

**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)

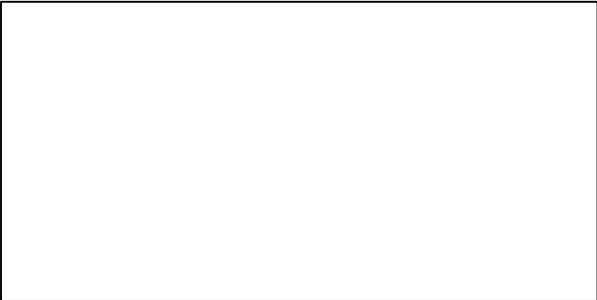


11. Was this event associated with: (AVASSOCI)

- 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
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)

1-1 - 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

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

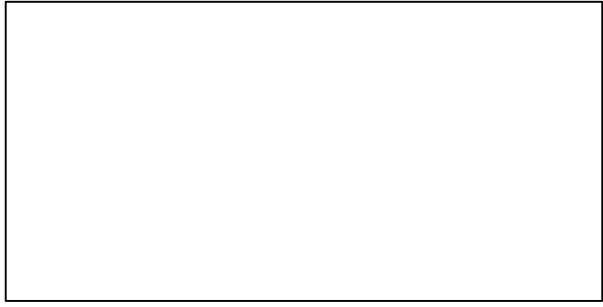
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

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

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

(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 - 0302 (BL1)

Web Version: 1.0; 3.01; 03-09-10

Segment (PROTSEG):

Visit Number (VISNO):

Pre-transplant Status

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

1. Patient's primary diagnosis pre-transplant: (PM0302DX)

1-1 - Acute Myelogenous Leukemia (AML)
2-2 - Acute Lymphoblastic Leukemia (ALL)
3-3 - Chronic Myelogenous Leukemia (CML)
4-4 - Myelodysplastic Syndrome (MDS)
5-5 - Lymphoma
*Additional Options Listed Below

2. If Other, specify primary diagnosis pre-transplant: (OPRIMDX)

3. If AML, record the disease stage pre-transplant: (AML302SG)

1-1 - First Remission
2-2 - Second Remission
3-3 - Third or Subsequent Remission
4-4 - Primary Induction Failure
5-5 - First Complete Remission
*Additional Options Listed Below

4. If ALL, record the disease stage pre-transplant: (ALL302SG)

1-1 - First Remission
2-2 - Second Remission
3-3 - Third or Subsequent Remission
4-4 - Primary Induction Failure
5-5 - First Complete Remission
*Additional Options Listed Below

5. If CML, record the disease stage pre-transplant: (CML302SG)

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

6. If MDS, record the disease stage pre-transplant: (MDS302SG)

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

7. If Lymphoma, record the disease stage pre-transplant: (LYM302SG)

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

8. If Other, record the disease stage pre-transplant: (ODISESG)

9. HLA Typing Method: (HLA302RE)

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

10. Record your institutions HLA match score for this patient: (HLA0302S)

01-3/6
02-4/6
03-5/6
04-6/6
05-3/8
*Additional Options Listed Below

11. Record the type of conditioning regimen: (CON0302R)

1 - Myeloablative 2 - Non-myeloablative or Reduced Intensity

12. Record the Karnofsky/Lansky performance score used to evaluate the patient: (KA0302SC)

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

Transplant

Complete the following questions regarding the patients transplant status.

13. Date of transplant: (T0302DT)

(mm/dd/yyyy)

14. Donor source: (REL0302U)

1 - Related 2 - Unrelated

15. Stem cell type: (T0302TY)

1-1 - Bone Marrow
2-2 - Peripheral Blood Stem Cells
3-3 - Cord Blood

16. Was the stem cell product T-Cell depleted? (T0302CEL)

1 - Yes 2 - No

17. Patient's weight at transplant: (BL0302WT)

(xxx) kg

18. Total nucleated cell dose infused at transplant: (CEL302DS)

(xxx) 10^7 cells/kg

19. CMV status at transplant: (CMV0302S)

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

Comments:

Additional Selection Options for BL1

Patient's primary diagnosis pre-transplant:

6-6 - Other

If AML, record the disease stage pre-transplant:

6-6 - Second Complete Remission
7-7 - Third or Subsequent Remission
8-8 - First Relapse
9-9 - Second Relapse

If MDS, record the disease stage pre-transplant:

6-6 - Refractory Anemia with Excess Blasts - 2 (10-20% blasts)
7-7 - Myelodysplastic Syndrome, Unclassified
8-8 - MDS Associated with Isolated Del(5q)
9-9 - Chronic Myelomonocytic Leukemia

If Lymphoma, record the disease stage pre-transplant:

6-6 - Greater Than Second Relapse

HLA Typing Method:

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

Record your institutions HLA match score for this patient:

06-4/8
07-5/8
08-6/8
09-7/8
10-8/8
11-3/10
12-4/10
13-5/10
14-6/10
15-7/10
16-8/10
17-9/10
18-10/10

Record the Karnofsky/Lansky performance score used to evaluate the patient:

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)

**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 10⁹/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

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

Use mL/day for adult recipients and mL/m² for pediatric recipients.

1-1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m²
2-2 - Diarrhea > 500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m²
3-3 - Diarrhea > 1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m²
4-4 - Diarrhea > 1500 mL/day or >833 mL/m²
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/yyyy)	(<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/yyyy)	(<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/yyyy)	(<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/yyyy)	(<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/yyyy)	(<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/yyyy)	(<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? (*THRPLYUSD*)

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: (*THRPLYATG*)

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

b. Azathioprine: (*THRPLYAZA*)

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

c. Cyclosporine: (*THRPLYCYC*)

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

d. Systemic Corticosteroids: (*THRPLYSCO*)

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

e. Topical Corticosteroids: (*THRPLYTCO*)

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

f. Thalidomide: (*THRPLYTHA*)

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

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

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

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

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

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

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

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

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

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

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

l. Etretnate: (*THRPLYETR*)

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

m. Lamprane: (*THRPLYLAM*)

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

n. Etanercept: (*THRPLYETA*)

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

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

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

p. Chloroquine Phosphate: (*THRPLYCPH*)

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: (THRPYIMM)

- 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: (THRPYOTH)

- 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 10⁹/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)

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

4. Gender: (GENDER)

 1 - Male 2 - Female

5. Date of Birth: (DOB)

6. Ethnicity: (ETHNIC)

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**

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**

0302A (ENR)

Web Version: 1.0; 7.00; 06-26-09

Acute GVHD Enrollment Form

1. Record the date informed consent form was signed: (CNSNT6) (mm/dd/yyyy)
2. Patient's birthdate: (GVBTRHDT) (mm/dd/yyyy)
3. Record patient's weight (PTENTRWT) (xxx.x) kg
4. Date patient's weight assessed: (PTWDATE) (mm/dd/yyyy)

Inclusion Criteria

5. Has the patient had an allogeneic hematopoietic stem cell transplant? (STEMCELL) 1 - Yes 2 - No
6. Date of transplant: (TRNSDT) (mm/dd/yyyy)
7. Transplant type: (TRNPLTYP)
 1-1 - Bone Marrow
 2-2 - Peripheral Blood Stem Cells
 3-3 - Cord Blood
8. Type of conditioning regimen: (MYELOABL) 1 - Myeloablative 2 - Non-myeloablative or Reduced Intensity
9. Does the patient have de novo Grade B-D acute GVHD requiring systemic therapy and is within 48 hours of diagnosis? (GVHDDIAG) 1 - Yes 2 - No
10. Record date and time of diagnosis of GVHD: (GVHDDATE) (mm/dd/yyyy) (GVHDTIME) (hh:mm) 24 hour clock
- Note: The date and time of diagnosis of GVHD is defined as when it is deemed necessary to initiate therapy for GVHD.*

11. Skin abnormalities: (SKIN_ABN)
 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
12. Upper GI abnormalities: (UPPER_GI)
 0-0 - No Protracted Nausea and Vomiting
 1-1 - Persistent Nausea, Vomiting or Anorexia
13. Lower GI abnormalities: (LOWER_GI)
 0-0 - No Diarrhea
 1-1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m²
 2-2 - Diarrhea >500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m²
 3-3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m²
 4-4 - Diarrhea >1500 mL/day or >833 mL/m²
 *Additional Options Listed Below
14. Liver abnormalities: (LIVER_AB)
 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
15. Did the patient receive immunosuppressive therapy for treatment of acute GVHD (other than a maximum 48 hours of prior corticosteroid therapy 1 mg/kg/day methylprednisolone)? (IMMUNTHR) 1 - Yes 2 - No
16. Is the patient currently receiving corticosteroid therapy? (CURSTER) 1 - Yes 2 - No
17. Corticosteroid given: (STERTYPE)
 1-1 - Prednisone
 2-2 - Methylprednisolone
 -
18. Record patient's current dose of prednisone: (PREDDOSE) (x.x) mg/kg/day
19. Record patient's current dose of methylprednisolone: (METHDOSE) (x.x) mg/kg/day
20. Has the patient undergone a scheduled donor lymphocyte infusion (DLI) as part of their original transplant therapy plan? (DLI0302P) 1 - Yes 2 - No
21. Does the patient's current clinical status allow for at least 0.6 mg/kg/day methylprednisolone (0.75 mg/kg/day prednisone) for the first 28 days of the study? (STERIODS) 1 - Yes 2 - No

22. Has the patient received Mycophenolate Mofetil (MMF) for GVHD prophylaxis within 7 days of enrollment? (MMFUSED) 1 - Yes 2 - No

	Most Recent Value	ULN for Your Institution	Date Sample Obtained
23. Absolute Neutrophil Count (ANC):	(REC_ANC) [] (xxxx) / μ L		(ANCDATE) [] (mm/dd/yyyy)
24. Creatinine:	(SCRGVH) [] (x.x) (mg/dL)	(CRULNGVH) [] (x.x) (mg/dL)	(CRDTGVH) [] (mm/dd/yyyy)
25. Creatinine Clearance (mL/min) (calculated or estimated):	(CRCLGVH) [] (xxx) (mL/min)		(CRCLDTGV) [] (mm/dd/yyyy)

Exclusion Criteria

- 26. Has the patient received Etanercept, Denileukin Diftitox (Ontak), or Pentostatin within 7 days of enrollment? (STDYAGNT) 1 - Yes 2 - No
- 27. Does the patient have an uncontrolled viral or bacterial infection? (BACVIRAL) 1 - Yes 2 - No
- 28. Was a GVHD diagnosis made following an unscheduled DLI or a DLI that was not part of their original transplant therapy plan? (GVHD_DLI) 1 - Yes 2 - No
- 29. Does the patient have any clinical syndrome resembling de novo chronic GVHD after allotransplantation? (ALLTRNSP) 1 - Yes 2 - No
- 30. Has the patient received other investigational drugs for GVHD, including GVHD prophylaxis, within 30 days of enrollment? (OTH_AGEN) 1 - Yes 2 - No
- 31. Is the patient willing to use contraceptive techniques for the duration of the study? (CNTRCPTV) 1 - Yes 2 - No 3 - Not Applicable
- 32. Is the patient pregnant (positive -HCG) or breastfeeding? (PREGANT) 1 - Yes 2 - No 3 - Not Applicable
- 33. Does the patient have a history of allergies or intolerance to any of the study drugs? (ALLERGVH) 1 - Yes 2 - No

Consent for Biological Samples

- 34. Did the patient give consent to have blood drawn for research purposes? (O3O2BLD) 1 - Yes 2 - No
- 35. Did the patient give consent to have skin biopsies taken for research purposes? (O3O2SKIN) 1 - Yes 2 - No

Comments: (COMMENTS)

Additional Selection Options for ENR

Lower GI abnormalities:

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

**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

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

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: (GVASENDT)

(mm/dd/yyyy)

The assessment for which you are entering data must have taken place within the above dates. If the patient was not seen during the assessment period specified above, please exit the form and request an exception for this form.

2. Immunosuppressant (prophylaxis) received: (IMMUNORC)

0-0 - Prednisone
1-1 - Cyclosporine
2-2 - Tacrolimus
3-3 - Not taken during assessment

3. Record most recent blood level of immunosuppressant (prophylaxis): (TROUGHVLV)

(xxx.x) ng/mL

4. Record date blood sample obtained: (TROUGHDT)

(mm/dd/yyyy)

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

5. Skin abnormalities: (GVHSKINA)

0-0 - 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

6. Skin etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SETGVHD) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No <input style="background-color: #90EE90;" type="button" value="?"/>	(SETDRGRX) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(SETCRTOX) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
Infection	Other	
(SETINFCT) <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: (GVHSKNSP)

7. Skin biopsy for GVHD: (GVHSKINB)

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

8. Upper GI abnormalities: (GVHUPGIA)

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

9. 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
TPN	Infection	Other
(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)

10. Upper intestinal tract biopsy for GVHD: (UGBIORS)

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

11. Lower GI abnormalities: (GVHINTA)

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

?

Use mL/day for a dult patients and mL/m² for pediatric patients

12. Lower intestinal tract etiologies:

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

Specify other lower intestinal tract etiologies: (LGIETSPC)

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

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

14. 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

15. Liver etiologies:

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

Specify other liver etiologies: (GVHLIVRS)

16. Liver biopsy for GVHD: (GVHLIVRB)

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

)}
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

**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, otherspecies)
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, otherspecies)
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-B01 - A cinetobacter (baumanii, calcoaceticus, lwoffii, other species)
BO2-B02 - A grobacterium radiobacter
BO3-B03 - A lcaligenes xylosoxidans
BO4-B04 - A naerobic bacteria (NOS , except for Bacteroides, Clostridium)
BO5-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)

1-1 - 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. 1st 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. 2nd 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. 3rd 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 mucilaginosus
 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

1st 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)
cefepime-cefepime (Vantin)
cefprozil-cefprozil (Cefzil)
ceftazidime-ceftazidime (Fortaz, Tazicef)
ceftriaxone-ceftioxa (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)
clotrimazole / betamethasone-clotrimazole / 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)
foscamet-foscamet (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 (Crivivan)
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, Nydrizid)
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)
nefazoline-nefazoline (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)
pentamidine-pentamidine (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**

Immune Reconstitution Form - 0302 (IRC)

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

Segment (PROTSEG):

Visit Number (VISNO):

Immunophenotyping

1. Date immunophenotyping was performed: (IRCFCDT)

(mm/dd/yyyy)

2. White blood cell count: (IRCWBC)

(xxxx) x 10⁹/L

3. Percent lymphocyte of CD45+ cells: (IRCLYMPH)

(xxx) %

4. CD3: (IRCCD3)

(xxx) cells/uL

5. CD4: (IRCCD4)

(xxx) cells/uL

6. CD8: (IRCCD8)

(xxx) cells/uL

7. CD25: (IRCCD25)

(xxx) cells/uL

8. CD69: (IRCCD69)

(xxx) cells/uL

9. CD20: (IRCCD20)

(xxx) cells/uL

10. CD4+/CD25+: (IRCCD425)

(xxx) cells/uL

Comments: (IRCCOMMT)

**Blood and Marrow Transplant Clinical
Trials Network**

Laboratory Assessment Form - 0302 (LAF)

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

Segment (PROTSEG):

Visit Number (VISNO):

Laboratory Assessments

1. Start of Assessment Period: (LAFAPST) (mm/dd/yyyy)
2. Target Assessment Date: (LAFAPEND) (mm/dd/yyyy)
3. End of Assessment Period: (LAFAPEND) (mm/dd/yyyy)

CBC

	Most Recent Value	Date of Sample
4. RBC	(LABRBC) <input type="text"/> (x.x) million/mm ³	(RBCDT) <input type="text"/> (mm/dd/yyyy)
5. RBC	(LABRBC) <input type="text"/> (x.x) million/mm ³	(RBCDT) <input type="text"/> (mm/dd/yyyy)
6. He matocrit	(LABHCT) <input type="text"/> (xx.x) %	(HCTDT) <input type="text"/> (mm/dd/yyyy)
7. He matocrit	(LABHCT) <input type="text"/> (xx.x) %	(HCTDT) <input type="text"/> (mm/dd/yyyy)
8. He moglobin	(LABHGB) <input type="text"/> (xx.x) g/dL	(HGBDT) <input type="text"/> (mm/dd/yyyy)
9. He moglobin	(LABHGB) <input type="text"/> (xx.x) g/dL	(HGBDT) <input type="text"/> (mm/dd/yyyy)
10. WBC	(LABWBC) <input type="text"/> (xxxxxx)	(WBCDT) <input type="text"/> (mm/dd/yyyy)
11. WBC	(LABWBC) <input type="text"/> (xxxxxx)	(WBCDT) <input type="text"/> (mm/dd/yyyy)
12. Platelet Count	(PLATELET) <input type="text"/> (xxxxxx) /mcL	(PLATDT) <input type="text"/> (mm/dd/yyyy)
13. Platelet Count	(PLATELET) <input type="text"/> (xxxxxx) /mcL	(PLATDT) <input type="text"/> (mm/dd/yyyy)
14. ANC	(NEUTAGVH) <input type="text"/> (xxxx) /mcL	(GRANDT) <input type="text"/> (mm/dd/yyyy)
15. ANC	(NEUTAGVH) <input type="text"/> (xxxx) /mcL	(GRANDT) <input type="text"/> (mm/dd/yyyy)
16. Lymphocytes	(LYMPHCYT) <input type="text"/> (xxxxx) /mcL	(LYMPHDT) <input type="text"/> (mm/dd/yyyy)
17. Lymphocytes	(LYMPHCYT) <input type="text"/> (xxxxx) /mcL	(LYMPHDT) <input type="text"/> (mm/dd/yyyy)

Chemistry and LFT's

	Most Recent Value	Date of Sample
18. Creatinine	(LABCREAT) <input type="text"/> (x.x) mg/dL	(LBCRTDT) <input type="text"/> (mm/dd/yyyy)
19. Creatinine	(LABCREAT) <input type="text"/> (x.x) mg/dL	(LBCRTDT) <input type="text"/> (mm/dd/yyyy)
20. Estimated Creatinine Clearance	(LABCRCL) <input type="text"/> (xxx) mL/min	(LBCRCLDT) <input type="text"/> (mm/d/yyyy)
21. Estimated Creatinine Clearance	(LABCRCL) <input type="text"/> (xxx) mL/min	(LBCRCLDT) <input type="text"/> (mm/d/yyyy)
22. Bilirubin	(LABBILI) <input type="text"/> (xx.x) mg/dL	(LBBILIDT) <input type="text"/> (mm/dd/yyyy)
23. Bilirubin	(LABBILI) <input type="text"/> (xx.x) mg/dL	(LBBILIDT) <input type="text"/> (mm/dd/yyyy)
24. Alkaline Phosphatase	(LBALKPHO) <input type="text"/> (xxxx) IU/L	(ALKPHDT) <input type="text"/> (mm/dd/yyyy)
25. Alkaline Phosphatase	(LBALKPHO) <input type="text"/> (xxxx) IU/L	(ALKPHDT) <input type="text"/> (mm/dd/yyyy)
26. AST	(LABAST) <input type="text"/> (xxx) IU/L	(LBA STDT) <input type="text"/> (mm/dd/yyyy)
27. AST	(LABAST) <input type="text"/> (xxx) IU/L	(LBA STDT) <input type="text"/> (mm/dd/yyyy)

28. ALT	(LBALT) <input type="text"/> (xxxx) IU/L	(LBALTDI) <input type="text"/> (mm/dd/yyyy)
29. ALT	(LBALT) <input type="text"/> (xxxx) IU/L	(LBALTDI) <input type="text"/> (mm/dd/yyyy)

30. What is the patient's Karnofsky / Lansky performance score? (LBKARLAN)

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

Comments: (LBCMNTS)

Additional Selection Options for LAF

What is the patient's Karnofsky / Lansky performance 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)

**Blood and Marrow Transplant Clinical
Trials Network**

Medication Form - 0302 (MD2)

Web Version: 1.0; 4.01; 02-25-10

Segment (PROTSEG):

Visit Number (VISNO):

1. Record the start of the assessment period: (MDSTAP) (mm/dd/yyyy)

2. Record the end of the assessment period: (MDENDAP) (mm/dd/yyyy)

3. Record the study drug assignment: (MDDRGASN)

1-1 - Etanercept
2-2 - Mycophenolate Mofetil (MMF)
3-3 - ONTAK
4-4 - Pentostatin

Steroid Dose

4. Did the prednisone dose ever drop below 1.4 mg/kg/day OR did the methylprednisolone dose ever drop below 1.0 mg/kg/day during this assessment period? (STERDROP) 1 - Yes 2 - No

5. If yes, record the date the steroid dose dropped below 1.4 mg/kg/day for prednisone or 1.0 mg/kg/day for methylprednisolone: (DTSTRDRP) (mm/dd/yyyy)

6. Record the dose of steroid given on this date: (STRLWDOS) (x.x) mg/kg/day

7. Record the steroid given: (LOWSTER)

1-1 - Prednisone
2-2 - Methylprednisolone
-

It is a protocol violation if the prednisone dose drops below 1.4 mg/kg/day or the methylprednisolone dose drops below 1.0 mg/kg/day before Day 28. If this has happened, please contact the protocol coordinator as soon as possible.

Patients Randomized to Receive Etanercept, ONTAK, or Pentostatin

8. Record the total number of doses given during this assessment period: (NUMBDOS) (x)

Patients Randomized to Receive MMF

9. Was the patient inpatient or outpatient during this assessment period? (INOUTPT) 1-1 - Inpatient
 2-2 - Outpatient
 3-3 - Both

10. Record the total number of inpatient doses of MMF given during this assessment period: (INPTDOSE) (xx)

11. For outpatients, record the number of MMF doses (expected to be taken twice daily) dispensed during this assessment period: (MMFDISP) (xx)

12. For outpatients, record the number of MMF doses returned by the patient: (MMFRET) (xx)

13. For outpatients, does the patient appear to be compliant with taking MMF during this assessment period? (If the patient is taking 90-110% of the prescribed doses, then indicate "Yes." If not, then indicate "No.") (PTCOMPLI) 1 - Yes 2 - No

All Patients

14. Was study drug withheld at any time during this assessment period? (MDSDRHLD) 1 - Yes 2 - No

15. If yes, record the reason study drug was withheld: (MDDRREA)

01-01 - Grade 3-4 toxicity probably related to study drug
02-02 - ANC < 500 /microliter
03-03 - Creatinine clearance < 30mL /minute
04-04 - Progression of GVHD by Day 7
05-05 - No response in GVHD by Day 14
*Additional Options Listed Below

Specify other reason study drug was withheld: (MDORSPEC)

16. Did the patient receive anything for GVHD treatment other than the assigned study drug, steroids, and CSA or FK506? (TRTOTHYN) 1 - Yes 2 - No

17. If yes, indicate the agent name: (GVHTREAT)

1-1 - CSA
2-2 - Pentostatin
3-3 - Tacrolimus
4-4 - Sirolimus
5-5 - Infliximab
*Additional Options Listed Below

Specify other agent: (MD2SPEC)

Comments: (MD2COMM)

Additional Selection Options for MD2

If yes, record the reason study drug was withheld:

- 06-06 - Sustained bacteremia
- 07-07 - Persistent culture negative fever
- 08-08 - Hemodynamic instability
- 09-09 - Patient refused
- 10-10 - Patient withdrew consent
- 11-11- Other, specify

If yes, indicate the agent name :

- 6-6 - Etanercept
- 7-7 - Dacluzimab
- 8-8 - Open Label MMF
- 9-9 - Ontak
- 99-10 - Other

**Blood and Marrow Transplant Clinical
Trials Network**

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:	(ANC1SGF) <input type="text"/> (xxx) /mm ³	(ANC1SGDT) <input type="text"/> (mm/dd/yyyy)
Day 2:	(ANC2SGF) <input type="text"/> (xxx) /mm ³	(ANC2SGDT) <input type="text"/> (mm/dd/yyyy)
Day 3:	(ANC3SGF) <input type="text"/> (xxx) /mm ³	(ANC3SGDT) <input type="text"/> (mm/dd/yyyy)

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 - 0302 (TX4)

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

Segment (*PROTSEG*):

Visit Number (*VISNO*):

1. Record date of evaluation: (*TX4EVLDT*) (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.

Blood/Bone Marrow Toxicity

2. Neutrophils: (*TX4ANC*)

0-0 - Grades 0-2
3-3 - < 1000 - 500/mm³
4-4 - < 500/mm³
5-5 - Death

3. Platelets: (*TX4PLAT*)

0-0 - Grades 0-2
3-3 - < 50,000 - 25,000/mm³
4-4 - < 25,000/mm³
5-5 - Death

4. Leukocytes: (*TX4LEUKO*)

0-0 - Grades 0-2
3-3 - < 2000 - 1000/mm³
4-4 - < 1000/mm³
5-5 - Death

5. Anemia: (*TX4ANEMI*)

0-0 - Grades 0-2
3-3 - < 8.0 - 6.5 g/dL
4-4 - < 6.5 g/dL
5-5 - Death

GI Toxicity

6. Mucositis/stomatitis (clinical exam): (*TX4MCS TS*)

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

Mouth pain or esophageal pain requiring IV hydration/harcotics.

Renal Toxicity

7. Did the patient experience renal failure severe enough to warrant dialysis? (*TX4RENAL*)

1 - Yes 2 - No

8. Did the patient receive dialysis? (*TX4DIALS*)

1 - Yes 2 - No

9. Hemorrhagic cystitis: (*TX4CYSTI*)

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

Hemorrhagic Toxicity

10. Hemorrhage: (*TX4HEMRG*)

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

Cardiovascular Toxicity

11. Hypotension: (*TX4HYPO T*)

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

12. Cardiac arrhythmia: (TX4CRDAR)

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

13. Left ventricular systolic dysfunction: (TX4LVENT)

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

Neurologic Toxicity

14. Somnolence: (TX4SMNLN)

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

15. Did the patient experience any seizures during this assessment period? (TX4SEIZR) 1 - Yes 2 - No

16. Record seizure toxicity grade: (TX4SZGRD)

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

Coagulation Toxicity

17. HUS/TTP/thrombotic microangiopathy: (TX4DIC)

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

Vascular Toxicity

18. Vascular leak syndrome: (TX4VASLK)

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

Pulmonary Toxicity

19. Hypoxia (for more than 24 hours): (TX4HYPXI)

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

20. Dyspnea: (TX4DYSPN)

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

21. During this assessment period, was an FEV1 performed? (TX4FEVDN) 1 - Yes 2 - No

22. Record FEV1 value obtained: (TX4FEVVL)

(xxx) % of predicted value

23. During this assessment period, was an FVC performed? (TX4FVCDN) 1 - Yes 2 - No

24. Record FVC value obtained: (TX4FVCVL)

(xxx) % of predicted value

Hepatic Toxicity

25. Did the patient develop abnormal liver function during this assessment period? (TX4ABNLF) 1 - Yes 2 - No

26. ALT: (TX4ALT)

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

27. AST: (TX4AST)

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

28. Bilirubin: (TX4BILI)

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

29. Creatinine: (TX4CREAT)

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

30. Hypoalbuminemia: (TX4ALBUM)

0-0 - Grades 0-2
 3-3 - < 2 g/dL
 5-5 - Death

31. Hypoglycemia: (TX4GLYCE)

0-0 - Grades 0-2
 3-3 - < 40 - 30 mg/dL
 4-4 - < 30 mg/dL
 5-5 - Death

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

32. Jaundice: (TX4JANDC) 1 - Yes 2 - No
 33. Hepatomegaly: (TX4HPTMG) 1 - Yes 2 - No
 34. Right upper quadrant pain: (TX4QUADP) 1 - Yes 2 - No
 35. Weight gain (>5%) from baseline: (TX4WGHTG) 1 - Yes 2 - No
 36. Other clinical signs/symptoms: (TX4OTHAB) 1 - Yes 2 - No

Specify other clinical signs/symptoms: (TX4SPEC1)

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
37. VOD:	<input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No (TX4VODET)	<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 (TX4VODBI)	<input type="checkbox"/> 1-1 - Confirmed <input type="checkbox"/> 2-2 - Not Confirmed <input type="checkbox"/> 3-3 - Not Done (TX4VODDP)
38. GVHD:	<input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No (TX4GVHET)	<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 (TX4GVHBI)	<input type="checkbox"/> 1-1 - Confirmed <input type="checkbox"/> 2-2 - Not Confirmed <input type="checkbox"/> 3-3 - Not Done (TX4GVHDP)
39. Infection:	<input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No (TX4INFET)	<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 (TX4INFBI)	<input type="checkbox"/> 1-1 - Confirmed <input type="checkbox"/> 2-2 - Not Confirmed <input type="checkbox"/> 3-3 - Not Done (TX4INFDP)
40. Other:	<input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No (TX4OTHET)	<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 (TX4OTHBI)	<input type="checkbox"/> 1-1 - Confirmed <input type="checkbox"/> 2-2 - Not Confirmed <input type="checkbox"/> 3-3 - Not Done (TX4OTHDP)
41. Unknown:	<input type="checkbox"/> 1-1 - Yes <input type="checkbox"/> 2-2 - No (TX4UNKET)		

Specify other etiology: (TX4SPEC2)

Comments: (TX4COMM)