Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Web Version: 1.0; 4.05; 06-11-14

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; 3.11; 03-26-14

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; 3.11; 03-26-14

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; 4.04; 03-26-14

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

1. Report activation status:*(AVSTAT_B)*

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

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

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

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

Comments:*(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 3.10; 03-26-14

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

1. Report activation status:*(AVSTAT_C)*

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

Laboratory Test Results

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

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

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

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

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

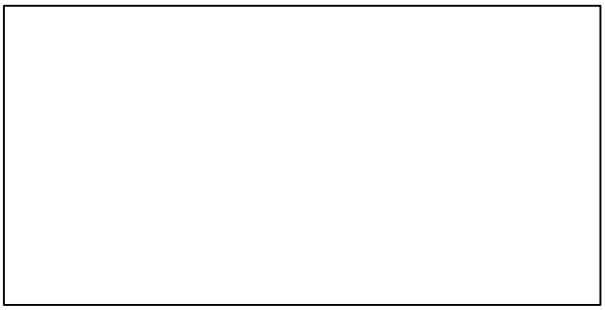
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

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

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

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

Comments:*(AE4COMM)*



Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 3.11; 03-26-14

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; 6.02; 03-26-14

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

1. Adverse event status:*(AVSTAT_E)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason
2. Has this event been determined to be an unexpected, grade 3-5 adverse event? *(AMDETER)* ☐ 1 - Yes ☐ 2 - No
3. Does this require expedited reporting to the DSMB?*(AMEXPDSM)* ☐ 1 - Yes ☐ 2 - No
4. Do you recommend the patient be withdrawn from further protocol therapy? *(AMWITHDR)* ☐ 1 - Yes ☐ 2 - No
5. Is the review complete?*(AMREVDNE)* ☐ 1 - Yes ☐ 2 - No
6. If **No**, what additional information is required:*(AMREVINF)*
7. Medical Monitor event description:*(AMMMEVDS)*
8. Medical Monitor CTCAE grade of event:*(CTCAEGRD)*
   - 1 - Grade 1
   - 2 - Grade 2
   - 3 - Grade 3
   - 4 - Grade 4
   - 5 - Grade 5

Comments:*(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

CIBMTR Recipient ID (CID)

Web Version: 1.0; 1.06; 03-26-14

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

1. CRID # (CIBMTR Recipient ID):*(CRIDNM)* *(xxxxxxxxx)*

Comments:*(CIDCOMM)*

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)* ☐ 1 - Male ☐ 2 - Female

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

5. Ethnicity:*(ETHNIC)*

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

6. Race:*(RACE)*

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

Specify race:*(RACESP)*

7. Secondary Race:*(RACE2)*

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

Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

Web Version: 1.0; 4.12; 03-26-14

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

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

If yes, attach de-identified autopsy report or death summary to the form below.

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

Endpoint Review Form- 0803 (E09)

Web Version: 1.0; 1.00; 06-02-14

Case ID *(CASEID)*:

Site:*(EXXSITE)* *(xxxxx)*

Patient ID:*(EXXPATID)*

1. Review Date:*(REVIEWDT)* *(mm/dd/yyyy)*
2. Primary Reviewer Name:*(REVNAME)*
   - Ernesto Ayala
   - Joe Alvarnas
   - Richard Ambinder
   - Uday Popat
   - Willis Navarro
3. Case Status:*(CASESTAT)*
   - 1-Complete (C)
   - 2-Query (Q)
   - 3-Ready for Review (R)
4. Review Committee Comments:*(REVCOMM)*
5. EMMES Comments:*(EMMCOMM)*

Reviewer Adjudicated Fields

6. Did the patient die?*(PATDIED)* ☐ 1 - Yes ☐ 2 - No
   a. Primary cause of death:*(REVCOD)*
   - 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

   b. Specify other COD:*(REVCODSP)*
7. Progression or relapse:*(PRGRLP)* ☐ 1 - Yes ☐ 2 - No
   a. Date of progression or relapse:*(PRGRLPDT)* *(mm/dd/yyyy)*
8. Exclude patient from the primary analysis population?*(EXCLUDE)* ☐ 1 - Yes ☐ 2 - No
   a. Specify reason for exclusion:*(EXCLUDSP)*
9. Was the patient eligible?*(ELIGIBLE)* ☐ 1 - Yes ☐ 2 - No
   a. Specify reason for ineligibility:*(ELIGIBSP)*
10. Were treatment compliance issues identified?*(TRTCMPLY)* ☐ 1 - Yes ☐ 2 - No

a. Specify compliance issues:*(TRTCMPSP)*

11. Disease Status at Study Entry:*(ENTRYDS)*

```
1-Complete Remission
2-Partial Remission
3-Stable Disease
4-Relapsed or Progressive Disease
5-Not Evaluable
```

12. Disease Response at Day 100:*(D100DR)*

```
1-Complete Remission
2-Partial Remission
3-Stable Disease
4-Relapsed or Progressive Disease
5-Not Evaluable
```

13. Hematologic function at Day 100:*(D100HF)*

```
1 -Yes
2 -No
3 -Patient Died
4 -Unknown
```

14. Hematologic function at Day 365:*(D365HF)*

```
1 -Yes
2 -No
3 -Patient Died
4 -Unknown
```

15. Number of Queries:*(QUERYNUM)*

```
00-Is A Miracle!
01
02
03
04
*Additional Options Listed Below
```

Number of queries indicated will determine how many queries are captured on the query form.

Comments:*(EXXCOMM)*

Additional Selection Options for E09

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

Number of Queries:
05 - Could Be Worse
06
07
08
09
10 - Just Start Over

Blood and Marrow Transplant Clinical Trials Network

0803A (ENR)

Web Version: 1.0; 3.01; 06-14-12

1. Record date patient informed consent signed:*(PTICDT)* _____ *(mm/dd/yyyy)*
2. Patient's date of birth:*(PATDOB)* 06/23/1974 *(mm/dd/yyyy)*
3. Record the start date of mobilization:*(MOBILDT)* _____ *(mm/dd/yyyy)*
4. Record the proposed date of initiation of conditioning:*(HVCONDDT)* _____ *(mm/dd/yyyy)*

Inclusion Criteria

5. Record patient diagnosis:*(DIAGNOS)*
   1 - Diffuse Large B-cell Lymphoma
   2 - Composite Lymphoma with > 50% Diffuse Large B-cell Lymphoma
   3 - Mediastinal B-cell Lymphoma
   4 - Immunoblastic Lymphoma
   5 - Plasmablastic Lymphoma
   *Additional Options Listed Below
   a. Indicate the patient's current lymphoma status:*(DISSTAGE)*
   1 - Complete Remission
   2 - Partial Remission
   3 - Stable Disease
   4 - Relapsed or Progressive Disease
6. Has the patient received three or fewer prior regimens of chemotherapy over the entire course of his/her disease (including one induction chemotherapy and no more than 2 salvage chemotherapies)?*(PRIOCHEM)* ☐ 1 - Yes ☐ 2 - No
   7. Record the number of regimens of induction chemotherapy the patient has received:*(INDCHEM)* _____ *(x)*
   8. Record the number of regimens of salvage chemotherapy the patient has received:*(SALVCHEM)* _____ *(x)*
9. Does the patient have chemosensitive disease as demonstrated by at least a partial response to induction or salvage therapy?*(CHEMSENS)* ☐ 1 - Yes ☐ 2 - No
10. Record patients bone marrow involvement with lymphoma:*(PCTBNMW)* _____ *(xx)* %
11. Record the date of bone marrow biopsy:*(BNMWDT)* _____ *(mm/dd/yyyy)*
12. Does the patient have cardiac disease?*(CARDDISE)* ☐ 1 - Yes ☐ 2 - No
    13. Indicate the American Heart Association (AHA) classification for the patient's cardiac disease:*(AHACLASS)*
    1 - Class I
    2 - Class II
    3 - Class III
    4 - Class IV

	Most Recent Value	ULN for Your Institution	Date of Assessment
14. LVEF:	*(LVEFRAC)* _____ *(xxx)* %		*(LVEFDT)* _____ *(mm/dd/yyyy)*
15. Bilirubin:	*(BILIRUB)* _____ *(x.x)* mg/dL		*(HVBILIDT)* _____ *(mm/dd/yyyy)*
16. ALT:	*(HIVALT)* _____ *(xxx)* Units/L	*(HIVALTUL)* _____ *(xxx)* Units/L	*(HVALTDT)* _____ *(mm/dd/yyyy)*
17. AST:	*(HIVAST)* _____ *(xxx)* Units/L	*(HIVASTUL)* _____ *(xxx)* Units/L	*(HVASTDT)* _____ *(mm/dd/yyyy)*
18. Creatinine Clearance:	*(CRECLEAR)* _____ *(xxx)* mL/min		*(CCLDT)* _____ *(mm/dd/yyyy)*
19. DLCO:	*(HIVDLCO)* _____ *(xxx)* % pred		*(HVDLCODT)* _____ *(mm/dd/yyyy)*
20. FEV1:	*(HIVFEV1)* _____ *(xxx)* % pred		*(HVFEV1DT)* _____ *(mm/dd/yyyy)*
21. FVC:	*(HIVFVC)* _____ *(xxx)* % pred		*(HVFVCDT)* _____ *(mm/dd/yyyy)*

22. If the patient has a bilirubin >2.0 mg/dL, is it attributed to Gilbert Syndrome or antiretroviral therapy?*(GILBANTI)* ☐ 1 - Yes ☐ 2 - No
23. Does the patient have an undetectable HIV viral load (<50 copies/mL)? *(UNDETVIR)* ☐ 1 - Yes ☐ 2 - No
    24. Record the patients viral load:*(HIVVIRLD)* _____ *(xxxxx)* copies/mL

25. Has an Infectious Disease specialist review been completed which indicates the ability to fully suppress HIV by the addition of drugs to which the patient's HIV virus is sensitive?*(ANTISENS)* ☐ 1 - Yes ☐ 2 - No

26. Has a current HIV genotype and/or phenotype been done and a review by an Infectious Disease specialist been completed which indicates that a HAART regimen can be determined to which the patient's virus is sensitive? *(GENPHEN)* ☐ 1 - Yes ☐ 2 - No

Exclusion Criteria

27. Record the patient's Karnofsky performance score:*(KARNLAN)*

```
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
```

28. Does the patient have an uncontrolled bacterial, viral, or fungal infection (currently taking medication and with progression or no clinical improvement)? *(UNCINFEC)* ☐ 1 - Yes ☐ 2 - No

29. Does the patient have chronic hepatitis B or C?*(HEPATIT)* ☐ 1 - Yes ☐ 2 - No

30. Does the patient have an undetectable hepatitis viral load (<500 copies/mL) by PCR?*(HEPVIRLD)* ☐ 1 - Yes ☐ 2 - No

31. Does the patient have clinical or pathologic evidence of irreversible chronic liver disease?*(CHRLVDIS)* ☐ 1 - Yes ☐ 2 - No

32. Does the patient have a prior malignancy in the 5 years prior to enrollment except resected basal cell carcinoma, treated cervical carcinoma in situ or Kaposi's sarcoma?*(PRIOMALI)*

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

33. Record the date of approval from Medical Monitor or Protocol Chair: *(HVAPRVDT)* ☐ *(mm/dd/yyyy)*

34. Is the patient pregnant (positive ß-HCG) or breastfeeding? (PREGBFBX)*(PTPREGO)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

35. Is the patient pregnant (positive ß-HCG) or breastfeeding? (PREGBFBX)*(PTPREGO)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

36. Is the patient unwilling to use contraceptive techniques from the time of initiation of mobilization until six months post-transplant?*(USECONTR)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

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

38. Does the patient have evidence of MDS/AML or an abnormal cytogenetic analysis indicative of MDS on the pre-transplant bone marrow exam?*(ABNOMDS)* ☐ 1 - Yes ☐ 2 - No

Consent for Use of Biological Specimens for Research

39. Did the patient agree to provide blood for future research?*(PTRSCHSM)* ☐ 1 - Yes ☐ 2 - No

Comments:*(COMMHIV)*

Additional Selection Options for ENR

Record patient diagnosis:
6 - Burkitt's or Burkitt's-like Lymphoma
7 - Hodgkins Lymphoma

Record 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

Follow Up Status Form - 0803 (FU8)

Web Version: 1.0; 3.00; 03-18-13

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

1. Date of last contact:*(FU8CONDT)* _____ *(mm/dd/yyyy)*

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

2. Has the patient died?*(FU8PTDIE)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Death Form must be submitted.
3. Date of patient death:*(FU8DTHDT)* _____ *(mm/dd/yyyy)*
4. Has the patient relapsed or experienced disease progression?*(FU8RELPR)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Relapse Form must be submitted.
5. Date of relapse or progression*(FU8RELDT)* _____ *(mm/dd/yyyy)*
6. Has the patient been treated for relapse or progression?*(FU8RELTR)* ☐ 1 - Yes ☐ 2 - No
7. Date treatment administered:*(FU8TRTDT)* _____ *(mm/dd/yyyy)*
8. Indicate type of treatment:*(FU8TRTYP)*

```
1 - DLI
2 - Chemotherapy
3 - Radiation
4 - Second Transplant
5 - Other Cellular Therapy
*Additional Options Listed Below
```

9. Specify other treatment:*(FU8SPOTH)* _____
10. Has the patient received anti-lymphoma therapy?*(FU8THER)* ☐ 1 - Yes ☐ 2 - No
11. Date therapy initiated:*(FU8THRDT)* _____ *(mm/dd/yyyy)*
12. Has the patient experienced any new clinically significant infections?*(FU8NEWIN)* ☐ 1 - Yes ☐ 2 - No
If Yes, an Infection Form must be submitted.
13. Date of infection:*(FU8INFDT)* _____ *(mm/dd/yyyy)*
14. Has the patient been hospitalized?*(FU8HOSP)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Re-Admission Form must be submitted.
15. Date of hospitalization:*(FU8HOSDT)* _____ *(mm/dd/yyyy)*
16. Has the patient experienced any Unexpected, Grade 3-5 Adverse Events? *(FU8UAE)* ☐ 1 - Yes ☐ 2 - No
If Yes, an Unexpected, Grade 3-5 Adverse Event Form must be submitted.
17. Date of onset of Unexpected, Grade 3-5 Adverse Event:*(FU8UAEDT)* _____ *(mm/dd/yyyy)*

Current Disease Status

18. Was disease status assessed during this assessment period?*(FU8DISAS)* ☐ 1 - Yes ☐ 2 - No
If current disease status was assessed, submit appropriate pathology, radiology, molecular, and/or cytogenetics report.
19. Indicate the patient's current lymphoma status:*(FU8CURDS)*

```
1 - Complete Remission
2 - Partial Remission
3 - Stable Disease
4 - Relapsed or Progressive Disease
```

20. Date the current disease status was established:*(FU8CURDT)* _____ *(mm/dd/yyyy)*
21. Was the patient's current disease status assessed by radiologic assessment (CT, MRI or PET, etc.)?*(FU8RADIO)* ☐ 1 - Yes ☐ 2 - No
22. Date of most recent radiologic assessment:*(FU8RADDT)* _____ *(mm/dd/yyyy)*
23. Was the patient's current disease status assessed by biopsy (bone marrow, extranodal, etc.) ?*(FU8BIOP)* ☐ 1 - Yes ☐ 2 - No
24. Date of most recent biopsy:*(FU8BIODT)* _____ *(mm/dd/yyyy)*

Best Disease Status

Submit appropriate pathology, radiology, molecular, and/or cytogenetics report indicating best disease status.

25. Indicate the patient's best lymphoma status during the assessment period: *(FU8BEST)*

1 - Complete Remission
2 - Partial Remission
3 - Stable Disease
4 - Relapsed or Progressive Disease

26. Date the best disease status was established: *(FU8BSTDT)*

(mm/dd/yyyy)

Comments: *(FU8COMM)*

Additional Selection Options for FU8

Indicate type of treatment:
6 - 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 *(INFSTDT)*:

INFECTION I

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

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

   If other specify:*(INFSPEC1)*

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

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

INFECTION II

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

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

   If other specify:*(INFSPEC2)*

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

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

INFECTION III

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

10. Organism III:*(ORGN03)*

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

If other specify:*(INFSPEC3)*

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

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

12. Severity of infection:*(SVRTY03)*

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

13. Was an agent(s) administered to treat the infection(s)?*(TRTINF)* ☐ 1 - Yes ☐ 2 - No

Provide agent(s) administered for this infectious period:

14. 1st agent:*(AGENT1)*

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

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 - Woundsite
34 - Catheter Tip
35 - Eyes
36 - Ears
37 - Joints
38 - Bone Marrow
39 - Bone Cortex (Osteomyelitis)
40 - Muscle (Excluding Cardiac)
41 - Cardiac (Endocardium, Myocardium, Pericardium)
42 - Lymph Nodes
43 - Spleen
99 - Other Unspecified

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Laboratory Assessment Form - 0803 (LA7)

Web Version: 1.0; 4.00; 03-01-12

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

1. Did the patient's ANC drop below 500/µL post transplant?*(LA7ANCDR)* ☐ 1 - Yes ☐ 2 - No
2. Did the patient's ANC drop below 500/µL post transplant?*(LA7ANCDR)* ☐ 1 - Yes ☐ 2 - No
3. Did the patient's ANC recover to ≥500/µL for two consecutive days?*(LA7ANCRE)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Previously Reported
4. Record ANC count and specimen collection dates:

	Value	Date
1st ANC >500/µL:	*(LA7ANC1V)* *(xxxxx)* /µL	*(LA7AN1DT)* *(mm/dd/yyyy)*
2nd ANC >500/µL:	*(LA7ANC2V)* *(xxxxx)* /µL	*(LA7AN2DT)* *(mm/dd/yyyy)*

5. Record the most recent ANC count:*(LA7RCANC)* *(xxxxx)* /µL
6. Record the date of the most recent ANC count:*(LA7RANDT)* *(mm/dd/yyyy)*
7. Did the patient's platelet count drop below 20,000/µL post transplant? *(LA7PLTDR)* ☐ 1 - Yes ☐ 2 - No
8. Did the patient's platelet count drop below 20,000/µL post transplant? *(LA7PLTDR)* ☐ 1 - Yes ☐ 2 - No
9. Did the patient's platelet count recover to ≥20,000/µL for two consecutive measurements with no platelet transfusion in the previous 7 days?*(LA7PTREC)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Previously Reported
10. Record platelet count and specimen collection dates:

	Value	Date
1st platelet count ≥20,000/µL:	*(LA7PLT1V)* *(xxxxxx)* /µL	*(LA7PT1DT)* *(mm/dd/yyyy)*
2nd platelet count ≥20,000/µL:	*(LA7PLT2V)* *(xxxxxx)* /µL	*(LA7PT2DT)* *(mm/dd/yyyy)*

11. Record the most recent platelet count:*(LA7RCPLT)* *(xxxxxx)* /µL
12. Record the date of the most recent platelet count:*(LA7RPLDT)* *(mm/dd/yyyy)*
13. Enter the patient's most recent hemoglobin value without transfusion support: *(LA7HGVAL)* *(xx.x)* g/dL
14. Enter the date the hemoglobin level was obtained:*(LA7HGDT)* *(mm/dd/yyyy)*
15. Record the date the quantitative immunoglobulin assay was performed: *(LA7IMMDT)* *(mm/dd/yyyy)*

	Value	Lower Limit of Normal	Upper Limit of Normal
16. IgA:	*(LA7IGA)* *(xxx)* mg/dL	*(LA7IGALL)* *(xxx)* mg/dL	*(LA7IGAUL)* *(xxx)* mg/dL
17. IgG:	*(LA7IGG)* *(xxxx)* mg/dL	*(LA7IGGLL)* *(xxxx)* mg/dL	*(LA7IGGUL)* *(xxxx)* mg/dL
18. IgM:	*(LA7IGM)* *(xxx)* mg/dL	*(LA7IGMLL)* *(xxx)* mg/dL	*(LA7IGMUL)* *(xxx)* mg/dL

19. Were growth factors given during the assessment period?*(LA7GWFCT)* ☐ 1 - Yes ☐ 2 - No
20. Record the date growth factors were last given:*(LA7GFTDT)* *(mm/dd/yyyy)*
21. Record the patient's HIV viral copy number:*(HIVCOPY)* *(xxxxx)* copies/mL
22. Record the date the patient's HIV viral copy number was obtained: *(HIVCOPDT)* *(mm/dd/yyyy)*
23. Record the patient's baseline CD4 count:*(LA7CD4CT)* *(xxxx)* cells/µL
24. Record the date the patient's CD4 count was obtained:*(LA7CD4DT)* *(mm/dd/yyyy)*

Comments:*(LA7CMMTS)*

Blood and Marrow Transplant Clinical Trials Network

Mucositis Assessment Form (MUC)

Web Version: 1.0; 4.03; 06-28-10

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

1. Did the patient receive Kepivance pre- or post-transplant?*(RCVKEPIV)* ☐ 1 - Yes ☐ 2 - No

2. Start of assessment period:*(MUCSTRDT)* _____ *(mm/dd/yyyy)*

3. End of assessment period:*(MUCENDDT)* _____ *(mm/dd/yyyy)*

First Mucositis Assessment

4. Indicate the date of the first mucositis assessment in the assessment period: *(MUC1DATE)* _____ *(mm/dd/yyyy)*

5. Indicate what the patient was able to consume:*(MUC1DIET)*
   1 - Solids
   2 - Liquids Only
   3 - Nothing Per Oral

6. If the patient is consuming liquids only or nothing per oral, is it due to oral mucositis?*(MUC1ORAL)* ☐ 1 - Yes ☐ 2 - No

7. If no, what does the patient believe he/she could eat based on how his/her mouth feels:*(MUC1EATS)*
   1 - Solids
   2 - Liquids Only
   3 - Nothing Per Oral

8. Indicate if patient is experiencing any mouth soreness or pain:*(MUC1PAIN)* ☐ 1 - Yes ☐ 2 - No

Anatomical Site	Presence of Ulceration	Degree of Erythema
9. Maxillary labial mucosa:	*(MAX1ULCR)* 1 - Yes 2 - No	*(MAX1ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
10. Mandibular labial mucosa:	*(MAN1ULCR)* 1 - Yes 2 - No	*(MAN1ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
11. Right buccal mucosa:	*(RBU1ULCR)* 1 - Yes 2 - No	*(RBU1ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
12. Left buccal mucosa:	*(LBU1ULCR)* 1 - Yes 2 - No	*(LBU1ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
13. Right lateral and ventral tongue:	*(RTN1ULCR)* 1 - Yes 2 - No	*(RTN1ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
14. Left lateral and ventral tongue:	*(LTN1ULCR)* 1 - Yes 2 - No	*(LTN1ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
15. Floor of mouth and lingual frenum:	*(MTH1ULCR)* 1 - Yes 2 - No	*(MTH1ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe

16. Soft palate and fauces:	*(PAL1ULCR)* 1 - Yes 2 - No	*(PAL1ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe

17. WHO toxicity grade:*(TOX1SCR)*

0 - Grade 0
1 - Grade 1
2 - Grade 2
3 - Grade 3
4 - Grade 4

Second Mucositis Assessment

18. Indicate the date of the second mucositis assessment in the assessment period: *(MUC2DATE)* *(mm/dd/yyyy)*

19. Indicate what the patient was able to consume:*(MUC2DIET)*

1 - Solids
2 - Liquids Only
3 - Nothing Per Oral

20. If the patient is consuming liquids only or nothing per oral, is it due to oral mucositis?*(MUC2ORAL)* ☐ 1 - Yes ☐ 2 - No

21. If no, what does the patient believe he/she could eat based on how his/her mouth feels:*(MUC2EATS)*

1 - Solids
2 - Liquids Only
3 - Nothing Per Oral

22. Indicate if patient is experiencing any mouth soreness or pain:*(MUC2PAIN)* ☐ 1 - Yes ☐ 2 - No

Anatomical Site	Presence of Ulceration	Degree of Erythema
23. Maxillary labial mucosa:	*(MAX2ULCR)* 1 - Yes 2 - No	*(MAX2ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
24. Mandibular labial mucosa:	*(MAN2ULCR)* 1 - Yes 2 - No	*(MAN2ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
25. Right buccal mucosa:	*(RBU2ULCR)* 1 - Yes 2 - No	*(RBU2ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
26. Left buccal mucosa:	*(LBU2ULCR)* 1 - Yes 2 - No	*(LBU2ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
27. Right lateral and ventral tongue:	*(RTN2ULCR)* 1 - Yes 2 - No	*(RTN2ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
28. Left lateral and ventral tongue:	*(LTN2ULCR)* 1 - Yes 2 - No	*(LTN2ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
29. Floor of mouth and lingual frenum:	*(MTH2ULCR)* 1 - Yes 2 - No	*(MTH2ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe
30. Soft palate and fauces:	*(PAL2ULCR)* 1 - Yes 2 - No	*(PAL2ERYT)* 0 - None 1 - Mild to Moderate 2 - Severe

31. WHO toxicity grade:*(TOX2SCR)*

0 - Grade 0
1 - Grade 1
2 - Grade 2
3 - Grade 3
4 - Grade 4

Comments:*(MUCCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Progression/Relapse Form (PRE)

Web Version: 1.0; 3.01; 04-23-10

Progression/Relapse Date *(PRRELPDT)*:

1. Record reason for form completion:*(RESFRFRM)* ☐ 1 - Progression ☐ 2 - Relapse
2. Indicate how progression or relapse was determined:

CT: *(CTDET)* ☐ 1 - Yes ☐ 2 - No

MRI: *(MRIDET)* ☐ 1 - Yes ☐ 2 - No

PET Scan: *(PETDET)* ☐ 1 - Yes ☐ 2 - No

Ultrasound: *(ULTSNDET)* ☐ 1 - Yes ☐ 2 - No

Physical Exam: *(PHYEXDET)* ☐ 1 - Yes ☐ 2 - No

Biopsy: *(BIOPSYPR)* ☐ 1 - Yes ☐ 2 - No

3. If biopsy was used, indicate the site(s) of biopsy:

Bone Marrow: *(BNEMRROW)* ☐ 1 - Yes ☐ 2 - No

Lymph Node: *(LYMPHNOD)* ☐ 1 - Yes ☐ 2 - No

Extra-nodal: *(EXTRANOD)* ☐ 1 - Yes ☐ 2 - No

4. Were there any new lesions or sites of disease?*(APPNEWLE)* ☐ 1 - Yes ☐ 2 - No
5. If yes, record the date of appearance of new lesions or sites of disease: *(DTAPPLES)* _____ *(mm/dd/yyyy)*

Questions 7-8 relate ONLY to patients who have progressed (that is patients who have, pre-transplant, been previously classified as Partial Remission or Stable Disease.)

6. Was there a > 50% increase from nadir in the SPD of any previously identified abnormal node?*(INCRSPD)* ☐ 1 - Yes ☐ 2 - No
7. If yes, record the date of occurrence:*(DTSPDINC)* _____ *(mm/dd/yyyy)*

Questions 9-12 relate ONLY to patients who have relapsed (that is patients who have, pre-transplant, been previously classified as Complete Remission, Continued Complete Remission or Complete Remission Undetermined.)

8. Was there a ≥ 50% increase in the greatest diameter of any previously identified node >1 cm in its short axis or in the SPD of more than 1 node?*(INCRDIAM)* ☐ 1 - Yes ☐ 2 - No
9. If yes, record the date of occurrence:*(DTINCDIA)* _____ *(mm/dd/yyyy)*
10. Was there was a ≥ 50% increase in the size of any previously involved, extra-nodal lesions or sites?*(INCRINST)* ☐ 1 - Yes ☐ 2 - No
11. If yes, record the date of occurrence:*(DATINCRE)* _____ *(mm/dd/yyyy)*

Comments:*(PRECOMM)*

Blood and Marrow Transplant Clinical Trials Network

Endpoint Review Query Form- 0803 (Q09)

Web Version: 1.0; 1.00; 05-29-14

Case ID *(CASEID)*:

Site:*(QXXSITE)*

Patient ID:*(QXXPATID)*

Number of Queries Indicated:*(QRYNUM)*

Queries

Query Status	Date Query Sent	Query	Date Response Received	Q
(QSTAT01) 1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(QSNTDT01)* *(mm/dd/yyyy)*	*(QDESC01)*	*(QRSPDT01)* *(mm/dd/yyyy)*	*(QRSPNS01)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT02) 1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(QSNTDT02)* *(mm/dd/yyyy)*	*(QDESC02)*	*(QRSPDT02)* *(mm/dd/yyyy)*	*(QRSPNS02)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT03) 1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(QSNTDT03)* *(mm/dd/yyyy)*	*(QDESC03)*	*(QRSPDT03)* *(mm/dd/yyyy)*	*(QRSPNS03)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT04) 1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(QSNTDT04)* *(mm/dd/yyyy)*	*(QDESC04)*	*(QRSPDT04)* *(mm/dd/yyyy)*	*(QRSPNS04)*
(QSTAT05) 1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(QSNTDT05)* *(mm/dd/yyyy)*	*(QDESC05)*	*(QRSPDT05)* *(mm/dd/yyyy)*	*(QRSPNS05)*
(QSTAT06) 1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(QSNTDT06)* *(mm/dd/yyyy)*	*(QDESC06)*	*(QRSPDT06)* *(mm/dd/yyyy)*	*(QRSPNS06)*
(QSTAT07) 1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(QSNTDT07)* *(mm/dd/yyyy)*	*(QDESC07)*	*(QRSPDT07)* *(mm/dd/yyyy)*	*(QRSPNS07)*
(QSTAT08) 1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(QSNTDT08)* *(mm/dd/yyyy)*	*(QDESC08)*	*(QRSPDT08)* *(mm/dd/yyyy)*	*(QRSPNS08)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT09)	*(QSNTDT09)*	*(QDESC09)*	*(QRSPDT09)*	*(QRSPNS09)*
1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(mm/dd/yyyy)*		*(mm/dd/yyyy)*	

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT10)	*(QSNTDT10)*	*(QDESC10)*	*(QRSPDT10)*	*(QRSPNS10)*
1-Resolved 2-NotYetSentToSite 3-PendingSiteResponse 4-NeverResolved	*(mm/dd/yyyy)*		*(mm/dd/yyyy)*	

Blood and Marrow Transplant Clinical Trials Network

Specimen Acquisition Form - 0803 (SA5)

Web Version: 1.0; 2.01; 09-14-12

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

Microbial Translocation Markers

1. Was a peripheral blood sample collected for Microbial Translocation Markers? *(MICTRANS)* ☐ 1 - Yes ☐ 2 - No
2. Record the date the sample was collected:*(MICTRADT)* _____ *(mm/dd/yyyy)*

HIV Single Copy PCR

HIV Single Copy PCR

3. Did the patient have an undetectable pre-transplant HIV titer by standard assay (<50 copies/mL)?*(NEGHIVTI)* ☐ 1 - Yes ☐ 2 - No
4. Record the date of the undetectable HIV titer:*(NEGHIVDT)* _____ *(mm/dd/yyyy)*
5. Were plasma samples collected for HIV Load Single-Copy PCR assessment? *(SNGLPCR)* ☐ 1 - Yes ☐ 2 - No
6. Were plasma samples collected for HIV Load Single-Copy PCR assessment? *(SNGLPCR)* ☐ 1 - Yes ☐ 2 - No
7. Record the date the samples were collected:*(SNGPCRDT)* _____ *(mm/dd/yyyy)*
8. Record the date the samples were collected:*(SNGPCRDT)* _____ *(mm/dd/yyyy)*

Plasma DNA Tumor Monitoring

9. Was a peripheral blood sample collected for Plasma DNA Monitoring? *(PLSDNAMN)* ☐ 1 - Yes ☐ 2 - No
10. Record the date the sample was collected:*(PLSDNADT)* _____ *(mm/dd/yyyy)*

Immune Reconstitution Studies

11. Were peripheral blood samples collected for Immune Reconstitution Studies? *(IMURECON)* ☐ 1 - Yes ☐ 2 - No
12. Record the date the samples were collected:*(IMURECDT)* _____ *(mm/dd/yyyy)*

Lymphoma Pathology Consultation

13. Was a tissue sample collected for the Lymphoma Pathology Consultation? *(LYMPHPTH)* ☐ 1 - Yes ☐ 2 - No
14. Record the date the tissue samples were collected:*(LYMPTHDT)* _____ *(mm/dd/yyyy)*

Optional Investigational Research

15. Was a peripheral blood sample collected for undefined future research? *(RESEARCH)* ☐ 1 - Yes ☐ 2 - No
16. Record the date the peripheral blood sample was collected:*(RSRCHDT)* _____ *(mm/dd/yyyy)*

Comments:*(SA5CMMNT)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0803 (T18)

Web Version: 1.0; 1.00; 06-28-10

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

1. Record date of evaluation:*(T18EVLDT)* _____ *(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.

Renal Toxicity

2. Did the patient experience renal failure severe enough to warrant dialysis?*(T18RENAL)* ☐ 1 - Yes ☐ 2 - No

3. Did the patient receive dialysis?*(T18DIALS)* ☐ 1 - Yes ☐ 2 - No

4. **Lower GI Toxicity**

5. Diarrhea:*(T18DIAR)*

0 - Grades 0-2
3 - Inc by 7+ stools over baseline; requires IVF >or= 24hrs; hosp; severe inc in ostomy output
4 - Resulting in hemodynamic insufficiency or life threatening consequences
5 - Death

6. Hemorrhagic cystitis:*(T18CYSTI)*

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:*(T18HEMRG)*

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

8. Record the site of bleeding:*(T18BLEED)*

1 - GI
2 - GU
3 - CNS
4 - Associated with surgery
5 - Pulmonary
*Additional Options Listed Below

Specify other site of bleeding:*(T18BLDOT)* _____

Cardiovascular Toxicity

9. Hypotension:*(T18HYPOT)*

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

10. Cardiac arrhythmia:*(T18CRDAR)*

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

11. Left ventricular systolic dysfunction:*(T18LVENT)*

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

12. Somnolence:*(T18SMNLN)*

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

13. Did the patient experience any seizures during this assessment period?*(T18SEIZR)* ☐ 1 - Yes ☐ 2 - No

14. Record seizure toxicity grade:*(T18SZGRD)*

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

15. HUS/TTP/thrombotic microangiopathy:*(T18DIC)*

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

Vascular Toxicity

16. Vascular leak syndrome:*(T18VASLK)*

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

Pulmonary Toxicity

17. Hypoxia (for more than 24 hours):*(T18HYPXI)*

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

18. Dyspnea:*(T18DYSPN)*

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

19. During this assessment period, was an FEV1 performed? *(T18FEVDN)* ☐ 1 - Yes ☐ 2 - No

20. Record FEV1 value obtained:*(T18FEVVL)* _____ *(xxx)* % of predicted value

21. During this assessment period, was an FVC performed? *(T18FVCDN)* ☐ 1 - Yes ☐ 2 - No

22. Record FVC value obtained:*(T18FVCVL)* _____ *(xxx)* % of predicted value

Hepatic Toxicity

23. Did the patient develop abnormal liver function during this assessment period?*(T18ABNLF)* ☐ 1 - Yes ☐ 2 - No

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

24. Jaundice:*(T18JANDC)* ☐ 1 - Yes ☐ 2 - No
25. Hepatomegaly:*(T18HPTMG)* ☐ 1 - Yes ☐ 2 - No
26. Right upper quadrant pain:*(T18QUADP)* ☐ 1 - Yes ☐ 2 - No
27. Weight gain (>5%) from baseline:*(T18WGHTG)* ☐ 1 - Yes ☐ 2 - No
28. Other clinical signs/symptoms:*(T18OTHAB)* ☐ 1 - Yes ☐ 2 - No

Specify other clinical signs/symptoms:*(T18SPEC1)* _____

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
29. VOD:	*(T18VODET)* 1 - Yes 2 - No	*(T18VODBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(T18VODDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
30. Infection:	*(T18INFET)* 1 - Yes 2 - No	*(T18INFBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(T18INFDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done

31. Other:	*(T18OTHET)* 1 - Yes 2 - No	*(T18OTHBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(T18OTHDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
32. Unknown:	*(T18UNKET)* 1 - Yes 2 - No		

Specify other etiology:*(T18SPEC2)*

Comments:*(T18COMM)*

Additional Selection Options for T18

Record the site of bleeding:
6 - Petechiae
9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Transplant Form - 0803 (TP1)

Web Version: 1.0; 3.02; 01-30-14

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

1. Record the patient's body surface area (BSA) prior to initiation of conditioning: *(TP1BSA)* _____ *(x.xx)* m^2
2. Record the date the BSA was determined: *(TP1BSADT)* _____ *(mm/dd/yyyy)*
3. Indicate the stem cell source: *(TP1SCSRC)* ☐ Peripheral Blood ☐ Bone Marrow

Mobilization

4. What type of mobilization did the patient receive? *(MOBILTYP)* ☐ 1 - Growth Factors ☐ 2 - Chemotherapy and Growth Factors

Chemotherapy Based Mobilization

5. Record the chemotherapy agent for mobilization: *(CHEMTAGE)*

```
1 - Cyclophosphamide
2 - Cyclophosphamide/Etoposide (VP-16)
3 - Etoposide (VP-16)
4 - ICE (Ifosfamide, carboplatin, and etoposide (VP-16))
5 - ESHAP (Etoposide (VP-16), solumedrol, ara-c, and cisplatinum)
*Additional Options Listed Below
```

If Other, specify: *(CHEMOTHR)* _____

6. Record start date of chemotherapy administration: *(CHEMODT)* _____ *(mm/dd/yyyy)*

Growth Factor Based Mobilization

7. Record the growth factor used for mobilization: *(GROWFACT)*

```
1 - Filgrastim (G-CSF)
2 - Sargramostim (GM-CSF)
3 - Filgrastim (G-CSF) and Sargramostim (GM-CSF)
9 - Other
```

If Other, specify: *(OTHERGRW)* _____

8. Record the start date of growth factor administration: *(GRWFCTDT)* _____ *(mm/dd/yyyy)*

9. Was plerixafor (AMD-3100) used for mobilization? *(PLERMOBL)* ☐ 1 - Yes ☐ 2 - No

Apheresis

10. Record the start date of Apheresis: *(APHERDT)* _____ *(mm/dd/yyyy)*
11. Record the number of collection days: *(COLLDAYS)* _____ *(xx)*

Conditioning

BCNU

12. Record the BCNU dose: *(BCNUDOSE)* _____ *(xxxx)* mg
13. Record the date of BCNU administration: *(BCNUDATE)* _____ *(mm/dd/yyyy)*

VP-16 (Etoposide)

14. Record the total VP-16 dose: *(VP16DOSE)* _____ *(xxxx)* mg
15. Record the start date of VP-16 administration: *(VP16STDT)* _____ *(mm/dd/yyyy)*
16. Record the end date of VP-16 administration: *(VP16ENDT)* _____ *(mm/dd/yyyy)*

Cytarabine (Ara-C)

17. Record the total Cytarabine dose:*(CYTARDS)* _____ *(xxxx)* mg

18. Record the start date of Cytarabine administration:*(CYTSTDT)* _____ *(mm/dd/yyyy)*

19. Record the end date of Cytarabine administration:*(CYTENDT)* _____ *(mm/dd/yyyy)*

Melphalan

20. Record the Melphalan dose:*(MELDOSE)* _____ *(xxx)* mg

21. Record the date of Melphalan administration:*(MELDATE)* _____ *(mm/dd/yyyy)*

Transplant

Antiretroviral Therapy

22. Was the patient's antiretroviral therapy stopped during conditioning? *(TP1AVSTP)* ☐ 1 - Yes ☐ 2 - No

23. Record the stop date of the antiretroviral therapy:*(TP1AVDT)* _____ *(mm/dd/yyyy)*

24. Record the date antiretroviral therapy was restarted:*(TP1AVRDT)* _____ *(mm/dd/yyyy)*

Bone Marrow

25. Record the date the bone marrow was collected:*(BNMRWDAT)* _____ *(mm/dd/yyyy)*

26. Record the total nucleated cell (TNC) dose of the infused bone marrow product: *(BNMRWTNC)* _____ *(xxx.x)* $x10^8$TNC/kg

27. If available, record the CD34+ cell dose of the infused bone marrow: *(CD34BNMW)* _____ *(xxx.x)* $x10^6$CD34+ cells/kg

Peripheral Blood

28. Record the CD34+ cell dose of the infused peripheral blood product:*(CD34PB)* _____ *(xxx.x)* $x10^6$CD34+ cells/kg

29. If available, record the total nucleated cell (TNC) dose of the infused peripheral blood product:*(PBTNC)* _____ *(xxx.x)* $x10^8$TNC/kg

30. Record the date of hematopoietic stem cell infusion:*(TXPDATE)* _____ *(mm/dd/yyyy)*

31. Record the patient's pre-transplant CMV status:*(PRECMVST)* ☐ 1 - Positive ☐ 2 - Negative

32. IUBMID for this patient (if available):*(TXIUBMID)* _____

Comments:*(TP1CMMNT)*

Additional Selection Options for TP1

Record the chemotherapy agent for mobilization:
6 - DHAP (Dexamethasone, ara-c, and cisplatinum)
7 - MINE (Ifosfamide, mitoxantrone, and etoposite (VP-16))
9 - Other