

Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Web Version: 1.0; 4.03; 06-19-12

Segment (PROTSEG):

Date of Admission (ADMITDT):

1. Date of discharge: (DISCHDT)

(mm/dd/yyyy)

2. Patient discharge status: (DISCPTST)

1 - Alive 2 - Dead

If Dead, a Death Form must be submitted.

3. Record PRIMARY discharge diagnosis: (PHSPREAS)

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



*Specify organ: (ADM4SPEC)

**Specify other: (ADM1SPEC)

4. Record secondary discharge diagnoses:

a. GVHD: (REASGVHD)

1 - Contributory 2 - Noncontributory



b. Relapse/progression: (REASRLPS)

1 - Contributory 2 - Noncontributory

c. Graft failure: (REASGF)

1 - Contributory 2 - Noncontributory

d. Infection: (REASINF)

1 - Contributory 2 - Noncontributory

e. Fever: (REASFVR)

1 - Contributory 2 - Noncontributory

f. Seizure: (REASSZR)

1 - Contributory 2 - Noncontributory

g. Bleeding/hemorrhage: (REASGIBL)

1 - Contributory 2 - Noncontributory

h. Diarrhea: (REASDRH)

1 - Contributory 2 - Noncontributory

i. Nausea/vomiting: (REASNV)

1 - Contributory 2 - Noncontributory

j. Organ failure: (REASORGF)

1 - Contributory 2 - Noncontributory

Specify organ: (ADM3SPEC)

k. Trauma: (REASTRAM)

1 - Contributory 2 - Noncontributory

l. Psychiatric: (REASPSYC)

1 - Contributory 2 - Noncontributory

m. Secondary malignancy: (REASMALG)

1 - Contributory 2 - Noncontributory

n. Scheduled procedure/treatment: (REASPROC)

1 - Contributory 2 - Noncontributory

o. Thrombosis/thrombus/embolism: (REASTRMB)

1 - Contributory 2 - Noncontributory

p. Other: (REASOTHR)

1 - Contributory 2 - Noncontributory

Specify other: (ADM2SPEC)

5. Record re-admission institution: (ADMCENTR)

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

Comments: (ADMCOMM1)

Additional Selection Options for ADM

Record PRIMARY discharge diagnosis:

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

**Blood and Marrow Transplant Clinical
Trials Network**

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

Web Version: 1.0; 3.07; 06-14-12

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

1. Report activation status:(AVSTATUS)

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



If Other, specify reason for deactivation:(AESPEC1)

2. Record date transplant center became aware of the event:(AVAWARDT)

(mm/dd/yyyy)

3. Indicate weight at time of the event:(AVWGHTKG)

(xxx.x) kg

4. Was this event expected or anticipated?(AVEXPECT)

1 - Yes 2 - No

5. Record the severity of event:(AVEVENT)

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



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

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

7. Is there an alternative etiology:(AVETIOL)

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

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

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

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

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



10. Record the date of resolution:(AVRESDT)

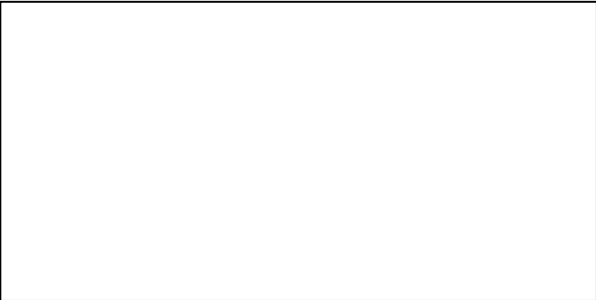
(mm/dd/yyyy)

11. Was this event associated with:(AVASSOCI)

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



Comments:(AE1COMM)



Additional Selection Options for AE1

Was this event associated with:

5 - Required Intervention to Prevent Permanent Impairment or Damage

6 - Hospitalization (Initial or Prolonged)

9 - Other SAE

**Blood and Marrow Transplant Clinical
Trials Network**

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

Web Version: 1.0; 3.07; 07-24-12

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

1. Report activation status:(AVSTAT_A)

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

Relevant Past Medical History

2. Does the patient have any relevant history, including pre-existing medical conditions?(SEMEDHXS)

1 - Yes 2 - No

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

(SEMEDHX)

3. Event Summary

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

(SESUMM)

4. Initial submitter:(SEISUBBY)

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

5. Authorized submitter:(SEASUBBY)

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

**Blood and Marrow Transplant Clinical
Trials Network**

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

Web Version: 1.0; 4.00; 07-24-12

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

1. Report activation status: (AVSTAT_B)

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

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

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

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

Comments:(AE3COMM)

**Blood and Marrow Transplant Clinical
Trials Network**

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

Web Version: 1.0; 3.06; 07-24-12

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

1. Report activation status:(AVSTAT_C)

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

Laboratory Test Results

2. Were relevant laboratory tests performed?(LABTSTPF)

1 - Yes 2 - No

If Yes, record the relevant laboratory test results in the 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)

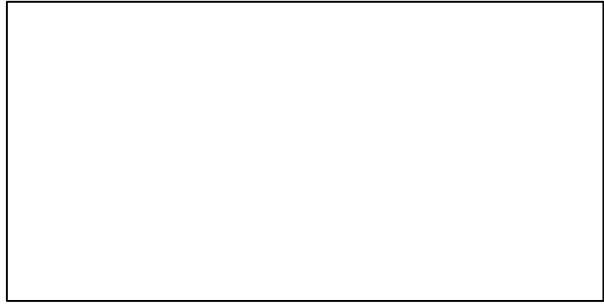
1 - Yes 2 - No

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"/>

Comments:(AE4COMM)



**Blood and Marrow Transplant Clinical
Trials Network**

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

Web Version: 1.0; 3.07; 07-24-12

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

1. Report activation status:(AVSTAT_D)

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

2. Reviewed:(AEREVIEW)

1 - Yes 2 - No

3. Reviewed by:(ARFREVBY)

4. Review date:(ARFREVDT)

 (mm/dd/yyyy)

5. Comment 1 - For Distribution:(ARCM1DIS)

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

**Blood and Marrow Transplant Clinical
Trials Network**

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

Web Version: 1.0; 5.01; 07-24-12

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

1. Adverse event status:(AVSTAT_E)

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

2. Has this event been determined to be an unexpected, grade 3-5 adverse event? 1 - Yes 2 - No
(AMDETER)

3. Does this require expedited reporting to the FDA? (AMEXPFDA) 1 - Yes 2 - No

4. Does this require expedited reporting to the DSMB? (AMEXPDSM) 1 - Yes 2 - No

5. Do you recommend the patient be withdrawn from further protocol therapy?
(AMWITHDR) 1 - Yes 2 - No

6. Is the review complete?(AMREVDNE) 1 - Yes 2 - No

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

8. Medical Monitor event description:(AMMMEVDS)

Comments:(AE6COMM)

**Blood and Marrow Transplant Clinical
Trials Network**

Baseline Form - 0403 (BL2)

Web Version: 1.0; 2.01; 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: (PM0403DX)

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

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

3. If AML, record the disease stage pre-transplant: (AML403SG)

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

4. If ALL, record the disease stage pre-transplant: (ALL403SG)

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

5. If CML, record the disease stage pre-transplant: (CML403SG)

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

6. If MDS, record the disease stage pre-transplant: (MDS403SG)

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

7. If Lymphoma, record the disease stage pre-transplant: (LYM403SG)

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

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

9. HLA Typing Method: (HLA403RE)

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

10. Record your institution's HLA match score for this patient:(HLA403S)

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

Transplant

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

11. Date of transplant:(T0403DT)

(mm/d/yyyy)

12. Donor Source:(REL0403U)

1 - Related Donor Marrow
2 - Unrelated Donor Marrow
3 - Related PBSC
4 - Unrelated PBSC
5 - Related Donor Umbilical Cord Blood
*Additional Options Listed Below

13. Was the stem cell product T-Cell depleted?(T0403CEL)

1 - Yes 2 - No

14. Patient's weight at transplant:(BL0403WT)

(xxx) kg

15. Record total nucleated cell dose infused:(CEL403DS)

(xxx) 10⁷ cells/kg

16. CMV status at transplant:(CM V0403S)

1 - Positive 2 - Negative 3 - Not Done

Comments:(B0403COM)

Additional Selection Options for BL2

Patient's primary diagnosis pre-transplant:

6 - Other

If AML, record the disease stage pre-transplant:

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

If MDS, record the disease stage pre-transplant:

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

If Lymphoma, record the disease stage pre-transplant:

- 6 - Greater Than Second Relapse

HLA Typing Method:

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

Record your institution's HLA match score for this patient:

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

Donor Source:

- 6 - Unrelated Donor Umbilical Cord Blood

**Blood and Marrow Transplant Clinical
Trials Network**

Follow Up GVHD Form (CGV)

Web Version: 1.0; 7.03; 10-30-12

Segment (PROTSEG):

Visit Number (VISNO):

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

Answer questions 3-9 relating to acute GVHD.

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

Answer questions 10-20 relating to chronic GVHD.

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

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

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

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

(xxx.x) x 10⁹/L

17. Alkaline phosphatase at time of diagnosis: (ALKP HOSP)

(xxx) U/L

18. Weight at time of diagnosis: (CGVWEIGH)

(xxx.x) kg

19. Total bilirubin at time of diagnosis: (BILIRUBN)

(xx.x) mg/dL

20. Body surface area involved with rash at time of diagnosis: (BSA)

(xxx) % ?

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

Skin/Hair

21. Extent of skin involvement: (CGVRASH)

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

?

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

a. Lichenoid: (RASHLICH)

1 - Yes 2 - No

b. Maculopapular: (RASHMACU)

1 - Yes 2 - No

c. Sclerodermatous: (RASHSCLR)

1 - Yes 2 - No

Ocular

22. Xerophthalmia: (DRYEYES)

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

Oral

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

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

Pulmonary

24. Dyspnea: (CGVDYSPN)

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

25. Pulmonary fibrosis: (PULMFIBR)

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

26. Bronchiolitis obliterans: (BRNCOBLT)

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

27. FEV1: (CGVFEV1)

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

28. Oxygen saturation:(O2SAT)

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

Gastrointestinal

29. Esophagus:(ESOPHAGS)

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

30. Nausea and vomiting:(NAUSVOMT)

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

31. Diarrhea:(CGVDIARRH)

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

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

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

33. Diarrhea (number of stools):(DIARRHEA1)

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

34. Diarrhea (volume of stools):(DIARRHEA2)

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

- 1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m²
- 2 - Diarrhea > 500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m²
- 3 - Diarrhea > 1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m²
- 4 - Diarrhea > 1500 mL/day or >833 mL/m²
- 5 - Severe Abdominal Pain with or without Ileus, or Stool with Frank Blood or Melena

35. Malabsorption:(MALABSRP)

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

Hepatic

36. Bilirubin level:(LIVERBIL)

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

Genitourinary

37. Vaginitis:(VAGNITIS)

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

Musculoskeletal

38. Contractures:(CONTRACTR)

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

39. Myositis:(MYOSITIS)

- 1 - Yes
- 2 - No

Hematologic

40. Eosinophilia:(EOSINPHL)

- 1 - Yes
- 2 - No

Other

41. Serositis: (*SEROSITS*) 1 - Yes 2 - No
42. Fasciitis: (*FASCITIS*) 1 - Yes 2 - No
43. Was there other organ involvement? (*ORGNO THR*) 1 - Yes 2 - No
- Specify other organ: (*ORG SPEC*) _____

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

Answer questions 51-54 relating to GVHD therapy.

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

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



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

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

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

b. Azathioprine:(*THRPYAZA*)

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

c. Cyclosporine:(*THRPYCYC*)

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

d. Systemic Corticosteroids:(*THRPYSCO*)

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

e. Topical Corticosteroids:(*THRPYTCO*)

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

f. Thalidomide:(*THRPYTHA*)

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

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

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

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

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

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

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

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

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

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

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

l. Etretnate:(*THRPYETR*)

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

m. Lamprone:(*THRPYLAM*)

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

n. Etanercept:(*THRPYETA*)

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

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

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

p. Chloroquine Phosphate:(*THRPYCPH*)

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

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

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

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

r. In Vivo Immunotoxin:(*THRPIIMM*)

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

Specify in vivo immunotoxin used:(*IMMAGNT*)

s. Other:(*THRPIOTH*)

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

Specify other agent used:(*OTHAGNT*)

52. Has treatment been discontinued?(*ONGTRT*)

- 1 - Yes
- 2 - No

53. If yes, enter date of discontinuation:(*TRTSTOP*)

(*mm/dd/yyyy*)

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

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



Answer questions 55-58 relating to current patient status.

55. Are symptoms of GVHD still present?(*GVHDSYMP*)

- 1 - Yes
- 2 - No

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

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

57. Current platelet count:(*CURPLTCT*)

(*xxx.x*) x 10⁹/L

58. Current weight:(*CURWGHT*)

(*xxx.x*) kg

Comments:(*CGVCOMM*)

Additional Selection Options for CGV

Minimum Karnofsky/Lansky Score at time of diagnosis:

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

Biopsy Type 1

- 6 - Lung Biopsy
- 7 - Other, Specify

Current Karnofsky/Lansky Score:

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

**Blood and Marrow Transplant Clinical
Trials Network**

Demographics (DEM)

Web Version: 1.0; 6.01; 06-21-12

1. Name Code:(NAMECODE)

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

3. Gender:(GENDER)

4. Date of Birth:(DOB)

5. Ethnicity:(ETHNIC)

6. Race:(RACE)

Specify race:(RACESP)

7. Secondary Race:(RACE2)

Specify secondary race:(RACE2SP)

Comments:(DEMCOMM1)

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

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

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

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

Additional Selection Options for DEM

Race:

15 - South or Central American

16 - Eastern European

17 - Northern European

18 - Western European

81 - White Caribbean

82 - North Coast of Africa

83 - Middle Eastern

Black

20 - Black (Not Otherwise Specified)

21 - African American

22 - African Black (Both Parents Born in Africa)

23 - Caribbean Black

24 - South or Central American Black

29 - Black, Other Specify

Asian

30 - Asian (Not Otherwise Specified)

31 - Indian/South Asian

32 - Filipino (Pilipino)

34 - Japanese

35 - Korean

36 - Chinese

37 - Other Southeast Asian

38 - Vietnamese

American Indian or Alaska Native

50 - Native American (Not Otherwise Specified)

51 - Native Alaskan/Eskimo/Aleut

52 - American Indian (Not Otherwise Specified)

53 - North American Indian

54 - South or Central American Indian

55 - Caribbean Indian

Native Hawaiian or Other Pacific Islander

60 - Native Pacific Islander (Not Otherwise Specified)

61 - Guamanian

62 - Hawaiian

63 - Samoan

Other

88 - Unknown

90 - Other, Specify

99 - Not Answered

**Blood and Marrow Transplant Clinical
Trials Network**

Death Form (DTH)

Web Version: 1.0; 4.07; 06-21-12

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



Specify other: (DTHSPEC1)

4. Secondary cause of death: (SCNDCZ1)

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

Specify other: (DTHSPEC2)

5. Secondary cause of death: (SCNDCZ2)

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

Specify other: (DTHSPEC3)

6. Secondary cause of death: (SCNDCZ3)

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

Specify other: (DTHSPEC4)

7. Secondary cause of death: (SCNDCZ4)

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

Specify other: (DTHSPEC5)

Comments: (DTCMMNTS)

Additional Selection Options for DTH

Primary cause of death:

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

**Blood and Marrow Transplant Clinical
Trials Network**

Early Study Drug Discontinuation Form (EDF)

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

Segment (PROTSEG):

1. Record date of early discontinuation of study drug:(DISCODT)

 (mm/dd/yyyy)

Record reason(s) study drug was discontinued prior to the 8th dose:

- 2. Pre-therapy BAL fluid cultures, special stains, or PCR analysis positive for potentially infectious pathogen:(DISBALFL) 1 - Yes 2 - No
- 3. Pre-therapy blood cultures positive for infectious pathogen:(DISBLCL) 1 - Yes 2 - No
- 4. Signs and symptoms consistent with sepsis syndrome (as defined in protocol Section 2.9.1):(DISSEPSI) 1 - Yes 2 - No
- 5. Invasive fungal or systemic viral infection:(DISINVFI) 1 - Yes 2 - No
- 6. CMV disease or CMV infection (positivity for CMV on two consecutive assays > 72 hours apart):(DISCMVIN) 1 - Yes 2 - No
- 7. Bacteremia for > 72 hours despite antibiotic therapy, resulting in more than 2 study drug doses missed:(DISBACTR) 1 - Yes 2 - No
- 8. Hypersensitivity to study drug injection or serious allergic or anaphylactic reaction:(DISHYPSN) 1 - Yes 2 - No
- 9. Refusal of further protocol therapy by patient or legal guardian:(DISREFSL) 1 - Yes 2 - No
- 10. Per physician discretion:(DISINVDI) 1 - Yes 2 - No

Explain physician's reason for discontinuation:(DISEXPLN)

11. Other reason:(DISOTHER)

 1 - Yes 2 - No

Specify other reason:(DISSPECI)

Comments:(COMMEDF)

**Blood and Marrow Transplant Clinical
Trials Network**

0403B (ENR)

Web Version: 1.0; 2.00; 12-17-09

Etanercept Protocol Enrollment Form - Segment B

1. Transplant Date: (TRANS DT) (mm/dd/yyyy)

2. Is the patient on ventilation? (ONMVENT)

0 - None 1 - Mechanical V entila tion 2 - Oscillator V entila tion
--

3. Was a broncho-alveolar lavage (BAL) performed on this patient? (BRONC PER) 1 - Yes 2 - No

4. Date broncho-alveolar lavage (BAL) obtained: (BALOBTDT) (mm/dd/yyyy)

5. Was a deep endotracheal aspirate performed? (DPENASP) 1 - Yes 2 - No

6. Date deep endotracheal aspirate performed: (DPENDDT) (mm/dd/yyyy)

7. Is the patient's clinical condition such that a BAL or deep endotracheal aspirate was deemed "not possible to be performed" by the treating physician? (CLCNNOBR) 1 - Yes 2 - No

8. Date of virology cultures: (NASASWDT) (mm/dd/yyyy)

9. Record the results of the virologic cultures from the nasal swab or wash: (NASALSW)

1 - Positive 2 - Negative

Record the results of the BAL fluid assessments required prior to randomization:

Assessment	Result
10. Gram stain: (BALGRAM)	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative
11. Fungal stain: (BALFUNG)	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative

Record the status of the following BAL fluid assessments:

Assessment	Result
12. Acid fast bacilli stain (AFB): (BALAFB)	<input type="text"/> 1 - Pending 2 - Positive 3 - Negative
13. Bacterial cultures ($\geq 10^4$ CFU/mL is positive): (BALBACT)	<input type="text"/> 1 - Pending 2 - Positive 3 - Negative
14. Viral cultures (RSV, adenovirus, parainfluenza, influenza A and B, and CMV): (BALVIRAL)	<input type="text"/> 1 - Pending 2 - Positive 3 - Negative
15. Fungal cultures: (BALFUNCL)	<input type="text"/> 1 - Pending 2 - Positive 3 - Negative
16. Mycobacterial cultures: (BALMYCOB)	<input type="text"/> 1 - Pending 2 - Positive 3 - Negative

17. *Pneumocystis carinii* pneumonia (PCP) assay:

(BAL PCP)

1 - Pending
2 - Positive
3 - Negative

Comments:(ETBCOMM)

--

**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 experienced secondary graft failure?(SECGRFAL) 1 - Yes 2 - No

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

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

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

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

If Yes, an Infection Form must be submitted.

12. Date of infection:(INFDT) (mm/dd/yyyy)

13. Has the patient been hospitalized?(HOSPITAL) 1 - Yes 2 - No

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

14. Date of hospitalization:(HOSP TLDT) (mm/dd/yyyy)

15. Has the patient received a non-protocol specified transplant?(TRANS TWO) 1 - Yes 2 - No

16. Date of non-protocol specified transplant:(DA TRANSP) (mm/dd/yyyy)

Comments:(FUS1 COMM)

Blood and Marrow Transplant Clinical Trials Network

Acute GVHD Form (GVH)

Web Version: 1.0; 10.06; 07-05-12

Segment (PROTSEG):

Visit Number (VISNO):

1. Date of staging: (STAGEDT)

(mm/dd/yyyy)

Start of GVHD Assessment Period: (GVASSTDT)

(mm/dd/yyyy)

End of GVHD Assessment Period: (GVASENDT)

(mm/dd/yyyy)

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

2. Immunosuppressant (prophylaxis) received: (IMMUNORC)

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

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

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

6. Skin etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SETGVHD) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(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 - Positive
2 - Negative
3 - Equivocal
4 - Not Done

8. Upper GI abnormalities: (GVHUPGIA)

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

9. Upper intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(UGIETGVH) <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:(UGIBIORS)

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

11. Lower GI abnormalities:(GVHINTA)

- 0 - No Diarrhea
- 1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m²
- 2 - Diarrhea >500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m²
- 3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m²
- 4 - Diarrhea >1500 mL/day or >833 mL/m²
- *Additional Options Listed Below

Use mL/day for adult patients and mL/m² for pediatric patients

12. Lower intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(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
TPN	Infection	Other
(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)

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

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

14. Liver abnormalities:(GVHLIVRA)

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

15. Liver etiologies:

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

Specify other liver etiologies:(GVHLIVRS)

16. Liver biopsy for GVHD:(GVHLIVRB)

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

17. Was any treatment of GVHD modified during this assessment period?
(GVHTHERP)

- 1 - Yes 2 - No

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

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

- 1 - CSA
- 2 - FK 506
- 3 - Topical Steroids
- 4 - Prednisone
- 5 - ATG
- *Additional Options Listed Below

Specify other agent:(GVHAGNSP)

19. Indicate treatment modification:(G *VHTRMOD*)

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

Comments:(G *VHCOMM*)

Additional Selection Options for GVH

Lower GI abnormalities:

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

If yes, specify agent name:

6 - MMF

7 - Daclizumab

8 - Methylprednisolone

9 - Other

**Blood and Marrow Transplant Clinical
Trials Network**

Infection Form (INF)

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

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

INFECTION I

1. Type of infection:(*INFYP01*)

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

2. Organism I:(*ORGN01*)

BO1 - Acinetobacter (baumanii, calcoaceticus, lwoffii, other species)
BO2 - Agrobacterium radiobacter
BO3 - Alcaligenes xylosoxidans
BO4 - Anaerobic bacteria (NO S, except for Bacteroides, Clostridium)
BO5 - Bacillus (cereus, other species)
*Additional Options Listed Below



If other specify:(*INFSPEC1*)

3. Record the level of certainty of the fungal infection diagnosis:(*CERTNTY1*)

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

4. Severity of infection:(*SVRTY01*)

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

INFECTION II

5. Type of infection:(*INFYP02*)

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

6. Organism II:(*ORGN02*)

BO1 - Acinetobacter (baumanii, calcoaceticus, lwoffii, other species)
BO2 - Agrobacterium radiobacter
BO3 - Alcaligenes xylosoxidans
BO4 - Anaerobic bacteria (NO S, except for Bacteroides, Clostridium)
BO5 - Bacillus (cereus, other species)
*Additional Options Listed Below

If other specify:(*INFSPEC2*)

7. Record the level of certainty of the fungal infection diagnosis:(*CERTNTY2*)

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

8. Severity of infection:(*SVRTY02*)

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

INFECTION III

9. Type of infection:(*INFYP03*)

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

10. Organism III:(*ORGNO3*)

BO1 - Acinetobacter (baumanii, calcoaceticus, Iwoffii, other species)
BO2 - Agrobacterium radiobacter
BO3 - Alcaligenes xylosoxidans
BO4 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
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 - Proven Fungal Infection
2 - Probable Fungal Infection
3 - Possible Fungal Infection

12. Severity of infection:(*SVRTY03*)

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

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

1 - Yes 2 - No

Provide agent(s) administered for this infectious period:

14. 1st agent:(*AGENT1*)

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

If other specify:(*AGTSPEC1*)

15. 2nd agent:(*AGENT2*)

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

If other specify:(*AGTSPEC2*)

16. 3rd agent:(*AGENT3*)

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

If other specify:(*AGTSPEC3*)

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

1 - Yes 2 - No

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

Comments:(*INFCOM*)

Additional Selection Options for INF

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

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

Organism I:

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

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

1st agent:

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

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

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

**Blood and Marrow Transplant Clinical
Trials Network**

Laboratory Assessment Form - 0403 (LA2)

Web Version: 1.0; 2.02; 10-30-12

Segment (PROTSEG):

Visit Number (VISNO):

Laboratory Assessments

1. Start of Assessment Period: (LA2APST) (mm/dd/yyyy)
2. End of Assessment Period: (LA2APEND) (mm/dd/yyyy)

CBC

	Most Recent Value	Date of Sample
3. RBC	(LA2BRBC) <input type="text"/> (x.x) million/mm ³	(LA2RBCDT) <input type="text"/> (mm/dd/yyyy)
4. Hematocrit	(LA2BHCT) <input type="text"/> (xx.x) %	(LA2HCTDT) <input type="text"/> (mm/dd/yyyy)
5. Hemoglobin	(LA2BHGB) <input type="text"/> (xx.x) g/dL	(LA2HGBDT) <input type="text"/> (mm/dd/yyyy)
6. WBC	(LA2BWBC) <input type="text"/> (xxxxxx) /mcL	(LA2WBCDT) <input type="text"/> (mm/dd/yyyy)
7. Platelet Count	(LA2PLATE) <input type="text"/> (xxxxxx) /mcL	(LA2PLATD) <input type="text"/> (mm/dd/yyyy)
8. Neutrophils	(LA2NEUTA) <input type="text"/> (xxxxxx) /mcL	(LA2GRAND) <input type="text"/> (mm/dd/yyyy)
9. Lymphocytes	(LA2LYMPH) <input type="text"/> (xxxxxx) /mcL	(LA2LYMPD) <input type="text"/> (mm/dd/yyyy)

Chemistry and LFT's

	Most Recent Value	Date of Sample
10. Creatinine	(LA2BCREA) <input type="text"/> (x.x) mg/dL	(LA2CRTDT) <input type="text"/> (mm/dd/yyyy)
11. Bilirubin	(LA2BILI) <input type="text"/> (xx.x) mg/dL	(LA2BILID) <input type="text"/> (mm/dd/yyyy)
12. AST	(LA2AST) <input type="text"/> (xxx) IU/L	(LA2ASTDT) <input type="text"/> (mm/dd/yyyy)
13. ALT	(LA2ALT) <input type="text"/> (xxx) IU/L	(LA2ALTDT) <input type="text"/> (mm/dd/yyyy)

14. What is the patient's Karnofsky performance score? (LA2KARLA)

- O1 - 100 (Normal; No Complaints/Fully Active)
 O2 - 90 (Normal Activity/Minor Restriction in Strenuous Play)
 O3 - 80 (Normal Activity with Effort/Restricted in Strenuous Play)
 O4 - 70 (Unable to Carry On Normal Activity/Less Time Spent in Play)
 O5 - 60 (Requires Occasional Assistance/Minimal Active Play)
 *Additional Options Listed Below

Comments: (LA2CMNTS)

Additional Selection Options for LA2

What is the patient's Karnofsky performance score?

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

**Blood and Marrow Transplant Clinical
Trials Network**

Medication Form - 0403 (MD3)

Web Version: 1.0; 2.01; 08-09-11

Segment (PROTSEG):

Visit Number (VISNO):

Study Drug Administration

1. Date of first study drug dose: (FRSTSDDT) (mm/dd/yyyy)
2. Patient weight at first administration of study drug: (WGHTDSKG) (xxx.x) Kg
3. Date of last study drug dose: (LASTSDDT) (mm/dd/yyyy)
4. Total number of study drug doses received: (TOTALDOS) (x)
5. Was study drug permanently discontinued prior to the patient receiving 8 doses? (SDDISCON) 1 - Yes 2 - No
If yes, complete Early Study Drug Discontinuation Form.
6. If less than 8 study drug doses were given but the patient was not permanently discontinued prematurely, record the reason for missed study drug dose(s): (RSMISDOS)

1 - Infection
 2 - Allergic Reaction
 3 - Other, Specify Below
7. Specify other reason for missed study drug dose(s): (RSMDOSSP)
8. Did the patient receive open label etanercept between Day 0 and Day 28? (ETANBF28) 1 - Yes 2 - No
9. Did the patient receive open label etanercept between Day 29 and Day 56? (ETANBY56) 1 - Yes 2 - No

Steroid Administration

Day Post Randomization:	Date:	Steroid Type:	Specify Steroid Type:	Steroid Dose:
10. Day 0:	(STER00DT) <input type="text"/> (mm/dd/yyyy)	(STER00TY) <div style="border: 1px solid black; padding: 2px;"> 1 - Methylprednisolone 2 - Prednisone 3 - Hydrocortisone 4 - Dexamethasone 9 - Other, Specify </div>	(STER00SP) <input type="text"/>	(STER00DS) <input type="text"/> (x.xx) mg/kg/day
11. Day 7:	(STER07DT) <input type="text"/> (mm/dd/yyyy)	(STER07TY) <div style="border: 1px solid black; padding: 2px;"> 1 - Methylprednisolone 2 - Prednisone 3 - Hydrocortisone 4 - Dexamethasone 9 - Other, Specify </div>	(STER07SP) <input type="text"/>	(STER07DS) <input type="text"/> (x.xx) mg/kg/day
12. Day 14:	(STER14DT) <input type="text"/> (mm/dd/yyyy)	(STER14TY) <div style="border: 1px solid black; padding: 2px;"> 1 - Methylprednisolone 2 - Prednisone 3 - Hydrocortisone 4 - Dexamethasone 9 - Other, Specify </div>	(STER14SP) <input type="text"/>	(STER14DS) <input type="text"/> (x.xx) mg/kg/day
13. Day 21:	(STER21DT) <input type="text"/> (mm/dd/yyyy)	(STER21TY) <div style="border: 1px solid black; padding: 2px;"> 1 - Methylprednisolone 2 - Prednisone 3 - Hydrocortisone 4 - Dexamethasone 9 - Other, Specify </div>	(STER21SP) <input type="text"/>	(STER21DS) <input type="text"/> (x.xx) mg/kg/day
14. Day 28:	(STER28DT) <input type="text"/> (mm/dd/yyyy)	(STER28TY) <input type="text"/>	(STER28SP) <input type="text"/>	(STER28DS) <input type="text"/> (x.xx) mg/kg/day

		1 - Methylprednisolone 2 - Prednisone 3 - Hydrocortisone 4 - Dexamethasone 9 - Other, Specify		
15. Date of Study Drug Discontinuation (if prior to 8th dose):	(STERDSDT) <input type="text"/> (mm/dd/yyyy)	(STERDSTY) 1 - Methylprednisolone 2 - Prednisone 3 - Hydrocortisone 4 - Dexamethasone 9 - Other, Specify	(STERDSSP) <input type="text"/>	(STERDSDS) <input type="text"/> (x.xx) mg/kg/day
16. Day 56:	(STER56DT) <input type="text"/> (mm/dd/yyyy)	(STER56TY) 1 - Methylprednisolone 2 - Prednisone 3 - Hydrocortisone 4 - Dexamethasone 9 - Other, Specify	(STER56SP) <input type="text"/>	(STER56DS) <input type="text"/> (x.xx) mg/kg/day

Comments:(EMDCOMM)

**Blood and Marrow Transplant Clinical
Trials Network**

Supplemental Oxygen Form - 0403 (OXY)

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

Segment (PROTSEG):

Visit Number (VISNO):

Record if the patient required supplemental oxygen on each day of the assessment period (Day 0 - Day 28)

Day of Assessment	Date of Assessment	Supplemental Oxygen Required
1. Day 00	(OXYD00DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY00) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
2. Day 01	(OXYD01DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY01) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
3. Day 02	(OXYD02DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY02) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
4. Day 03	(OXYD03DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY03) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
5. Day 04	(OXYD04DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY04) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
6. Day 05	(OXYD05DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY05) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
7. Day 06	(OXYD06DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY06) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
8. Day 07	(OXYD07DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY07) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
9. Day 08	(OXYD08DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY08) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
10. Day 09	(OXYD09DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY09) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
11. Day 10	(OXYD10DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY10) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
12. Day 11	(OXYD11DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY11) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
13. Day 12	(OXYD12DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY12) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
14. Day 13	(OXYD13DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY13) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
15. Day 14	(OXYD14DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY14) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
16. Day 15	(OXYD15DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY15) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
17. Day 16	(OXYD16DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY16) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
18. Day 17	(OXYD17DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY17) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
19. Day 18	(OXYD18DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY18) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
20. Day 19	(OXYD19DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY19) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
21. Day 20	(OXYD20DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY20) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
22. Day 21	(OXYD21DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY21) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
23. Day 22	(OXYD22DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY22) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
24. Day 23	(OXYD23DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY23) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
25. Day 24	(OXYD24DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY24) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
26. Day 25	(OXYD25DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY25) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
27. Day 26	(OXYD26DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY26) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
28. Day 27	(OXYD27DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY27) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
29. Day 28	(OXYD28DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY28) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No

Record if the patient required supplemental oxygen on each day of the assessment period (Day 29 - Day 56)

Day of Assessment	Date of Assessment	Supplemental Oxygen Required
30. Day 29	(OXYD29DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY29) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
31. Day 30	(OXYD30DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY30) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
32. Day 31	(OXYD31DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY31) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
33. Day 32	(OXYD32DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY32) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
34. Day 33	(OXYD33DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY33) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
35. Day 34	(OXYD34DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY34) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
36. Day 35	(OXYD35DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY35) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
37. Day 36	(OXYD36DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY36) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
38. Day 37	(OXYD37DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY37) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
39. Day 38	(OXYD38DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY38) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
40. Day 39	(OXYD39DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY39) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
41. Day 40	(OXYD40DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY40) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
42. Day 41	(OXYD41DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY41) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
43. Day 42	(OXYD42DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY42) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
44. Day 43	(OXYD43DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY43) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
45. Day 44	(OXYD44DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY44) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
46. Day 45	(OXYD45DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY45) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
47. Day 46	(OXYD46DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY46) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
48. Day 47	(OXYD47DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY47) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
49. Day 48	(OXYD48DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY48) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
50. Day 49	(OXYD49DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY49) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
51. Day 50	(OXYD50DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY50) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
52. Day 51	(OXYD51DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY51) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
53. Day 52	(OXYD52DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY52) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
54. Day 53	(OXYD53DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY53) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
55. Day 54	(OXYD54DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY54) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
56. Day 55	(OXYD55DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY55) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No
57. Day 56	(OXYD56DT) <input type="text"/> (mm/dd/yyyy)	(OXYDAY56) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No

Comments:(OXYCOMM1)

**Blood and Marrow Transplant Clinical
Trials Network**

Specimen Acquisition Form - 0403 (SA2)

Web Version: 1.0; 3.01; 10-30-12

Segment (PROTSEG):

Visit Number (VISNO):

Samples for Cytokine Gene Polymorphism

1. Is there a pre-transplant blood sample available for research testing?
(PTXBLDIV) 1 - Yes 2 - No
2. If yes, record the date the blood sample was collected: (PTXBLDDT) (mm/dd/yyyy)
3. Was a buccal swab collected for research testing? (BUCSWAIV) 1 - Yes 2 - No
4. If yes, record the date the buccal swab sample was collected: (BUCSWADT) (mm/dd/yyyy)

Samples for Cytokine & Inflammatory Markers

5. Was BAL (broncho-alveolar lavage) fluid collected pre-randomization?
(BALFLUIV) 1 - Yes 2 - No
6. If yes, record the date BAL was performed: (BALFLUDT) (mm/dd/yyyy)
7. Was a blood (plasma) sample drawn during this assessment period?
(PLASMAIV) 1 - Yes 2 - No
8. If yes, record the date the blood sample was collected: (PLASMA DT) (mm/dd/yyyy)

Comments: (SA2COMMT)

**Blood and Marrow Transplant Clinical
Trials Network**

Toxicity Form - 0403 (TX9)

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

Segment (PROTSEG):

Visit Number (VISNO):

1. Record date of evaluation: (TX9EVLDT) (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.

Dermatologic Toxicity

2. Rash with desquamation: (TX9RASHD)

0 - Grades 0-2
3 - Severe erythroderma or macular, papular or vesicular eruption; desquamation covering \geq 50% BSA
4 - Generalized Exfoliative Ulcerative or Bullous Dermatitis
5 - Death

GI Toxicity

3. Mucositis/stomatitis (clinical exam): (TX9MCSTS)

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

Mouth pain or esophageal pain requiring IV hydration/narcotics.

Renal Toxicity

4. Did the patient experience renal failure severe enough to warrant dialysis? (TX9RENAL)

1 - Yes 2 - No

5. Did the patient receive dialysis? (TX9DIALS)

1 - Yes 2 - No

6. Hemorrhagic cystitis: (TX9CYSTI)

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

Hemorrhagic Toxicity

7. Hemorrhage: (TX9HEMRG)

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

Cardiovascular Toxicity

8. Hypotension: (TX9HYPOT)

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

9. Cardiac arrhythmia: (TX9CRDAR)

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

10. Left ventricular systolic dysfunction: (TX9LVENT)

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

Neurologic Toxicity

11. Somnolence:(TX9SMNLN)

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

12. Did the patient experience any seizures during this assessment period?(TX9SEZR)

1 - Yes 2 - No

Record seizure toxicity grade:(TX9SZGRD)

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

Coagulation Toxicity

13. HUS/TTP/thrombotic microangiopathy:(TX9DIC)

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

Vascular Toxicity

14. Vascular leak syndrome:(TX9VASLK)

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

Pulmonary Toxicity

15. Hypoxia (for more than 24 hours):(TX9HYPXJ)

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

16. Dyspnea:(TX9DYSNP)

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

17. During this assessment period, was an FEV1 performed? (TX9FEVDN)

1 - Yes 2 - No

18. Record FEV1 value obtained:(TX9FEVVL)

(xxx) % of predicted value

19. During this assessment period, was an FVC performed? (TX9FVCDN)

1 - Yes 2 - No

20. Record FVC value obtained:(TX9FVCVL)

(xxx) % of predicted value

Hepatic Toxicity

21. Did the patient develop abnormal liver function during this assessment period?(TX9ABNLF)

1 - Yes 2 - No

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

22. Jaundice:(TX9JANDC)

1 - Yes 2 - No

23. Hepatomegaly:(TX9HPTMG)

1 - Yes 2 - No

24. Right upper quadrant pain:(TX9QUADP)

1 - Yes 2 - No

25. Weight gain (>5%) from baseline:(TX9WGHTG)

1 - Yes 2 - No

26. Other clinical signs/symptoms:(TX9OTHAB)

1 - Yes 2 - No

Specify other clinical signs/symptoms:(TX9SPEC1)

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
27. VOD: (TX9VODET)	<input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done (TX9VODBI)	<input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done (TX9VODDP)
28. GVHD: (TX9GVHET)	<input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	<input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done (TX9GVHBI)	<input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done (TX9GVHDP)

29. Infection:	(TX9INFET) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(TX9INFBI) <input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done	(TX9INFDP) <input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done
30. Other:	(TX9OTHET) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(TX9OTHBI) <input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done	(TX9OTHDP) <input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done
31. Unknown:	(TX9UNKET) <input type="checkbox"/> 1 - Yes <input type="checkbox"/> 2 - No	(TX9UNKBI) <input type="checkbox"/> 1 - Positive <input type="checkbox"/> 2 - Negative <input type="checkbox"/> 3 - Equivocal <input type="checkbox"/> 4 - Not Done	(TX9UNKDP) <input type="checkbox"/> 1 - Confirmed <input type="checkbox"/> 2 - Not Confirmed <input type="checkbox"/> 3 - Not Done

Specify other etiology: (TX9SPEC2)

Comments: (TX9COMM)