Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Web Version: 1.0; 4.02; 06-09-11

Segment *(PROTSEG)*:
Date of Admission *(ADMITDT)*:

1. Date of discharge: *(DISCHDT)* *(mm/dd/yyyy)*
2. Patient discharge status: *(DISCPTST)* ☐ 1 - Alive ☐ 2 - Dead
   If Dead, a Death Form must be submitted.
3. Record PRIMARY discharge diagnosis: *(PHSPREAS)*

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

   *Specify organ: *(ADM4SPEC)*
   **Specify other: *(ADM1SPEC)*
4. Record secondary discharge diagnoses:
   a. GVHD: *(REASGVHD)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   b. Relapse/progression: *(REASRLPS)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   c. Graft failure: *(REASGF)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   d. Infection: *(REASINF)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   e. Fever: *(REASFVR)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   f. Seizure: *(REASSZR)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   g. Bleeding/hemorrhage: *(REASGIBL)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   h. Diarrhea: *(REASDRH)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   i. Nausea/vomiting: *(REASNV)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   j. Organ failure: *(REASORGF)* ☐ 1 - Contributory ☐ 2 - Noncontributory
      Specify organ: *(ADM3SPEC)*
   k. Trauma: *(REASTRAM)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   l. Psychiatric: *(REASPSYC)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   m. Secondary malignancy: *(REASMALG)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   n. Scheduled procedure/treatment: *(REASPROC)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   o. Thrombosis/thrombus/embolism: *(REASTRMB)* ☐ 1 - Contributory ☐ 2 - Noncontributory
   p. Other: *(REASOTHR)* ☐ 1 - Contributory ☐ 2 - Noncontributory
      Specify other: *(ADM2SPEC)*
5. Record re-admission institution: *(ADMCENTR)*

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

Comments: *(ADMCOMM1)*

Additional Selection Options for ADM

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

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 3.06; 06-09-11

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

1. Report activation status: *(AVSTATUS)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason

   If Other, specify reason for deactivation: *(AESPEC1)*
2. Record date transplant center became aware of the event: *(AVAWARDT)* *(mm/dd/yyyy)*
3. Indicate weight at time of the event: *(AVWGHTKG)* *(xxx.x)* kg
4. Was this event expected or anticipated? *(AVEXPECT)* ☐ 1 - Yes ☐ 2 - No
5. Record the severity of event: *(AVEVENT)*
   - 1 - Mild
   - 2 - Moderate
   - 3 - Severe
   - 4 - Life Threatening
   - 5 - Fatal
6. What is the relationship to study therapy/intervention: *(AVRELAT)*
   - 1 - Unrelated
   - 2 - Unlikely
   - 3 - Possible
   - 4 - Probable
   - 5 - Definite
7. Is there an alternative etiology: *(AVETIOL)*
   - 0 - None Apparent
   - 1 - Study Disease
   - 2 - Other Pre-Existing Disease or Condition
   - 3 - Accident, Trauma, or External Factors
   - 4 - Concurrent Illness/Condition (Not Pre-Existing)
8. What is the effect on study therapy/intervention schedule: *(AVEFFECT)*
   - 1 - No Change - Completed
   - 2 - No Change - Ongoing
   - 3 - Dose Modified
   - 4 - Temporarily Stopped
   - 5 - Permanently Stopped
9. Record the most severe outcome of the event: *(AVOUTCOM)*
   - 1 - Resolved, No Residual Effects
   - 2 - Resolved with Sequelae
   - 3 - Persistent Condition
   - 4 - Resolved by Death
10. Record the date of resolution: *(AVRESDT)* *(mm/dd/yyyy)*
11. Was this event associated with: *(AVASSOCI)*
    - 0 - None of the Following
    - 1 - Death
    - 2 - Life-Threatening Event
    - 3 - Disability
    - 4 - Congenital Anomaly
    - *Additional Options Listed Below

Comments: *(AE1COMM)*

Additional Selection Options for AE1

Was this event associated with:
5 - Required Intervention to Prevent Permanent Impairment or Damage
6 - Hospitalization (Initial or Prolonged)
9 - Other SAE

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 3.06; 06-09-11

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

1. Report activation status: *(AVSTAT_A)*

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

Relevant Past Medical History

2. Does the patient have any relevant history, including pre-existing medical conditions? *(SEMEDHXS)*
☐ 1 - Yes ☐ 2 - No

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

(SEMEDHX)

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

(SESUMM)

4. Initial submitter: *(SEISUBBY)*
Name: Date: *(SEISUBDT)* *(mm/dd/yyyy)*

5. Authorized submitter: *(SEASUBBY)*
Name: Date: *(SEASUBDT)* *(mm/dd/yyyy)* ?

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 3.06; 06-09-11

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

1. Report activation status: *(AVSTAT_B)*

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

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

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

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

Comments: *(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 3.05; 06-09-11

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

1. Report activation status: *(AVSTAT_C)*

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

Laboratory Test Results

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

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

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

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

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

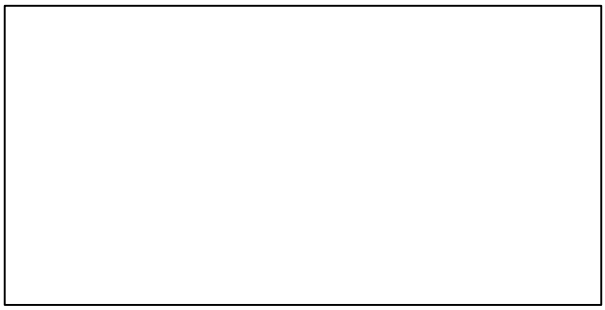
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

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

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

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

Comments: *(AE4COMM)*



Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 3.06; 06-09-11

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

1. Report activation status: *(AVSTAT_D)*

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

2. Reviewed: *(AEREVIEW)*

☐ 1 - Yes ☐ 2 - No

3. Reviewed by: *(ARFREVBY)*

4. Review date: *(ARFREVDT)*

(mm/dd/yyyy)

5. Comment 1 - For Distribution: *(ARCM1DIS)*

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

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 4.06; 06-09-11

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

1. Adverse event status: *(AVSTAT_E)*

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

2. Has this event been determined to be an unexpected, grade 3-5 adverse event? *(AMDETER)* ☐ 1 - Yes ☐ 2 - No
3. Does this require expedited reporting to the FDA? *(AMEXPFDA)* ☐ 1 - Yes ☐ 2 - No
4. Does this require expedited reporting to the DSMB? *(AMEXPDSM)* ☐ 1 - Yes ☐ 2 - No
5. Do you recommend the patient be withdrawn from further protocol therapy? *(AMWITHDR)* ☐ 1 - Yes ☐ 2 - No
6. Is the review complete? *(AMREVDNE)* ☐ 1 - Yes ☐ 2 - No
7. If **No**, what additional information is required: *(AMREVINF)*

8. Medical Monitor event description: *(AMMMEVDS)*

Comments: *(AE6COMM)*

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Consolidative Localized Radiation Therapy Form (CLR)

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

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

1. Indicate the number of sites to which the patient received consolidative localized radiation therapy: *(SITESCLR)*

0 - None
1 - One Site
2 - Two Sites
3 - Three Sites

If the patient received consolidative localized radiation therapy, provide information regarding the therapy below:

Site	Specify Other Site	Start Date	Total Dose
2. *(SIT1CLR)* Nodal Sites 1 - Axillary 2 - Cervical 3 - Hilar 4 - Iliac *Additional Options Listed Below	*(SIT1SPEC)*	*(SIT1DATE)* *(mm/dd/yyyy)*	*(SIT1DOSE)* *(xxxx)* cGy
3. *(SIT2CLR)* Nodal Sites 1 - Axillary 2 - Cervical 3 - Hilar 4 - Iliac *Additional Options Listed Below	*(SIT2SPEC)*	*(SIT2DATE)* *(mm/dd/yyyy)*	*(SIT2DOSE)* *(xxxx)* cGy
4. *(SIT3CLR)* Nodal Sites 1 - Axillary 2 - Cervical 3 - Hilar 4 - Iliac *Additional Options Listed Below	*(SIT3SPEC)*	*(SIT3DATE)* *(mm/dd/yyyy)*	*(SIT3DOSE)* *(xxxx)* cGy

Comments: *(CLRCOMM)*

Additional Selection Options for CLR

CLR Site 1
5 - Inguinal
6 - Intra-abdominal
7 - Mediastinal
8 - Periaortic
9 - Retroperitoneal
10 - Spleen
11 - Supraclavicular
12 - Waldeyer's Ring
13 - Other Nodal Site, Specify
Extra Nodal Sites
14 - Bone
15 - Bone Marrow
16 - Brain
17 - GI Tract
18 - Kidney
19 - Liver
20 - Lung
21 - Pleura
22 - Skin
23 - Spinal Cord
24 - Other Extra Nodal Site, Specify

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Conditioning Regimen Form - 0401 (CND)

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

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

1. Record the patient's body surface area (BSA): *(BSURFARE)* _____ *(x.xx)* m^2
2. Record the date the BSA was determined: *(BSURFDT)* _____ *(mm/dd/yyyy)*

Treatment Arm:

3. Patient is randomized to receive: *(TRMNTR)*

1- Rituxan
2- Bexxar

Rituxan

Record the doses and dates of Rituxan administration:

	Dose	Date
4. Rituxan-1st Dose:	*(FSTRTXDS)* _____ *(xxxx)* mg	*(FSTRTXDT)* _____ *(mm/dd/yyyy)*
5. Rituxan-2nd Dose:	*(SECRTXDS)* _____ *(xxxx)* mg	*(SECRTXDT)* _____ *(mm/dd/yyyy)*

Bexxar

Record the doses and dates of Bexxar administration:

	Dose		Date
6. Bexxar-Dosimetric:	*(BXRDDS)* _____ *(x)* mCi		*(BXRDDT)* _____ *(mm/dd/yyyy)*
7. Bexxar-Therapeutic:	*(BXRTDS)* _____ *(xxx)* mCi	*(TTLBDTHD)* _____ *(xx)* cGy	*(BXRTDT)* _____ *(mm/dd/yyyy)*

BEAM Regimen:

BCNU

Record the dose and date of BCNU administration:

	Dose	Date
8. BCNU:	*(BCNUDS)* _____ *(xxxx)* mg	*(BCNUDT)* _____ *(mm/dd/yyyy)*

VP-16 (Etoposide)

9. Record **Total** VP-16 dose: *(VPTDOSE)* _____ *(xxxx)* mg
10. Enter the start date of VP-16 administration: *(VPSTDT)* _____ *(mm/dd/yyyy)*
11. Enter the end date of VP-16 administration: *(VPENDDT)* _____ *(mm/dd/yyyy)*

Cytarabine (Ara-C)

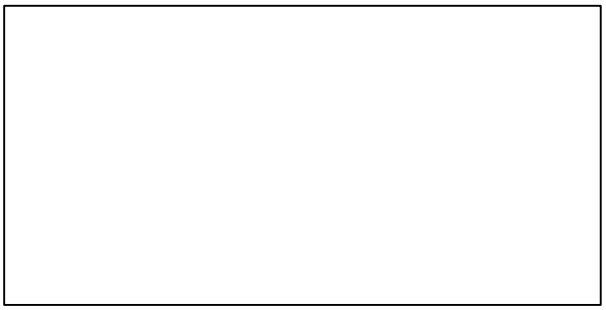
12. Record **Total** Cytarabine dose: *(CYTDOSE)* _____ *(xxxx)* mg
13. Enter the start date of Cytarabine administration: *(CYSTDT)* _____ *(mm/dd/yyyy)*
14. Enter the end date of Cytarabine administration: *(CYENDDT)* _____ *(mm/dd/yyyy)*

Melphalan

Record the dose and date of Melphalan administration:

	Dose	Date
15. Melphalan:	*(MELPHDS)* _____ *(xxx)* mg	*(MELPHDT)* _____ *(mm/dd/yyyy)*

Comments: *(COMMCND)*



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Cytoreductive Therapy/ Mobilization Regimen (CYM)

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

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

1. Record patient's weight: *(PWEIGHT)* _____ *(xxx.x)* kg
2. Record the date the weight was obtained: *(WEIGHDT)* _____ *(mm/dd/yyyy)*

3. Record the patient's actual body surface area (BSA): *(PBSA)* _____ *(x.xx)* m^2
4. Record the date the BSA was determined: *(PBSADT)* _____ *(mm/dd/yyyy)*

Rituxan

5. Most recent date of Rituxan administration: *(LTRTXDT)* _____ *(mm/dd/yyyy)*
6. Record the most recent dose of Rituxan the patient received: *(RTXDOSE)* _____ *(xxxx)* mg
7. Start date of apheresis: *(APHESTDT)* _____ *(mm/dd/yyyy)*
8. Did the patient receive any additional doses of Rituxan within four weeks prior to start of apheresis? *(ADDLRTX)* ☐ 1 - Yes ☐ 2 - No
9. How many additional doses of Rituxan did the patient receive? *(NUMBRTX)*
   1 - One dose
   2 - Two doses
   3 - Three doses

*Record the doses and dates of additional **Rituxan** administration:*

	Dose	Date
10. 1st additional Rituxan dose:	*(RTX1ADD)* _____ *(xxxx)* mg	*(RTX1ADDT)* _____ *(mm/dd/yyyy)*
11. 2nd additional Rituxan dose:	*(RTX2ADD)* _____ *(xxxx)* mg	*(RTX2ADDT)* _____ *(mm/dd/yyyy)*
12. 3rd additional Rituxan dose:	*(RTX3ADD)* _____ *(xxxx)* mg	*(RTX3ADDT)* _____ *(mm/dd/yyyy)*

13. What type of of mobilization therapy did the patient receive? *(TYPMOBL)*
   1 - Chemotherapy
   2 - Growth Factors

Chemotherapy Based Mobilization

14. Record the chemotherapy agent for mobilization: *(CHEMAGEN)*
   1-Cyclophosphamide
   2-Cyclophosphamide/VP-16
   3-VP-16
   4-ICE (ifosfamide,carboplatin,etoposide)
   5-ESHAP (etoposide,solumedrol,ara-C,and cisplatinum)
   *Additional Options Listed Below

   If Other, specify: *(OTHER)* _____

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

16. Record total daily G-CSF dose: *(GCSFDS)* _____ *(xxxx)* mcg
17. Enter the start date of G-CSF administration: *(GCSFSDT)* _____ *(mm/dd/yyyy)*
18. Record the end date of G-CSF administration: *(GCSFEDT)* _____ *(mm/dd/yyyy)*

Growth Factor Based Mobilization

19. Record the growth factor used for mobilization: *(GRWTFACT)*

1 - G-CSF
2 - GM-CSF
3 - G-CSF and GM-CSF
4 - AMD-3100
5 - Parathyroid Hormone
*Additional Options Listed Below

If Other, specify: *(GRWTOTHR)*

20. Record start date of growth factor administration: *(GRWTDT)*

(mm/dd/yyyy)

Comments: *(COMMCYM)*

Additional Selection Options for CYM

Record the chemotherapy agent for mobilization:
6- DHAP (dexamethasone, ara-C, cisplatinum)
7- MINE (ifosfamide, mitoxantrone, and etoposide)
9- Other

Record the growth factor used for mobilization:
9 - Other

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 6.00; 06-22-11

1. Name Code: *(NAMECODE)*

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

3. CRID # (CIBMTR Recipient ID): *(CRIDNUM)* *(xxxxxxxxxx)*

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

4. Gender: *(GENDER)* ☐ 1 - Male ☐ 2 - Female

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

6. Ethnicity: *(ETHNIC)*

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

7. Race: *(RACE)*

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

Specify race: *(RACESP)*

8. Secondary Race: *(RACE2)*

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

Specify secondary race: *(RACE2SP)*

Comments: *(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

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

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

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

If yes, submit autopsy report to DCC

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

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

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

?

Specify other: *(DTHSPEC1)*

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

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

Specify other: *(DTHSPEC2)*

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

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

Specify other: *(DTHSPEC3)*

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

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

Specify other: *(DTHSPEC4)*

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

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

Specify other: *(DTHSPEC5)*

Comments: *(DTCMMNTS)*

Additional Selection Options for DTH

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

Blood and Marrow Transplant Clinical Trials Network

0401A (ENR)

Web Version: 1.0; 7.01; 08-25-09

Bexxar Enrollment Form - Segment A

1. Record date patient informed consent signed: *(CNSTDTBX)* _____ *(mm/dd/yyyy)*
2. Patient's date of birth: *(DOBBX)* _____ *(mm/dd/yyyy)*
3. SWOG ID: *(O4O1SWOG)* _____
4. Record the proposed date of initiation of conditioning: *(STCONDDT)* _____ *(mm/dd/yyyy)*
5. Record the start date of mobilization: *(MOBLDTBX)* _____ *(mm/dd/yyyy)*
6. Record the start date of apheresis: *(STAPHERE)* _____ *(mm/dd/yyyy)*
7. Record the date of the most recent Rituxan administration: *(LASTRTX)* _____ *(mm/dd/yyyy)*

Patient Inclusion Criteria

8. Does the patient have persistent or recurrent REAL classification diffuse large B-cell lymphoma, composite lymphoma with > 50% diffuse large B-cell lymphoma, or medistinal B-cell lymphoma? *(REALDXBX)* ☐ 1 - Yes ☐ 2 - No
9. Is the patient CD20+ as demonstrated on at least one histologic specimen? *(CD20BX)* ☐ 1 - Yes ☐ 2 - No
10. Record the date the first CD20+ histologic specimen was obtained: *(SPECDTBX)* _____ *(mm/dd/yyyy)*
11. How many prior regimens of chemotherapy (including induction and salvage chemotherapies) has the patient received? *(PRCHEMBX)*
    - 1 - One Prior Regimen
    - 2 - Two Prior Regimens
    - 3 - Three Prior Regimens
12. Indicate the patient's disease status: *(DXSTATBX)*
    - 1 - Primary Induction Failure
    - 2 - First Relapse
    - 3 - Second Complete Remission
    - 4 - Second Partial Response
13. Does the patient have chemosensitive disease as demonstrated by at least a partial response to induction or salvage chemotherapy? *(CHEMPR)* ☐ 1 - Yes ☐ 2 - No
14. What is the percentage of bone marrow involvement with lymphoma? *(BMINVLBX)* _____ *(xxx)* %
15. Does the patient have either no cardiac disease or AHA Class I cardiac disease? *(AHACLSBX)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value	ULN for Your Institution	Date of Assessment
16. LVEF:	*(LVEFVLBX)* _____ *(xxx)* %	N/A	*(LVEFDTBX)* _____ *(mm/dd/yyyy)*
17. Bilirubin:	*(BILIVLBX)* _____ *(x.x)* mg/dL	N/A	*(BILIDTBX)* _____ *(mm/dd/yyyy)*
18. ALT:	*(ALTVLBX)* _____ *(xxx)* Units/L	*(ALTULNBX)* _____ *(xxx)* Units/L	*(ALTDTBX)* _____ *(mm/dd/yyyy)*
19. AST:	*(ASTVLBX)* _____ *(xxx)* Units/L	*(ASTULNBX)* _____ *(xxx)* Units/L	*(ASTDTBX)* _____ *(mm/dd/yyyy)*
20. Creatinine:	*(CRTVLBX)* _____ *(x.x)* mg/dL	N/A	*(CRTDTBX)* _____ *(mm/dd/yyyy)*
21. Creatinine Clearance:	*(CRCLVLBX)* _____ *(xxx)* mL/min	N/A	*(CRCLDTBX)* _____ *(mm/dd/yyyy)*
22. DLCO:	*(DLCOVLBX)* _____ *(xxx)* %	N/A	*(DLCODTBX)* _____ *(mm/dd/yyyy)*
23. FEV1:	*(FEV1VLBX)* _____ *(xxx)* %	N/A	*(FEV1DTBX)* _____ *(mm/dd/yyyy)*
24. FVC:	*(FVCVLBX)* _____ *(xxx)* %	N/A	*(FVCDTBX)* _____ *(mm/dd/yyyy)*

25. Indicate the patient's most recent platelet count (independent of transfusions): *(PLTCNTBX)* _____ *(xxxxxx)* /uL
26. Indicate the date of the most recent platelet count: *(PLTDTBX)* _____ *(mm/dd/yyyy)*
27. Indicate the patient's most recent ANC (independent of growth factors): *(ANCBX)* _____ *(xxxxx)* /mm^3

28. Indicate the date of the most recent ANC: *(ANCDTBX)* _____ *(mm/dd/yyyy)*

Patient Exclusion Criteria

29. Record the patient's Karnofsky performance score: *(KPSBX)*

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

30. Does the patient have transformed follicular lymphoma? *(FOLLYMBX)* ☐ 1 - Yes ☐ 2 - No

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

32. Does the patient have a history of any malignant disease that was treated with curative intent < 5 years ago (other than DLBCL, basal cell carcinoma, or cervical cancer in situ)? *(CAHXBX)*

1 - Yes
2 - Yes, Approved by Medical Monitor
3 - No

33. Date approved by Study Chair or Medical Monitor: *(CAAPRVBX)* _____ *(mm/dd/yyyy)*

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

35. Is the patient willing to use contraceptive techniques from the time of initiation of mobilization until six months post-transplant? *(CNTECHBX)* ☐ 1 - Yes ☐ 2 - No

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

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

39. Has the patient had a prior severe reaction to G-CSF or Rituxan? *(RXGRTXBX)* ☐ 1 - Yes ☐ 2 - No

40. Has the patient received prior radioimmunotherapy? *(IMMUNOBX)* ☐ 1 - Yes ☐ 2 - No

41. Does the patient have known hypersensitivity to murine proteins? *(KWNMURIN)* ☐ 1 - Yes ☐ 2 - No

Consent for Use of Biological Specimens for Research

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

Comments: *(COMMBXA)*

Additional Selection Options for ENR

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

0401B (ENR)

Web Version: 1.0; 4.00; 06-26-09

Bexxar Enrollment Form - Segment B

1. Indicate the stem cell type of the patient's autograft. *(CELPERBM)*

   Peripheral Blood
   Bone Marrow

2. Indicate the total number of CD34+ cells/kg collected in the autograft: *(CD34BX)* _____ *(xx.x)* x 10^6 cells/kg

3. Indicate the total number of nucleated cell/kg collected in the autograft. *(TOTNUCEL)* _____ *(xx.x)* x 10^6 cells/kg

Comments: *(COMMBXB)*

Blood and Marrow Transplant Clinical Trials Network

Follow Up Status Form (FUS)

Web Version: 1.0; 12.01; 06-27-11

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

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

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

2. Has the patient died? *(DIED)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Death Form must be submitted.

3. Date of patient death: *(DEATHDT)* *(mm/dd/yyyy)*

4. Has the patient relapsed or experienced disease progression? *(RELAPSE)* ☐ 1 - Yes ☐ 2 - No

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

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

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

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

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

Specify other treatment: *(FUS1SPEC)*

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

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

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

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

13.

14. Has the patient experienced any new clinically significant infections? *(NEWINFX)* ☐ 1 - Yes ☐ 2 - No
If Yes, an Infection Form must be submitted.

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

16. Has the patient been hospitalized? *(HOSPITAL)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Re-Admission Form must be submitted.

17. Date of hospitalization: *(HOSPTLDT)* *(mm/dd/yyyy)*

18. Has the patient received a non-protocol specified transplant? *(TRANSTWO)* ☐ 1 - Yes ☐ 2 - No

19. Date of non-protocol specified transplant: *(DATRANSP)* *(mm/dd/yyyy)*

Comments: *(FUS1COMM)*

Additional Selection Options for FUS

Indicate type of treatment:
6 - Other Cellular Therapy
7 - Other

Blood and Marrow Transplant Clinical Trials Network

Immune Reconstitution/Lab Form - 0401 (IMR)

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

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

Immune and Hematologic Function

1. Did the patient's ANC recover to ≥500/uL for two consecutive days? *(ANCRCVR)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Previously Reported
2. Record neutrophil count and specimen collection dates:

	Value	Date
1st ANC > 500/uL:	*(ANCVL1IR)* *(xxxxx)* /uL	*(ANCDT1IR)* *(mm/dd/yyyy)*
2nd ANC > 500/uL:	*(ANCVL2IR)* *(xxxxx)* /uL	*(ANCDT2IR)* *(mm/dd/yyyy)*

3. Enter the patient's most recent ANC value: *(ANCRECNT)* *(xxxxx)* /uL
4. Enter the date the ANC was obtained: *(ANCRCNTD)* *(mm/dd/yyyy)*

5. Did the patient's platelet count recover to ≥20,000/uL for two consecutive labs with no platelet transfusions 7 days prior? *(PLTRCVR)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Previously Reported
6. Record platelet count and specimen collection dates:

	Value	Date
1st platelet count ≥20,000/uL:	*(PLTVL1IR)* *(xxxxxx)* /uL	*(PLTDT1IR)* *(mm/dd/yyyy)*
2nd platelet count ≥20,000/uL:	*(PLTVL2IR)* *(xxxxxx)* /uL	*(PLTDT2IR)* *(mm/dd/yyyy)*

7. Enter the patient's most recent platelet count without transfusion support: *(PLTRECNT)* *(xxxxxx)* /uL
8. Enter the date the platelet count was obtained: *(PLTRCNTD)* *(mm/dd/yyyy)*

9. Enter the patient's most recent hemoglobin level without transfusion support: *(HEMGLBIR)* *(xx.x)* g/dL
10. Enter the date the hemoglobin level was obtained: *(HEMGDTIR)* *(mm/dd/yyyy)*

Immune Reconstitution

11. Were immune reconstitution assays normal at one year post-transplant? *(NORMIR)* ☐ 1 - Yes ☐ 2 - No
    If Yes, immune reconstitution assays are not required two years post-transplant.

Flow Cytometry

12. Date flow cytometry was performed: *(DTFCIMR)* *(mm/dd/yyyy)*
13. White blood cell count: *(WBCIR)* *(xxxxx)* x 10^9/L
14. Percent lymphocyte of CD45+ cells: *(LMYPHIR)* *(xxx)* %
15. CD2: *(CD2IMR)* *(xxxx)* cells/uL
16. CD3: *(CD3IMR)* *(xxxx)* cells/uL
17. CD4: *(CD4IMR)* *(xxxx)* cells/uL
18. CD8: *(CD8IMR)* *(xxxx)* cells/uL
19. CD19: *(CD19IMR)* *(xxxx)* cells/uL
20. CD3/CD25: *(CD325IMR)* *(xxxx)* cells/uL
21. CD45 RA: *(CD45RA)* *(xxxx)* cells/uL
22. CD45 RO: *(CD45RO)* *(xxxx)* cells/uL
23. CD56+/CD3-: *(CD563IMR)* *(xxxx)* cells/uL

Quantitative Immunoglobulins

24. Date quantitative immunoglobulins assay was performed: *(DTQIIMR)* *(mm/dd/yyyy)*

25. IgA: *(IGAIMR)* _____ *(xxx)* mg/dL

26. IgG: *(IGGIMR)* _____ *(xxxx)* mg/dL

27. IgM: *(IGMIMR)* _____ *(xxx)* mg/dL

Patient Research Specimens

28. Date patient research sample collected: *(DTPTCLL)* _____ *(mm/dd/yyyy)*

29. Record the research sample ID#: *(IDPTRS)* _____

Comments: *(COMMIMR)*

Blood and Marrow Transplant Clinical Trials Network

Infection Form (INF)

Web Version: 1.0; 3.04; 04-26-11

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

INFECTION I

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

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

   If other specify: *(INFSPEC1)*

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

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

INFECTION II

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

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

   If other specify: *(INFSPEC2)*

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

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

INFECTION III

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

10. Organism III: *(ORGN03)*

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

If other specify: *(INFSPEC3)*

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

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

12. Severity of infection: *(SVRTY03)*

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

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

☐ 1 - Yes ☐ 2 - No

Provide agent(s) administered for this infectious period:

14. 1st agent: *(AGENT1)*

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

15. 2nd agent: *(AGENT2)*

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

16. 3rd agent: *(AGENT3)*

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

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

☐ 1 - Yes ☐ 2 - No

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

Comments: *(INFCOM)*

Additional Selection Options for INF

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

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

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

Toxicity Form - 0401 (TX6)

Web Version: 1.0; 4.01; 06-28-10

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

1. Record date of evaluation: *(TX6EVLDT)* _____ *(mm/dd/yyyy)*

Record the highest grade of mobilization-related toxicities diagnosed. The toxicity grades are based on the NCI CTCAE Version 3.0.
Record the highest grade of Bexxar or Rituxan-related toxicities. The toxicity grades are based on the NCI CTCAE Version 3.0.
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? *(TX6RENAL)* ☐ 1 - Yes ☐ 2 - No
3. Did the patient receive dialysis? *(TX6DIALS)* ☐ 1 - Yes ☐ 2 - No

4. **Lower GI Toxicity**
5. Diarrhea: *(TX6DIARR)*

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: *(TX6CYSTI)*

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: *(TX6HEMRG)*

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

Cardiovascular Toxicity

8. Hypotension: *(TX6HYPOT)*

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: *(TX6CRDAR)*

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: *(TX6LVENT)*

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: *(TX6SMNLN)*

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? *(TX6SEIZR)* ☐ 1 - Yes ☐ 2 - No

13. Record seizure toxicity grade: *(TX6SZGRD)*

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

14. HUS/TTP/thrombotic microangiopathy: *(TX6DIC)*

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

Vascular Toxicity

15. Vascular leak syndrome: *(TX6VASLK)*

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

Pulmonary Toxicity

16. Hypoxia (for more than 24 hours): *(TX6HYPXI)*

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

17. Dyspnea: *(TX6DYSPN)*

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

18. During this assessment period, was an FEV1 performed? *(TX6FEVDN)* ☐ 1 - Yes ☐ 2 - No

19. Record FEV1 value obtained: *(TX6FEVVL)* _____ *(xxx)* % of predicted value

20. During this assessment period, was an FVC performed? *(TX6FVCDN)* ☐ 1 - Yes ☐ 2 - No

21. Record FVC value obtained: *(TX6FVCVL)* _____ *(xxx)* % of predicted value

Hepatic Toxicity

22. Did the patient develop abnormal liver function during this assessment period? *(TX6ABNLF)* ☐ 1 - Yes ☐ 2 - No

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

23. Jaundice: *(TX6JANDC)* ☐ 1 - Yes ☐ 2 - No
24. Hepatomegaly: *(TX6HPTMG)* ☐ 1 - Yes ☐ 2 - No
25. Right upper quadrant pain: *(TX6QUADP)* ☐ 1 - Yes ☐ 2 - No
26. Weight gain (>5%) from baseline: *(TX6WGHTG)* ☐ 1 - Yes ☐ 2 - No
27. Other clinical signs/symptoms: *(TX6OTHAB)* ☐ 1 - Yes ☐ 2 - No

Specify other clinical signs/symptoms: *(TX6SPEC1)* _____

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
28. VOD:	*(TX6VODET)* 1 - Yes 2 - No	*(TX6VODBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX6VODDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
29. Infection:	*(TX6INFET)* 1 - Yes 2 - No	*(TX6INFBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX6INFDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
30. Other:	*(TX6OTHET)* 1 - Yes 2 - No	*(TX6OTHBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX6OTHDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done

31. Unknown:	(TX6UNKET) 1 -Yes 2 -No		

Specify other etiology: *(TX6SPEC2)*

CBC

	Most Recent Value	Date of Sample
32. RBC	*(TX6RBC)* *(x.x)* million/mm^3	*(TX6RBCDT)* *(mm/dd/yyyy)*
33. Hematocrit	*(TX6HCT)* *(xx.x)* %	*(TX6HCTDT)* *(mm/dd/yyyy)*
34. Hemoglobin	*(TX6HMG)* *(xx.x)* g/dL	*(TX6HMGDT)* *(mm/dd/yyyy)*
35. WBC	*(TX6WBC)* *(xxxxxx)* /mcL	*(TX6WBCDT)* *(mm/dd/yyyy)*
36. Platelet Count	*(TX6PLTL)* *(xxxxxx)* /mcL	*(TX6PLTDT)* *(mm/dd/yyyy)*
37. Neutrophils	*(TX6NEUT)* *(xxxxxx)* /mcL	*(TX6NETDT)* *(mm/dd/yyyy)*
38. Lymphocytes	*(TX6LYMP)* *(xxxxx)* /mcL	*(TX6LYMDT)* *(mm/dd/yyyy)*

Chemistry and LFTs

	Most Recent Value	Date of Sample
39. Creatinine	*(TX6CRT)* *(x.x)* mg/dL	*(TX6CRTDT)* *(mm/dd/yyyy)*
40. Bilirubin	*(TX6BIR)* *(x.x)* mg/dL	*(TX6BIRDT)* *(mm/dd/yyyy)*
41. ALT	*(TX6ALT)* *(xxxx)* IU/L	*(TX6ALTDT)* *(mm/dd/yyyy)*
42. AST	*(TX6AST)* *(xxxx)* IU/L	*(TX6ASTDT)* *(mm/dd/yyyy)*
43. Alkaline Phosphatase	*(TX6ALPH)* *(xxxx)* IU/L	*(TX6ALPDT)* *(mm/dd/yyyy)*
44. LDH	*(TX6LDH)* *(xxx)* U/l	*(TX6LDHDT)* *(mm/dd/yyyy)*

Pulmonary Function Tests

	Most Recent Value	Date of Sample
45. DLCO	*(TX6DLCO)* *(xxx)* % of predicted value	*(TX6DLCDT)* *(mm/dd/yyyy)*
46. FEV1	*(TX6FEV)* *(xxx)* % of predicted value	*(TX6FEVDT)* *(mm/dd/yyyy)*
47. FVC	*(TX6FVC)* *(xxx)* % of predicted value	*(TX6FVCDT)* *(mm/dd/yyyy)*
48. O^2 Saturation	*(TX6OXYST)* *(xxx)* %	*(TX6OXYDT)* *(mm/dd/yyyy)*

Comments: *(TX6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

Web Version: 1.0; 10.00; 06-22-11

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

1. Record date of hematopoietic stem cell infusion: *(TXDTTXP)* _____ *(mm/dd/yyyy)*
2. Record the patient's pre-transplant CMV status: *(CMVSTAT)* ☐ 1 - Positive ☐ 2 - Negative
3. IUBMID for this patient (if available): *(T_IUBMID)* _____
4. CRID # (CIBMTR Recipient ID): *(TXPCRID)* _____ *(xxxxxxxxx)*

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

Comments: *(COMMTXP1)*