Donor gender: *(DGENDER)*
  6. Donor ethnicity: *(DETHNIC)*
  7. Donor race: *(DRACE)*
  8. Does the donor have adequate peripheral venous access for leukapheresis or agreed to central venous catheter placement? *(DVENACCE)*
  9. Does donor meet general inclusion criteria as specified in the Donor Center Companion Manual? *(DCRITERI)*
  10. Has the donor had a serious adverse reaction to anesthesia? *(DSAEANES)*
  11. Is donor pregnant (positive -HCG) or breastfeeding? *(DPREGN)*
  12. Does donor have a known allergy to G-CSF or to E. Coli derived recombinant protein products? *(DALLERGY)*
  13. Does donor have a history of autoimmune disorders? *(DAUTOIHX)*
  14. Does the donor have a history of deep vein thrombosis or venous thromboembolism? *(DDVTHX)*
  15. Does the donor have a history of iritis or episcleritis? *(DIRIEHX)*
  16. Is the donor currently undergoing treatment with lithium? *(DLITHIUM)*
  17. Has the donor had a positive test for sickle cell trait? *(DPOSHST)*
  18. Is the donor currently receiving experimental therapy or investigational agents? *(DEXPERIM)*
  19. Indicate the donor's CMV status: *(DCMVS T)*
  20. Platelet count at time of baseline evaluation: *(DPLATELE)*
  21. Has the donor agreed to participate in routine Quality of Life assessments? *(DQOLAGRE)*
- Donor Eligibility Status**
22. Has donor become ineligible for donation since the time of randomization? *(DINELIG)*
  23. If Yes, specify reason: *(DINELSP)*
- Comments: *(COMMENDN)*

(mm/dd/yyyy)  
 (xx)  
 1 - Male     2 - Female

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

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

1 - Yes     2 - No  
 1 - Yes     2 - No  
 1 - Yes     2 - No     3 - Not Applicable  
 1 - Yes     2 - No  
 1 - Yes     2 - No  
 1 - Yes     2 - No  
 1 - Yes     2 - No  
 1 - Yes     2 - No  
 1 - Yes     2 - No  
 1 - Positive     2 - Negative  
 (xxxxxx) per mL  
 1 - Yes     2 - No

1 - Yes     2 - No

## Additional Selection Options for DNR

### Donor race:

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

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



Specify other: (DTHSPEC1)

4. Secondary cause of death: (SCNDCZ1)

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

Specify other: (DTHSPEC2)

5. Secondary cause of death: (SCNDCZ2)

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

Specify other: (DTHSPEC3)

6. Secondary cause of death: (SCNDCZ3)

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

Specify other: (DTHSPEC4)

7. Secondary cause of death: (SCNDCZ4)

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

Specify other: (DTHSPEC5)

Comments: (DTCMMNTS)

## Additional Selection Options for DTH

### Primary cause of death:

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

**Blood and Marrow Transplant Clinical  
Trials Network**

**0201A (ENR)**

Web Version: 1.0; 7.00; 08-20-09

**URD Peripheral Blood vs. Bone Marrow Enrollment Form: Segment A - Prior to Randomization**

1. Date Informed Consent form signed: *(CNSNTDT0)*

(mm/dd/yyyy)

2. Recipient's birthdate: *(RECPBD)*

03/26/1972 (mm/dd/yyyy)

3. Recipient ID: *(RECNDMP)*

4. Donor ID: *(DNMDPNUM)*

5. GVHD prophylaxis regimen: *(GVHDREG)*

1-1 - Cyclosporine/Methotrexate  
2-2 - Tacrolimus/Methotrexate  
3-3 - COG ASCT0431 Protocol  
9-9 - Other, Specify

Specify other: *(GVHDOTHR)*

6. Proposed conditioning regimen: *(CONDREGI)*

1-1 - Cyclophosphamide and Total Body Irradiation (C-TBI)  
2-2 - Busulfan and Cyclophosphamide (Bu-Cy)  
3-3 - Fludarabine and Melphalan (Flu-Mel)  
4-4 - Fludarabine, Busulfan, and ATG (Flu-Bu-ATG)

7. Will Campath-1H (Alemtuzumab) be used as part of conditioning? *(CAMPATH)*

1 - Yes  2 - No

**Inclusion Criteria**

8. Record the study participant's primary diagnosis: *(PPRIMDX)*

1-1 - Acute Myelogenous Leukemia  
2-2 - Acute Lymphoblastic Leukemia  
3-3 - Chronic Myelogenous Leukemia  
4-4 - Myelodysplastic Syndrome  
5-5 - Chronic Myelomonocytic Leukemia  
\*Additional Options Listed Below

9. If AML, record disease stage: *(AMLDSSTG)*

1-1 - First Remission  
2-2 - Second Remission  
3-3 - Third or Subsequent Remission  
4-4 - Not in Remission

10. If ALL, record disease stage: *(ALLDSSSTG)*

1-1 - First Remission  
2-2 - Second Remission  
3-3 - Third or Subsequent Remission  
4-4 - Not in Remission

11. If CML, record disease stage: *(CMLDSSTG)*

1-1 - Chronic Phase  
2-2 - Accelerated Phase  
3-3 - Blast Phase

12. If MDS, record disease stage: *(MDSDSSTG)*

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

13. Does the study participant have therapy-related AML or MDS? *(TRPYAML)*

1 - Yes  2 - No

14. If yes, indicate the time period the study participant's prior malignancy has been in remission: *(PMALTIME)*

1-1 - Less than 12 months  
2-2 - Greater than or equal to 12 months

15. If the duration of remission is < 12 months, has enrollment been approved by the medical monitor or protocol chair? *(MMAAPPROV)*

1 - Yes  2 - No

16. Record the date approved by the medical monitor or protocol chair: (MMAPPRDT)  (mm/dd/yyyy)

## Exclusion Criteria

17. Has the study participant had a prior allogeneic or autologous transplant? (PPRALLOC)  1 - Yes  2 - No
18. If the study participant has the rapy-related AML or MDS, indicate the type of prior transplant: (PRTRNSPL)  1-1 - A llogeneic  2-2 - A utologous
19. Was the transplant performed for the primary malignancy? (PMALAUTO)  1 - Yes  2 - No
20. If yes, is the date of the prior transplant more than 12 months prior to enrollment? (AUTOPRDT)  1 - Yes  2 - No

## Consent for Use of Biological Specimens for Research

21. Did the patient (or if the patient is a minor, the parent/legal guardian) give consent to have blood drawn for research purposes? (CNSTRSCH)  1 - Yes  2 - No

### HLA Typing

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

DNA\_HIGH-High Level DNA  
DNA\_LOW-LowLevel DNA  
SEROLOGY-Serologic  
AB\_SEROLOGY\_DRB1\_DNA\_LOW-Loci A, B: Serologic, Locus DRB1: Low Level DNA  
AB\_DNA\_LOW\_DRB1\_DNA\_HIGH-Loci A, B: Low Level DNA, Locus DRB1: High Level DNA  
\*Additional Options Listed Below

## 22. Recipient HLA Typing

### HLA-A

Typing method: (RHLAAMET)

1-1 - DNA Technology  
2-2 - Serology

Antigens/all eles provided: (RHLAANUM)

1-1 - One  
2-2 - Two

1st: (RHLAA11X)  (RHLAA12X) /  (RHLAA13X) /  (RHLAA14X) /   
(RHLAA15X)  (RHLAA16X) /  (RHLAA17X) /  (RHLAA18X) /   
2nd: (RHLAA21X)  (RHLAA22X) /  (RHLAA23X) /  (RHLAA24X) /   
(RHLAA25X)  (RHLAA26X) /  (RHLAA27X) /  (RHLAA28X) /

### HLA-B

Typing method: (RHLABMET)

1-1 - DNA Technology  
2-2 - Serology

Antigens/all eles provided: (RHLABNUM)

1-1 - One  
2-2 - Two

1st: (RHLAB11X)  (RHLAB12X) /  (RHLAB13X) /  (RHLAB14X) /   
(RHLAB15X)  (RHLAB16X) /  (RHLAB17X) /  (RHLAB18X) /   
2nd: (RHLAB21X)  (RHLAB22X) /  (RHLAB23X) /  (RHLAB24X) /   
(RHLAB25X)  (RHLAB26X) /  (RHLAB27X) /  (RHLAB28X) /

### HLA-C

1st:

2nd:

### HLA-DRB1

Typing method: (RHLADMET)

1-1 - DNA Technology  
2-2 - Serology

Antigens/all eles provided: (RHLADNUM)

1-1 - One  
2-2 - Two

1st: (RHLAD11X)  (RHLAD12X) /  (RHLAD13X) /  (RHLAD14X) /   
 (RHLAD15X)  (RHLAD16X) /  (RHLAD17X) /  (RHLAD18X) /   
 2nd: (RHLAD21X)  (RHLAD22X) /  (RHLAD23X) /  (RHLAD24X) /   
 (RHLAD25X)  (RHLAD26X) /  (RHLAD27X) /  (RHLAD28X) /

23. Donor HLA Typing

**HLA-A**

Typing method: (DHAAAMET)

1-1 - DNA Technology  
 2-2 - Serology

Antigens/all eles provided: (DHAAANUM)

1-1 - One  
 2-2 - Two

1st: (DHAA11X)  (DHAA12X) /  (DHAA13X) /  (DHAA14X) /   
 (DHAA15X)  (DHAA16X) /  (DHAA17X) /  (DHAA18X) /   
 2nd: (DHAA21X)  (DHAA22X) /  (DHAA23X) /  (DHAA24X) /   
 (DHAA25X)  (DHAA26X) /  (DHAA27X) /  (DHAA28X) /

**HLA-B**

Typing method: (DHABMET)

1-1 - DNA Technology  
 2-2 - Serology

Antigens/all eles provided: (DHABNUM)

1-1 - One  
 2-2 - Two

1st: (DHAB11X)  (DHAB12X) /  (DHAB13X) /  (DHAB14X) /   
 (DHAB15X)  (DHAB16X) /  (DHAB17X) /  (DHAB18X) /   
 2nd: (DHAB21X)  (DHAB22X) /  (DHAB23X) /  (DHAB24X) /   
 (DHAB25X)  (DHAB26X) /  (DHAB27X) /  (DHAB28X) /

**HLA-C**

1st

2nd

**HLA-DRB1**

Typing method: (DHADMET)

1-1 - DNA Technology  
 2-2 - Serology

Antigens/all eles provided: (DHADNUM)

1-1 - One  
 2-2 - Two

1st: (DHAD11X)  (DHAD12X) /  (DHAD13X) /  (DHAD14X) /   
 (DHAD15X)  (DHAD16X) /  (DHAD17X) /  (DHAD18X) /   
 2nd: (DHAD21X)  (DHAD22X) /  (DHAD23X) /  (DHAD24X) /   
 (DHAD25X)  (DHAD26X) /  (DHAD27X) /  (DHAD28X) /

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)

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



Comments (COMMENTS)

A large, empty rectangular box with a thin black border, intended for entering comments. It is positioned to the right of the 'Comments (COMMENTS)' label.

## Additional Selection Options for ENR

**Record the study participant's primary diagnosis:**

6-6 - Agnogenic Myeloid Metaplasia with Myelofibrosis  
7-7 - Juvenile Myelomonocytic Leukemia

**If MDS, record disease stage:**

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

**Type of HLA Match required by this protocol:**

AB\_SEROLOGY\_DRB1\_DNA\_HIGH-Loci A, B: Serologic, Locus DRB1: High Level DNA  
ABC\_DNA\_LOW\_DRB1\_DNA\_HIGH-Loci A, B, C: Low Level DNA, Locus DRB1: High Level DNA  
ABCDQ\_DNA\_LOW\_DRB1\_DNA\_HIGH-Loci A, B, C, DQ: Low Level DNA, Locus DRB1: High Level DNA

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

5/8-5/8  
6/8-6/8  
0/8-0/8  
1/8-1/8  
2/8-2/8  
3/8-3/8  
4/8-4/8  
5/8-5/8  
6/8-6/8  
7/8-7/8  
8/8-8/8

**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 Relapse Form must be submitted.*

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

6. Has the patient been treated for progression/relapse? (*RELAPSTX*)  1 - Yes  2 - No

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

8. Indicate type of treatment: (*TREATYPE*)

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

Specify other treatment: (*FUS1SPEC*)

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

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

*If Yes, a Secondary Graft Failure Form must be submitted.*

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

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

13.  
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*)

## **Additional Selection Options for FUS**

**Indicate type of treatment:**

6-6 - Other Cellular Therapy

7-7 - Other

## 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: (GVAENDT)  (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) 0-0 - Prednisone  
1-1 - Cyclosporine  
2-2 - Tacrolimus  
3-3 - Not taken during assessment

3. Record most recent blood level of immunosuppressant (prophylaxis): (TROUGH LV)  (xxx.x) ng/mL

4. Record date blood sample obtained: (TROUGHDT)  (mm/dd/yyyy) ?

5. Were any additional immunosuppressants received for prophylaxis? (ADDIMMUN)  1 - Yes  2 - No

Additional immunosuppressant(s) received:

6. Methotrexate: (GVHMTX)  1 - Yes  2 - No

7. Etanercept: (GVHETANR)  1 - Yes  2 - No

8. Steroids: (GVHSTER)  1 - Yes  2 - No

9. MMF: (GVHMMF)  1 - Yes  2 - No

10. Other: (GVHOTH)  1 - Yes  2 - No

11. If other, specify: (GVHOTHSP)

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

12. Skin abnormalities: (GVHSKINA) 0-0 - No Rash  
1-1 - Maculopapular Rash, <25% of Body Surface  
2-2 - Maculopapular Rash, 25-50% of Body Surface  
3-3 - Generalized Erythroderma  
4-4 - Generalized Erythroderma with Bullus Formation and Desquamation ?

13. Skin etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SETGVHD) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No <span style="border: 1px solid black; padding: 2px;">?</span>	(SETDRGRX) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(SETCRTOX) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
Infection	Other	
(SETINFACT) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(SETOTHER) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	

Specify other skin etiologies: (GVHKNSP)

14. Skin biopsy for GVHD: (GVHSKINB) 1-1 - Positive  
2-2 - Negative  
3-3 - Equivocal  
4-4 - Not Done

15. Upper GI abnormalities: (GVHUPGIA) 0-0 - No Prolonged Nausea and Vomiting  
1-1 - Persistent Nausea, Vomiting or Anorexia

16. Upper intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(UGIETGVH) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(UGIETDRG) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(UGIETCON) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No

<b>TPN</b>	<b>Infection</b>	<b>Other</b>
(UGIETTPN) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(UGIETINF) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(UGIETOTH) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No

Specify other upper intestinal tract etiologies: (UGIETSPC)

17. Upper intestinal tract biopsy for GVHD: (UGIBIORS)

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

18. Lower GI abnormalities: (GVHINTA)

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

?

Use mL/day for adult patients and mL/m<sup>2</sup> for pediatric patients

19. Lower intestinal tract etiologies:

<b>GVHD</b>	<b>Drug Reaction</b>	<b>Conditioning Regimen Toxicity</b>
(LGIETGVH) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(LGIETDRG) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(LGIETCON) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
<b>TPN</b>	<b>Infection</b>	<b>Other</b>
(LGIETTPN) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(LGIETINF) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(LGIETOTH) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No

Specify other lower intestinal tract etiologies: (LGIETSPC)

20. Lower intestinal tract biopsy for GVHD: (LGIIBIORS)

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

21. Liver abnormalities: (GVHLIVRA)

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

22. Liver etiologies:

<b>GVHD</b>	<b>Drug Reaction</b>	<b>Conditioning Regimen Toxicity</b>	<b>TPN</b>
(LIVETGVH) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(LIVETDRG) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(LIVETCND) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(LIVETTPN) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
<b>Infection</b>	<b>VOD</b>	<b>Other</b>	
(LIVETINF) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(LIVETVOD) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(LIVETOOTH) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	

Specify other liver etiologies: (GVHLIVRS)

23. Liver biopsy for GVHD: (GVHLIVRB)

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

}}

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".

24. If yes, specify agent name: (GVHAGENT)

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

Specify other agent: (GVHAGNSP)

25. Indicate treatment modification: (GVHTRMOD)

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

Comments: (GVHCOMM)

## **Additional Selection Options for GVH**

### **Lower GI abnormalities:**

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

### **If yes, specify agent name:**

6-6 - MMF

7-7 - Daclizumab

8-8 - Methylprednisolone

9-9 - Other



**Blood and Marrow Transplant Clinical  
Trials Network**

**Myeloablative Hematopoiesis Form (HEM)**

Web Version: 1.0; 7.01; 03-09-10

**Segment (PROTSEG):**

**Visit Number (VISNO):**

1. Did the patient achieve ANC recovery  $\geq 500/\text{mm}^3$  on three consecutive days? (ENGRFT1)  1 - Yes  2 - No  3 - Previously Reported

2. Record neutrophil count and specimen collection dates:

Day 1:	(ANCDAY1) <input type="text"/> (xxxx) /mm <sup>3</sup>	(ANC1DT) <input type="text"/> (mm/dd/yyyy)
Day 2:	(ANCDAY2) <input type="text"/> (xxxx) /mm <sup>3</sup>	(ANC2DT) <input type="text"/> (mm/dd/yyyy)
Day 3:	(ANCDAY3) <input type="text"/> (xxxx) /mm <sup>3</sup>	(ANC3DT) <input type="text"/> (mm/dd/yyyy)

**Record Chimerism Assay Data for Marrow and/or Blood**

**Marrow**

3. Was a chimerism performed on a marrow sample? (MRWDONE)  1 - Yes  2 - No

4. Date specimen collected: (MRWDT2)  (mm/dd/yyyy)

5. Method of evaluation: (MTHOD1)

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

Specify other: (MRWSPEC)

6. Cell type: (MRWCLTYP)

- 1 - Unmanipulated
- 2 - Granulocytes

7. Marrow assay results: (MRWASSAY)

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

8. % Donor: (PCNTDNR1)  (xx) %

**Blood**

9. Was a chimerism performed on a blood sample? (BLDDONE)  1 - Yes  2 - No

10. Date specimen collected: (BLDCHMDT)  (mm/dd/yyyy)

11. Method of evaluation: (MTHOD2)

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

Specify other: (BLDSPEC)

12. Cell type: (BLDCLTYP)

- 1 - Unmanipulated
- 2 - Granulocytes

13. Blood assay results: (BLDASSAY)

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

14. % Donor: (PCNTDNR2)  (xx) %

**T Cell Chimerism**

15. Was a chimerism performed on a T cell sample? (TCLDONE)  1 - Yes  2 - No

16. Type of sample: (TCLSMPL)  1 - Blood  2 - Marrow

17. Date specimen collected: (TCLDATE)  (mm/dd/yyyy)

18. Method of evaluation: (MTHOD3)

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

Specify other: (TCLSPEC)

19. T cell assay results: (TCLASSAY)

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

20. % Donor: (PCNTDNR3)

(xx) %

21. Did the patient receive a stem cell re-infusion due to inadequate hematopoietic function? (REINFUSE)

1 - Yes     2 - No

22. Record date of infusion: (INFUSEDT)

(mm/dd/yyyy)

Comments: (HEMCOMM1)

## Additional Selection Options for HEM

Method of evaluation:

9-9 - Other, specify

**Blood and Marrow Transplant Clinical  
Trials Network**

**Infection Form (INF)**

Web Version: 1.0; 4.00; 12-21-11

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

**INFECTION I**

1. Type of infection: (INFTYP01)

B-B - Bacteria
V-V - Viral
F-F - Fungal
P-P - Protozoal
O-O - Other

2. Organism I: (ORGN01)

B01-B01 - Acinetobacter (baumanii, calcoaceticus, lwoffii, other species)
B02-B02 - Agrobacterium radiobacter
B03-B03 - Alcaligenes xylosoxidans
B04-B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
B05-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)

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

4. Severity of infection: (SVRTY01)

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

**INFECTION II**

5. Type of infection: (INFTYP02)

B-B - Bacteria
V-V - Viral
F-F - Fungal
P-P - Protozoal
O-O - Other

6. Organism II: (ORGN02)

B01-B01 - Acinetobacter (baumanii, calcoaceticus, lwoffii, other species)
B02-B02 - Agrobacterium radiobacter
B03-B03 - Alcaligenes xylosoxidans
B04-B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
B05-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)

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

8. Severity of infection: (SVRTY02)

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

**INFECTION III**

9. Type of infection: (INFTYP03)

B-B - Bacteria
V-V - Viral
F-F - Fungal
P-P - Protozoal
O-O - Other

10. Organism III: (ORGN03)

BO1-BO1 - A cinetobacter (baumanii, calcoaceticus, lwoffii, other species)  
BO2-BO2 - A grobacterium radiobacter  
BO3-BO3 - A lcaligenes xylooxidans  
BO4-BO4 - A naerobic bacteria (NOS, except for Bacteroides, Clostridium)  
BO5-BO5 - Bacillus (cereus, other species)  
\*Additional Options Listed Below

If other specify: (INFSPEC3)

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

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

12. Severity of infection: (SVRTY03)

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

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

1 - Yes  2 - No

**Provide agent(s) administered for this infectious period:**

14. 1<sup>st</sup> agent: (AGENT1)

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

If other specify: (AGTSPEC1)

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

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

If other specify: (AGTSPEC2)

16. 3<sup>rd</sup> agent: (AGENT3)

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

If other specify: (AGTSPEC3)

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

1 - Yes  2 - No

If yes, specify additional agents administered: (INFSPEC4)

Comments: (INFCOM)

## Additional Selection Options for INF

### Infection Site (*INFSITE*) (key field):

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

### Organism I:

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

granulorum, other species)  
 B44-B44 - Pseudomonas (all species except cepacia and maltophilia)  
 B45-B45 - Pseudomonas or Burkholderia cepacia  
 B46-B46 - Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia  
 B47-B47 - Rhodococcus  
 B48-B48 - Rickettsia  
 B49-B49 - Salmonella (all species)  
 B50-B50 - Serratia marcescens  
 B51-B51 - Shigella  
 B52-B52 - Staphylococcus (coag -)  
 B53-B53 - Staphylococcus (coag +)  
 B54-B54 - Staphylococcus (NOS)  
 B55-B55 - Stomatococcus muliginosus  
 B56-B56 - Streptococcus (all species except Enterococcus)  
 B57-B57 - Treponema (syphilis)  
 B58-B58 - Tuberculosis (NOS, AFB, acid fast bacillus, Koch bacillus)  
 B59-B59 - Typical Tuberculosis (TB, Tuberculosis)  
 B60-B60 - Vibrio (all species)  
 B99-B99 - Other Bacteria  
 V01-V01 - Herpes Simplex (HSV1, HSV2)  
 V02-V02 - Herpes Zoster (Chicken pox, Varicella)  
 V03-V03 - Cytomegalovirus (CMV)  
 V04-V04 - Adenovirus  
 V05-V05 - Enterovirus (Coxsackie, Echo, Polio)  
 V06-V06 - Hepatitis A (HAV)  
 V07-V07 - Hepatitis B (HBV, Australian antigen)  
 V08-V08 - Hepatitis C (includes non-A and non-B, HCV)  
 V09-V09 - HIV-1, HTLV-III  
 V10-V10 - Influenza (Flu)  
 V11-V11 - Measles (Rubeola)  
 V12-V12 - Mumps  
 V13-V13 - Papovavirus  
 V14-V14 - Respiratory Syncytial virus (RSV)  
 V15-V15 - Rubella (German Measles)  
 V16-V16 - Parainfluenza  
 V17-V17 - HHV-6 (Human Herpes Virus)  
 V18-V18 - Epstein-Barr Virus (EBV)  
 V19-V19 - Polyomavirus  
 V20-V20 - Rotavirus  
 V21-V21 - Rhinovirus (Common Cold)  
 V22-V22 - Other Viral  
 P01-P1 - Pneumocystis (PCP)  
 P02-P2 - Toxoplasma  
 P03-P3 - Giardia  
 P04-P4 - Cryptosporidium  
 P05-P5 - Amebiasis  
 P06-P6 - Echinococcal cyst  
 P07-P7 - Trichomonas (either vaginal or gingivitis)  
 P08-P8 - Other Protozoal (Parasite)  
 O01-O1 - Mycobacterium Tuberculosis  
 O02-O2 - Other Mycobacterium  
 O03-O3 - Mycoplasma  
 O04-O4 - Other Organism  
 F01-F01 - Candida Albicans  
 F02-F02 - Candida Krusei  
 F03-F03 - Candida Parasitosis  
 F04-F04 - Candida Tropicalis  
 F05-F05 - Torulopsis Galbrata (a subspecies of Candida)  
 F06-F06 - Candida (NOS)  
 F07-F07 - Aspergillus Flavus  
 F08-F08 - Aspergillus Fumigatus  
 F09-F09 - Aspergillus Niger  
 F10-F10 - Aspergillus (NOS)  
 F11-F11 - Cryptococcus Species  
 F12-F12 - Fusarium Species  
 F13-F13 - Mucormycosis (Zygomycetes, Rhizopus)  
 F14-F14 - Yeast (NOS)  
 F15-F15 - Other Fungus

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

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

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



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

**Blood and Marrow Transplant Clinical  
Trials Network**

**Relapse Form (RLP)**

Web Version: 1.0; 4.00; 04-20-09

**Disease (RELAPSDX):**

**Acute Leukemia**

1. Have leukemia blast cells reappeared in the peripheral blood? (RLALLBPB)  1 - Yes  2 - No  
2. If yes, specify date of reappearance: (RLBPBDT)  (mm/dd/yyyy)
3. Have new dysplastic changes appeared within the bone marrow? (RLALLDYS)  1 - Yes  2 - No  
4. If yes, specify date changes appeared: (RLDYSDT)  (mm/dd/yyyy)
5. Were leukemic blasts documented in the bone marrow after transplantation? (RLALLBL1)  1 - Yes  2 - No  
If yes, indicate the following:  
6. Date blasts documented: (RLALLDT1)  (mm/dd/yyyy)  
7. % Leukemic blasts documented: (RLALLPR1)  (xxx) %
8. Were these blasts attributable to another cause (e.g. bone marrow regeneration)? (RLALLBAT)  1 - Yes  2 - No  
9. If yes, specify the other cause: (RLALLBA0)
10. Were leukemic blasts documented in the bone marrow after transplantation by a second biopsy? (RLALLBL2)  1 - Yes  2 - No  
If yes, indicate the following:  
11. Date blasts documented in second biopsy: (RLALLDT2)  (mm/dd/yyyy)  
12. % Leukemic blasts documented in second biopsy: (RLALLPR2)  (xxx) %
13. Was leukemia detected at an extramedullary site? (RLALEXTR)  1 - Yes  2 - No  
14. If yes, indicate date disease first detected: (RLALEXDT)  (mm/dd/yyyy)
15. Were leukemic cells detected in the cerebrospinal fluid? (RLALCSF)  1 - Yes  2 - No  
16. If yes, indicate date cells first detected: (RLALCSDT)  (mm/dd/yyyy)

**Chronic Myelogenous Leukemia (CML)**

**Hematologic Relapse**

17. Have immature hematopoietic cells been documented in the peripheral blood? (RLCMIMMC)  1 - Yes  2 - No  
18. If yes, indicate date cells first documented: (RLCMIMDT)  (mm/dd/yyyy)
19. Has myeloid hyperplasia been documented in the bone marrow in the presence of cytogenetics relapse? (RLCMMYHY)  1 - Yes  2 - No  
20. If yes, indicate date myeloid hyperplasia first documented: (RLCMMYDT)  (mm/dd/yyyy)

**Cytogenetic Relapse**

21. Have metaphases exhibiting 9;22 translocation been detected? (RLCMCYT1)  1 - Yes  2 - No  
If yes, indicate the following:  
22. Date of analysis: (RLCMCYD1)  (mm/dd/yyyy)  
23. Number of metaphases analyzed: (RLCMNAN1)  (xxx)  
24. Number of metaphases exhibiting 9;22 translocation detected: (RLCMNTR1)  (xxx)
25. Have metaphases exhibiting 9;22 translocation been detected on a second analysis? (RLCMCYT2)  1 - Yes  2 - No  
If yes, indicate the following:  
26. Date of second analysis: (RLCMCYD2)  (mm/dd/yyyy)  
27. Number of metaphases analyzed on second analysis: (RLCMNAN2)  (xxx)  
28. Number of metaphases exhibiting 9;22 translocation detected on second analysis: (RLCMNTR2)  (xxx)

**Myelodysplastic (MDS) and Myeloproliferative Syndromes (includes CMML, AMM or Idiopathic Myelofibrosis, and JMML)**

29. Have pre-transplant morphologic abnormalities reappeared in a bone marrow specimen? (RLMDMRA)  1 - Yes  2 - No  
If yes, indicate the following:

30. Date specimen obtained: (RLMDMAD1)  (mm/dd/yyyy)

31. Have the abnormalities reappeared on a second bone marrow specimen? (RLMD2MRA)  1 - Yes  2 - No

32. If yes, indicate date second specimen obtained: (RLMDMAD2)  (mm/dd/yyyy)

33. Have pre-transplant cytogenetic abnormalities reappeared? (RLMDCY1)  1 - Yes  2 - No

If yes, indicate the following:

34. Date of cytogenetic analysis: (RLMDCYD1)  (mm/dd/yyyy)

35. Number of metaphases analyzed: (RLMDCYA1)  (xxx)

36. Number of metaphases exhibiting pre-transplant cytogenetic abnormalities: (RLMDCYN1)  (xxx)

37. Have pre-transplant cytogenetic abnormalities reappeared on a second analysis? (RLMDCY2)  1 - Yes  2 - No

38. Date of second cytogenetic analysis: (RLMDCYD2)  (mm/dd/yyyy)

39. Number of metaphases analyzed on second analysis: (RLMDCYA2)  (xxx)

40. Number of metaphases exhibiting pre-transplant cytogenetic abnormalities on second analysis: (RLMDCYN2)  (xxx)

41. Has specific therapy, such as infusion of donor lymphocytes, use of interferon, or second transplant, been initiated for relapse reversal? (RLRLPREV)  1 - Yes  2 - No

42. If yes, specify date of initiation of therapy: (RLREVD1)  (mm/dd/yyyy)

Comments: (RLCOMM)

## Additional Selection Options for RLP

### Disease (*RELAPSDX*) (key field):

- 1-1 - Acute Myelogenous Leukemia
- 2-2 - Acute Lymphoblastic Leukemia
- 3-3 - Chronic Myelogenous Leukemia
- 4-4 - Myelodysplastic Syndrome
- 5-5 - Chronic Myelomonocytic Leukemia
- 6-6 - Agnogenic Myeloid Metaplasia with Myelofibrosis
- 7-7 - Juvenile Myelomonocytic Leukemia

**Blood and Marrow Transplant Clinical  
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**Secondary Graft Failure Form (SGF)**

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

Segment (*PROTSEG*):

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

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

Day 1:	( <i>ANC1SGF</i> )	<input type="text"/>	( <i>xxx</i> ) / $\text{mm}^3$	( <i>ANC1SGDT</i> )	<input type="text"/>	( <i>mm/dd/yyyy</i> )
Day 2:	( <i>ANC2SGF</i> )	<input type="text"/>	( <i>xxx</i> ) / $\text{mm}^3$	( <i>ANC2SGDT</i> )	<input type="text"/>	( <i>mm/dd/yyyy</i> )
Day 3:	( <i>ANC3SGF</i> )	<input type="text"/>	( <i>xxx</i> ) / $\text{mm}^3$	( <i>ANC3SGDT</i> )	<input type="text"/>	( <i>mm/dd/yyyy</i> )

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

4. Did the neutrophil count respond to growth factor therapy? (*RSPNDGF*)  1 - Yes  2 - No

Comments: (*SGFCOMM*)

**Blood and Marrow Transplant Clinical  
Trials Network**

**Toxicity Form - 0201 (TX2)**

Web Version: 1.0; 5.00; 04-20-09

**Segment (PROTSEG):**

**Visit Number (VISNO):**

1. Record date of evaluation: (TXEVALDT)

[ ] (mm/dd/yyyy)

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

**Cardiac Toxicity**

2. Hypotension:

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

(HYPOTENS)

3. Left ventricular systolic dysfunction:

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

(LVENTSYS)

4. Cardiac arrhythmia:

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

(CARDARYTH)

**Coagulation Toxicity**

5. HUS/TTP/thrombotic microangiopathy:

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

(DIC)

**Gastrointestinal Toxicity**

6. Mucositis/stomatitis (clinical exam):

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

(MUCOEXAM)

*Mouth pain or esophageal pain requiring IV hydration/narcotics.*

7. Mucositis/stomatitis (functional/symptomatic):

0-0 - Grades 0-2  
3-3 - No Adequate Oral Hydration; Respiratory Symptoms and Incontinence Interfering with ADL  
4-4 - Symptoms Associated with Life-Threatening Consequences  
5-5 - Death

(MUCOFUNC)

**Hemorrhage Toxicity**

8. Hemorrhage:

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

(HEMORRAG)

**Renal Toxicity**

9. Did the patient experience renal failure severe enough to warrant dialysis? (RNLFAIL)

1 - Yes     2 - No

10. If yes, did the patient receive dialysis? (DIALYSIS)

1 - Yes     2 - No

11. Hemorrhagic cystitis:

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

(CYSTITIS)

#### Neurologic Toxicity

12. Somnolence:

0-0 - Grades 0-2  
3-3 - Obtundation or Stupor; Difficult to Arouse; Interfering with ADL  
4-4 - Coma  
5-5 - Death

(SOMNOLNC)

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

14. If yes, record seizure toxicity grade:

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

(SEIZRGRD)

#### Vascular Toxicity

15. Vascular leak syndrome:

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

(VASCLEAK)

#### Musculoskeletal/Soft Tissue Toxicity

16. Osteonecrosis:

0-0 - Grade 0-2  
3-3 - Symptomatic and Interfering with ADL; Operative Intervention or Hyperbaric Oxygen Indicated  
4-4 - Disabling  
5-5 - Death

(OSTEONEC)

#### Sexual/Reproductive Function Toxicity

17. Vaginitis (not due to infection):

0-0 - None  
1-1 - Mild, Intervention Not Indicated  
2-2 - Moderate, Intervention Indicated  
3-3 - Severe, Not Relieved with Treatment; Ulceration, but Operative Intervention Not Indicated  
4-4 - Ulceration and Operative Intervention Indicated

(VAGINITIS)

#### Pulmonary Toxicity

18. Hypoxia (for more than 24 hours):

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

(HYPXIA)

19. Dyspnea:

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

(DYSPNEA)

20. Pulmonary fibrosis:

0-0 - Grades 0-1  
2-2 - Patchy or Bi-Basilar Changes; Proportion of Total Lung Volume Fibrotic of 25 - <50%  
3-3 - Widespread Infiltrates; Proportion of Total Lung Volume Fibrotic of 50 - <75%  
4-4 - Honeycombing; Proportion of Total Lung Volume Fibrotic is  $\geq$  75%  
5-5 - Death

(PULFIBRO)

21. During this assessment period, was an FEV1 performed? (FEVDONE)  1 - Yes  2 - No

22. Record FEV1 value obtained: (FEVVALUE)

(xxx) % of predicted value

23. During this assessment period, was an FVC performed? (FVCDONE)  1 - Yes  2 - No  
 24. Record FVC value obtained: (FVCVALUE)  (xxx) % of predicted value

**Hepatic Toxicity**

25. Did the patient develop abnormal liver function during this assessment period? (ABLVRFNC)  1 - Yes  2 - No

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

26. Jaundice: (JAUNDICE)  1 - Yes  2 - No  
 27. Hepatomegaly: (HEPATOMG)  1 - Yes  2 - No  
 28. Right upper quadrant pain: (QUADPAIN)  1 - Yes  2 - No  
 29. Weight gain (>5%) from baseline: (WIEGHTGN)  1 - Yes  2 - No  
 30. Other clinical signs/symptoms: (OTHERABN)  1 - Yes  2 - No

Specify other clinical signs/symptoms: (OTHSPEC1)

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

	Etiology	Biopsy Results	Doppler Ultrasound Results
31. VOD:	(TX2VODET) <input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No	(TX2VODBI) <input type="checkbox"/> 1-1 - Positive <input type="checkbox"/> 2-2 - Negative <input type="checkbox"/> 3-3 - Equivocal <input type="checkbox"/> 4-4 - Not Done	(TX2VODDP) <input type="checkbox"/> 1-1 - Confirmed <input type="checkbox"/> 2-2 - Not Confirmed <input type="checkbox"/> 3-3 - Not Done
32. GVHD:	(TX2GVHET) <input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No	(TX2GVHBI) <input type="checkbox"/> 1-1 - Positive <input type="checkbox"/> 2-2 - Negative <input type="checkbox"/> 3-3 - Equivocal <input type="checkbox"/> 4-4 - Not Done	(TX2GVHDP) <input type="checkbox"/> 1-1 - Confirmed <input type="checkbox"/> 2-2 - Not Confirmed <input type="checkbox"/> 3-3 - Not Done
33. Infection:	(TX2INFET) <input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No	(TX2INFBI) <input type="checkbox"/> 1-1 - Positive <input type="checkbox"/> 2-2 - Negative <input type="checkbox"/> 3-3 - Equivocal <input type="checkbox"/> 4-4 - Not Done	(TX2INFDP) <input type="checkbox"/> 1-1 - Confirmed <input type="checkbox"/> 2-2 - Not Confirmed <input type="checkbox"/> 3-3 - Not Done
34. Other:	(TX2OTHET) <input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No		
35. Unknown:	(TX2UKNET) <input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No		

Specify other etiology: (OTHSPEC2)

36. Did the patient receive methotrexate for GVHD prophylaxis? (RCVMTX)  1 - Yes  2 - No

If Yes, record the methotrexate dosing for GVHD prophylaxis in the grid below.

	Day 1	Day 3	Day 6	Day 11
37. Date:	(MTHDT1) <input type="text"/> (mm/dd/yyyy)	(MTHDT2) <input type="text"/> (mm/dd/yyyy)	(MTHDT3) <input type="text"/> (mm/dd/yyyy)	(MTHDT4) <input type="text"/> (mm/dd/yyyy)
38. Was the full dose given?	(MTHFULL1) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(MTHFULL2) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(MTHFULL3) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(MTHFULL4) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
39. Total dose given (mg/m <sup>2</sup> ):	(MTHDOSE1) <input type="text"/> (xx.x)	(MTHDOSE2) <input type="text"/> (xx.x)	(MTHDOSE3) <input type="text"/> (xx.x)	(MTHDOSE4) <input type="text"/> (xx.x)
40. Was the dose reduced or withheld due to renal dysfunction?	(WHLDRD1) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDRD2) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDRD3) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDRD4) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
41. Was the dose reduced or withheld due to mucosal toxicity?	(WHLDMTX1) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDMTX2) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDMTX3) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDMTX4) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
42. Was the dose reduced or withheld due	(WHLDFLA1) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDFLA2) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDFLA3) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDFLA4) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No



to fluid accumulation?				
43. Was the dose reduced or withheld due to liver dysfunction?	(WHLDLVR1) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDLVR2) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDLVR3) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDLVR4) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
44. Was the dose reduced or withheld for any other reason?	(WHLDO TH1) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDO TH2) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDO TH3) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(WHLDO TH4) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
Specify other reason for reducing or withholding the dose:	(MTHO THR1) <input type="text"/>	(MTHO THR2) <input type="text"/>	(MTHO THR3) <input type="text"/>	(MTHO THR4) <input type="text"/>

Comments: (TOXCOMM)

**Blood and Marrow Transplant Clinical  
Trials Network**

**Transplant Form (TXP)**

Web Version: 1.0; 11.01; 12-21-11

**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: (TXDTTTP)

(mm/dd/yyyy)

3. Record the patient's pre-transplant CMV status: (CMVSTAT)

1 - Positive     2 - Negative

4. IUBMD for this patient (if available): (T\_IUBMID)

5. CRID # (CIBMT R Recipient ID): (TXPCRID)

(xxxxxxxxxx)

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

Comments: (COMM TXP1)

**Blood and Marrow Transplant Clinical  
Trials Network**

**Vaccination Form (VAX)**

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

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Vaccine	Date of Vaccination	Time of Vaccination
1. Tetanus diphtheria toxoid (dT)	( <i>DTDATE</i> ) <input type="text"/> (mm/dd/yyyy)	( <i>DTTIME</i> ) <input type="text"/> (hh:mm)
2. Hepatitis B	( <i>HEPBDATE</i> ) <input type="text"/> (mm/dd/yyyy)	( <i>HEPBTIME</i> ) <input type="text"/> (hh:mm)
3. Heptavalent pneumococcal conjugate vaccine (PCV7)	( <i>PCV7DATE</i> ) <input type="text"/> (mm/dd/yyyy)	( <i>PCV7TIME</i> ) <input type="text"/> (hh:mm)
4. 23-valent polysaccharide vaccine (PPV23)	( <i>PPV23DAT</i> ) <input type="text"/> (mm/dd/yyyy)	( <i>PPV23TIM</i> ) <input type="text"/> (hh:mm)

Comments: (*VAXCOMNT*)