Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

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

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

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

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

   *Specify organ: *(ADM4SPEC)* _____
   **Specify other: *(ADM1SPEC)* _____
4. Record secondary discharge diagnoses:

a. GVHD: *(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)*

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

Comments: *(ADMCOMM1)*

Additional Selection Options for ADM

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

Blood and Marrow Transplant Clinical Trials Network

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

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

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

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

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

Comments: *(AE1COMM)*

Additional Selection Options for AE1

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

Blood and Marrow Transplant Clinical Trials Network

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

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

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

1. Report activation status: *(AVSTAT_A)*

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

Relevant Past Medical History

2. Does the patient have any relevant history, including pre-existing medical conditions? *(SEMEDHXS)*
If Yes, include any relevant history, including preexisting medical conditions below.

☐ 1 - Yes ☐ 2 - No

(SEMEDHX)

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

(SESUMM)

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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)*

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

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

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

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

Comments: *(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

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

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

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

1. Report activation status: *(AVSTAT_C)*

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

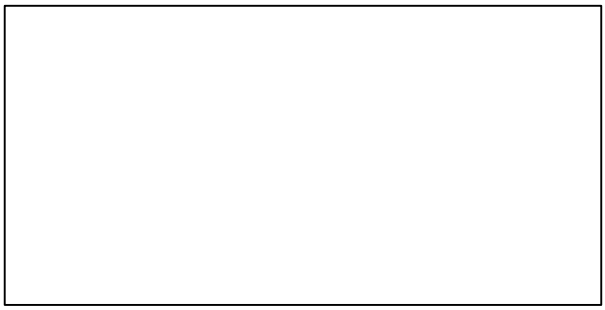
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

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)*

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

2. Reviewed: *(AEREVIEW)*

☐ 1 - Yes ☐ 2 - No

3. Reviewed by: *(ARFREVBY)*

4. Review date: *(ARFREVDT)*

(mm/dd/yyyy)

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

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

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 5.00; 10-14-11

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

1. Adverse event status: *(AVSTAT_E)*

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

2. Has this event been determined to be an unexpected, grade 3-5 adverse event? *(AMDETER)* ☐ 1 - Yes ☐ 2 - No
3. Does this require expedited reporting to the 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)*

Comments: *(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Follow Up GVHD Form (CGV)

Web Version: 1.0; 7.03; 06-22-11

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

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

Answer questions 3-9 relating to acute GVHD.

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

   Specify other agent used: *(PRPHOTSP)*
9. If GVHD prophylaxis was discontinued during this assessment, record the date: *(PRPHDISC)* *(mm/dd/yyyy)*

Answer questions 10-20 relating to chronic GVHD.

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

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

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

16. Minimum platelet count at time of diagnosis: *(PLTLTCNT)* *(xxx.x)* x 10^9/L
17. Alkaline phosphatase at time of diagnosis: *(ALKPHOSP)* *(xxxx)* U/L
18. Weight at time of diagnosis: *(CGVWEIGH)* *(xxx.x)* kg
19. Total bilirubin at time of diagnosis: *(BILIRUBN)* *(xx.x)* mg/dL
20. Body surface area involved with rash at time of diagnosis: *(BSA)* *(xxx)* % ?

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

Skin/Hair

21. Extent of skin involvement: *(CGVRASH)*

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

?

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

a. Lichenoid: *(RASHLICH)* ☐ 1 - Yes ☐ 2 - No
b. Maculopapular: *(RASHMACU)* ☐ 1 - Yes ☐ 2 - No
c. Sclerodermatous: *(RASHSCLR)* ☐ 1 - Yes ☐ 2 - No

Ocular

22. Xerophthalmia: *(DRYEYES)*

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

Oral

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

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

Pulmonary

24. Dyspnea: *(CGVDYSPN)*

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

25. Pulmonary fibrosis: *(PULMFIBR)*

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

26. Bronchiolitis obliterans: *(BRNCOBLT)*

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

27. FEV1: *(CGVFEV1)*

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

28. Oxygen saturation: *(O2SAT)*

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

Gastrointestinal

29. Esophagus: *(ESOPHAGS)*

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

30. Nausea and vomiting: *(NAUSVOMT)*

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

31. Diarrhea: *(CGVDIARH)*

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

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

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

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

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

Use mL/day for adult recipients and mL/m^2 for pediatric recipients.

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

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

35. Malabsorption: *(MALABSRP)*

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

Hepatic

36. Bilirubin level: *(LIVERBIL)*

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

Genitourinary

37. Vaginitis: *(VAGNITIS)*

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

Musculoskeletal

38. Contractures: *(CONTRCTR)*

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

39. Myositis: *(MYOSITIS)*

☐ 1 - Yes ☐ 2 - No

Hematologic

40. Eosinophilia: *(EOSINPHL)*

☐ 1 - Yes ☐ 2 - No

Other

41. Serositis: *(SEROSITS)* ☐ 1 - Yes ☐ 2 - No

42. Fascitis: *(FASCITIS)* ☐ 1 - Yes ☐ 2 - No

43. Was there other organ involvement? *(ORGNOTHR)* ☐ 1 - Yes ☐ 2 - No

Specify other organ: *(ORGSPEC)* _____

Answer questions 44-50 relating to biopsies performed during this assessment period.

44. Were any biopsies performed during this assessment period for suspected GVHD? *(BIOPSY)* ☐ 1 - Yes ☐ 2 - No

If yes, record the type, date, and result of any biopsies performed for suspected GVHD below.

Type of Biopsy:	If Other, Specify:	Date of Biopsy:	Result of Biopsy:
45. *(BIOTYP1)* 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	*(TYP1OSPE)*	*(BIODT1)* *(mm/dd/yyyy)*	*(BIORSLT1)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
46. *(BIOTYP2)* 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	*(TYP2OSPE)*	*(BIODT2)* *(mm/dd/yyyy)*	*(BIORSLT2)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
47. *(BIOTYP3)* 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	*(TYP3OSPE)*	*(BIODT3)* *(mm/dd/yyyy)*	*(BIORSLT3)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
48. *(BIOTYP4)* 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	*(TYP4OSPE)*	*(BIODT4)* *(mm/dd/yyyy)*	*(BIORSLT4)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
49. *(BIOTYP5)* 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	*(TYP5OSPE)*	*(BIODT5)* *(mm/dd/yyyy)*	*(BIORSLT5)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal
50. *(BIOTYP6)* 1-1 - Skin Biopsy 2-2 - Oral Biopsy 3-3 - Upper GI Biopsy 4-4 - Lower GI Biopsy 5-5 - Liver Biopsy *Additional Options Listed Below	*(TYP6OSPE)*	*(BIODT6)* *(mm/dd/yyyy)*	*(BIORSLT6)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal

Answer questions 51-54 relating to GVHD therapy.

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

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

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

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

b. Azathioprine: *(THRPYAZA)*

c. Cyclosporine: *(THRPYCYC)*

d. Systemic Corticosteroids: *(THRPYSCO)*

e. Topical Corticosteroids: *(THRPYTCO)*

f. Thalidomide: *(THRPYTHA)*

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

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

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

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

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

l. Etretinate: *(THRPYETR)*

m. Lamprene: *(THRPYLAM)*

n. Etanercept: *(THRPYETA)*

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

p. Chloroquine Phosphate: *(THRPYCPH)*

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

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

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

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

r. In Vivo Immunotoxin: *(THRPYIMM)*

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

Specify in vivo immunotoxin used: *(IMMAGNT)*

s. Other: *(THRPYOTH)*

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

Specify other agent used: *(OTHAGNT)*

52. Has treatment been discontinued? *(ONGTRT)* ☐ 1 - Yes ☐ 2 - No

53. If yes, enter date of discontinuation: *(TRTSTOP)* *(mm/dd/yyyy)*

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

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

?

Answer questions 55-58 relating to current patient status.

55. Are symptoms of GVHD still present? *(GVHDSYMP)* ☐ 1 - Yes ☐ 2 - No

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

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

57. Current platelet count: *(CURPLTCT)* *(xxx.x)* x 10^9/L

58. Current weight: *(CURWGHT)* *(xxx.x)* kg

Comments: *(CGVCOMM)*

Additional Selection Options for CGV

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

Biopsy Type 1
6-6 - Lung Biopsy
7-7 - Other, Specify

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

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

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

1. Name Code: *(NAMECODE)*
2. IUBMID # (if available): *(IUBMID)*
3. CRID # (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)*

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

7. Race: *(RACE)*

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

Specify race: *(RACESP)*

8. Secondary Race: *(RACE2)*

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

Specify secondary race: *(RACE2SP)*

Comments: *(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

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

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

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

If yes, submit autopsy report to DCC

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

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

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

?

Specify other: *(DTHSPEC1)*

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

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

Specify other: *(DTHSPEC2)*

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

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

Specify other: *(DTHSPEC3)*

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

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

Specify other: *(DTHSPEC4)*

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

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

Specify other: *(DTHSPEC5)*

Comments: *(DTCMMNTS)*

Additional Selection Options for DTH

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

Blood and Marrow Transplant Clinical Trials Network

Donor Toxicity Form (DTX)

Web Version: 1.0; 3.00; 04-26-11

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

For questions 1-28, record the highest grade of toxicity present after initation of mobilization, but prior to apheresis.
Record the grade of toxicity present at the time of contact with the donor, approximately 4 weeks after completion of apheresis.

Flu-Like Symptoms

1. Fever in absence of infections: *(DFLULIKE)*

1-1 - None (Grade 0)
2-2 - 38.0 - 39.0 degrees C (Grade 1)
3-3 - > 39.0 - 40.0 degrees C (Grade 2)
4-4 - > 40.0 degrees C for less than 24 hours (Grade 3)
5-5 - > 40.0 degrees C for more than 24 hours (Grade 4)

Constitutional Symptoms

2. Fatigue (lethargy, malaise, asthenia): *(DCONSTIT)*

1-1 - None (Grade 0)
2-2 - Mild fatigue over baseline (Grade 1)
3-3 - Moderate or causing difficulty performing some ADL (Grade 2)
4-4 - Severe fatigue interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

Ocular/Visual

3. Inflammation in the eyes: *(DOCVISIO)*

1-1 - None (Grade 0)
2-2 - Asymptomatic or minimally symptomatic but not interfering with function (Grade 1)
3-3 - Symptomatic, interfering with function but not w/ ADL; topical intervention indicated (Grade 2)
4-4 - Symptomatic, interfering with ADL; operative intervention indicated (Grade 3)

Dermatologic

4. Skin (rash): *(DSKIN)*

1-1 - None (Grade 0)
2-2 - Macular or papular eruption or erythema that is asymptomatic (Grade 1)
3-3 - Macular or papular eruption or erythema with pruritus or other associated symptoms (Grade 2)
4-4 - Severe, generalized erythroderma or macular, papular or vesicular eruption (Grade 3)
5-5 - Generalized exfoliative dermatitis or ulcerating dermatitis (Grade 4)

5. Local (site reaction): *(DLOCALDE)*

1-1 - None (Grade 0)
2-2 - Pain; itching; erythema (Grade 1)
3-3 - Pain and swelling with inflammation or phlebitis (Grade 2)
4-4 - Ulceration or necrosis that is severe; operative intervention indicated (Grade 3)

6. Ulceration: *(DULCERAT)*

1-1 - None (Grade 0)
2-2 - Superficial ulceration < 2 cm size; local wound care; medical intervention indicated (Grade 2)
3-3 - Ulceration at least 2 cm size; operative debridement, invasive intervention indicated (Grade 3)
4-4 - Life-threatening consequences; major invasive intervention indicated (Grade 4)

Cardiac

7. Hypotension (low blood pressure): *(DHYPOTEN)*

1-1 - Normal (Grade 0)
2-2 - Present, intervention not indicated (Grade 1)
3-3 - Brief (< 24 hours) fluid replacement or other therapy; no physiologic consequences (Grade 2)
4-4 - Sustained (at least 24 hours) therapy, resolved without physiologic consequences (Grade 3)
5-5 - Shock (Grade 4)

Pulmonary

8. Pneumothorax: *(DPULMONA)*

1-1 - Not present (Grade 0)
2-2 - Asymptomatic, radiographic findings only (Grade 1)
3-3 - Symptomatic; intervention indicated (Grade 2)
4-4 - Sclerosis and/or operative intervention indicated (Grade 3)
5-5 - Life-threatening, causing hemodynamic instability; ventilatory support indicated (Grade 4)

Gastrointestinal

9. Nausea: *(DNAUSEA)*

1-1 - None (Grade 0)
2-2 - Loss of appetite without alteration in eating habits (Grade 1)
3-3 - Oral intake decreased without significant weight loss, dehydration or malnutrition (Grade 2)
4-4 - Inadequate oral caloric or fluid intake (Grade 3)
5-5 - Life-threatening consequences (Grade 4)

10. Vomiting: *(DVOMITIN)*

1-1 - None (Grade 0)
2-2 - 1 episode in 24 hours (Grade 1)
3-3 - 2-5 episodes in 24 hours (Grade 2)
4-4 - At least 6 episodes in 24 hours (Grade 3)
5-5 - Life-threatening consequences (Grade 4)

11. Anorexia (loss of appetite): *(DANOREXI)*

1-1 - None (Grade 0)
2-2 - Loss of appetite without alteration in eating habits (Grade 1)
3-3 - Altered intake without significant weight loss or malnutrition (Grade 2)
4-4 - Significant weight loss or malnutrition (Grade 3)
5-5 - Life-threatening (Grade 4)

Vascular

12. Venous thrombosis/embolism: *(DEMBOLIS)*

1-1 - None (Grade 0)
2-2 - Deep vein thrombosis, or cardiac thrombosis; intervention not indicated (Grade 2)
3-3 - Deep vein thrombosis, or cardiac thrombosis; intervention indicated (Grade 3)
4-4 - Embolic event including pulmonary embolism or life-threatening thrombus (Grade 4)

Neurological

13. Insomnia (inability to sleep): *(DINSOMNI)*

1-1 - Normal (Grade 0)
2-2 - Occasional difficulty sleeping, not interfering with function (Grade 1)
3-3 - Difficulty sleeping, interfering with function but not interfering with ADL (Grade 2)
4-4 - Frequent difficulty sleeping, interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

14. Dizziness, vertigo, lightheadedness: *(DVERTIGO)*

1-1 - None (Grade 0)
2-2 - With head movements only; not interfering with function (Grade 1)
3-3 - Interfering with function, but not interfering with ADL (Grade 2)
4-4 - Interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

15. Syncope (fainting): *(DSYNCOPE)*

1-1 - None (Grade 0)
2-2 - Present (Grade 3)
3-3 - Life-threatening consequences (Grade 4)

Hematological

16. Low platelet count: *(DLOWPLAT)*

1-1 - Within normal limits (Grade 0)
2-2 - < LLN - 75.0 x 10^9/L (Grade 1)
3-3 - < 75.0 - 50.0 x 10^9/L (Grade 2)
4-4 - < 50.0 - 25.0 x 10^9/L (Grade 3)
5-5 - < 25.0 x 10^9/L (Grade 4)

Infection Sites

For each of the sites listed below, indicate the severity of infection present.

17. Peripheral IV site: *(DINFPERI)*

1-1 - None (Grade 0)
2-2 - Localized, local intervention indicated (Grade 2)
3-3 - IV antibiotic, antifungal, or antiviral intervention indicated (Grade 3)
4-4 - Life-threatening consequences (Grade 4)

18. Central catheter site: *(DINFCCS)*

1-1 - None (Grade 0)
2-2 - Localized, local intervention indicated (Grade 2)
3-3 - IV antibiotic, antifungal, or antiviral intervention indicated (Grade 3)
4-4 - Life-threatening consequences (Grade 4)

19. Other site: *(DINFOTHE)*

1-1 - None (Grade 0)
2-2 - Localized, local intervention indicated (Grade 2)
3-3 - IV antibiotic, antifungal, or antiviral intervention indicated (Grade 3)
4-4 - Life-threatening consequences (Grade 4)

Specify site: *(DINFSPEC)*

Pain Sites

For each of the sites listed below, indicate the severity of pain present.

20. Back: *(DPAIBACK)*

1-1 - None (Grade 0)
2-2 - Mild pain not interfering with function (Grade 1)
3-3 - Moderate pain interfering with function but not ADL (Grade 2)
4-4 - Severe pain severely interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

21. Bone: *(DPAIBONE)*

1-1 - None (Grade 0)
2-2 - Mild pain not interfering with function (Grade 1)
3-3 - Moderate pain interfering with function but not ADL (Grade 2)
4-4 - Severe pain severely interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

22. Limb (leg or arm): *(DPAILIMB)*

1-1 - None (Grade 0)
2-2 - Mild pain not interfering with function (Grade 1)
3-3 - Moderate pain interfering with function but not ADL (Grade 2)
4-4 - Severe pain severely interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

23. Joint: *(DPAIJOIN)*

1-1 - None (Grade 0)
2-2 - Mild pain not interfering with function (Grade 1)
3-3 - Moderate pain interfering with function but not ADL (Grade 2)
4-4 - Severe pain severely interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

24. Muscle: *(DPAIMUSC)*

1-1 - None (Grade 0)
2-2 - Mild pain not interfering with function (Grade 1)
3-3 - Moderate pain interfering with function but not ADL (Grade 2)
4-4 - Severe pain severely interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

25. Headache: *(DPAIHEAD)*

1-1 - None (Grade 0)
2-2 - Mild pain not interfering with function (Grade 1)
3-3 - Moderate pain interfering with function but not ADL (Grade 2)
4-4 - Severe pain severely interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

26. Neck: *(DPAINECK)*

1-1 - None (Grade 0)
2-2 - Mild pain not interfering with function (Grade 1)
3-3 - Moderate pain interfering with function but not ADL (Grade 2)
4-4 - Severe pain severely interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

27. IV site: *(DPAINIVS)*

1-1 - None (Grade 0)
2-2 - Mild pain not interfering with function (Grade 1)
3-3 - Moderate pain interfering with function but not ADL (Grade 2)
4-4 - Severe pain severely interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

28. Other site: *(DPAINOTH)*

1-1 - None (Grade 0)
2-2 - Mild pain not interfering with function (Grade 1)
3-3 - Moderate pain interfering with function but not ADL (Grade 2)
4-4 - Severe pain severely interfering with ADL (Grade 3)
5-5 - Disabling (Grade 4)

Specify site: *(DPAINSPE)*

Donor Pre-Apheresis Vital Signs

29. Pulse: *(DPULSE)* *(xxx)* beats per minute

30. Blood pressure: *(DBPSYSTO)* *(xxx)* mmHg (systolic)

(DBPDIAST) *(xxx)* mmHg (diastolic)

31. Temperature: *(DTEMPERA)* *(xx.x)* degrees C

Donor Pre-Apheresis Hematology

32. Date of sample collection: *(DDATESAM)* *(mm/dd/yyyy)*

33. WBC: *(DWBC)* *(xx.x)* x 10^9/L

34. Platelets: *(DPLATELE)* *(xxx)* x 10^9/L

35. Hematocrit: *(DHEMATOC)* *(xx.x)* %

36. Hemoglobin: *(DHEMOGLO)* *(xx.x)* g/dL

Apheresis Procedure

First Apheresis

37. Time procedure started: *(DTIMESTA)* _____ *(hh:mm)* (24-hour clock)
38. Time procedure ended: *(DTIMEEND)* _____ *(hh:mm)* (24-hour clock)
39. Does your center's blood cell separator calculate the time to complete the procedure? *(DBCSCALC)* ☐ 1 - Yes ☐ 2 - No
    Procedure time from the blood cell separator: *(DPROCTIM)* _____ *(hh:mm)*
40. Volume of whole blood processed: *(DVOLWBP)* _____ *(xx.x)* liters
41. Did the donor receive calcium replacement to treat or prevent symptoms of hypocalcemia? *(DCALREPL)* ☐ 1 - Yes ☐ 2 - No

    Specify therapy:

    a. Oral calcium for prevention: *(DOCAPREV)* ☐ 1 - Yes ☐ 2 - No
    b. IV calcium for prevention: *(DIVCAPRE)* ☐ 1 - Yes ☐ 2 - No
    c. Oral calcium for treatment: *(DOCATREA)* ☐ 1 - Yes ☐ 2 - No
    d. IV calcium for treatment: *(DIVCATRE)* ☐ 1 - Yes ☐ 2 - No

42. Did the donor experience symptoms of hypocalcemia? *(DHYPOCA)* ☐ 1 - Yes ☐ 2 - No
    Specify symptoms: *(DHCASYPT)*

    1-1 - Transient numbness or tingling
    2-2 - Persistent, moderate numbness or tingling
    3-3 - Severe numbness or tingling
    4-4 - Tetany

Second Apheresis

43. Was a second apheresis procedure performed? *(DSECONDA)* ☐ 1 - Yes ☐ 2 - No
44. Time procedure started: *(D2TIMSTA)* _____ *(hh:mm)* (24-hour clock)
45. Time procedure ended: *(D2TIMEEN)* _____ *(hh:mm)* (24-hour clock)
46. Does your center's blood cell separator calculate the time to complete the procedure? *(D2BCSCAL)* ☐ 1 - Yes ☐ 2 - No
    Procedure time from the blood cell separator: *(D2PROCTI)* _____ *(hh:mm)*
47. Volume of whole blood processed: *(D2VOLWBP)* _____ *(xx.x)* liters
48. Did the donor receive calcium replacement to treat or prevent symptoms of hypocalcemia? *(D2CALREP)* ☐ 1 - Yes ☐ 2 - No

    Specify therapy:

    a. Oral calcium for prevention: *(D2COAPRE)* ☐ 1 - Yes ☐ 2 - No
    b. IV calcium for prevention: *(D2IVCAPR)* ☐ 1 - Yes ☐ 2 - No
    c. Oral calcium for treatment: *(D2OCATRE)* ☐ 1 - Yes ☐ 2 - No
    d. IV calcium for treatment: *(D2IVCATR)* ☐ 1 - Yes ☐ 2 - No

49. Did the donor experience symptoms of hypocalcemia? *(D2HYPOCA)* ☐ 1 - Yes ☐ 2 - No
    a. Specify symptoms: *(D2HCASYP)*

    1-1 - Transient numbness or tingling
    2-2 - Persistent, moderate numbness or tingling
    3-3 - Severe numbness or tingling
    4-4 - Tetany

Third Apheresis

50. Was a third apheresis procedure performed? *(DTHIRDAP)* ☐ 1 - Yes ☐ 2 - No
51. Time procedure started: *(D3TIMSTA)* _____ *(hh:mm)* (24-hour clock)
52. Time procedure ended: *(D3TIMEEN)* _____ *(hh:mm)* (24-hour clock)
53. Does your center's cell separator calculate the time to complete the procedure? *(D3BCSCAL)* ☐ 1 - Yes ☐ 2 - No
    Procedure time from the blood cell separator: *(D3PROCTI)* _____ *(hh:mm)*
54. Volume of whole blood processed: *(D3VOLWBP)* _____ *(xx.x)* liters
55. Did the donor receive calcium replacement to treat or prevent symptoms of hypocalcemia? *(D3CALPRP)* ☐ 1 - Yes ☐ 2 - No

    Specify therapy:

    a. Oral calcium for prevention: *(D3OCAPRE)* ☐ 1 - Yes ☐ 2 - No
    b. IV calcium for prevention: *(D3IVCAPR)* ☐ 1 - Yes ☐ 2 - No
    c. Oral calcium for treatment: *(D3OCATRE)* ☐ 1 - Yes ☐ 2 - No
    d. IV calcium for treatment: *(D3IVCATR)* ☐ 1 - Yes ☐ 2 - No

56. Did the donor experience symptoms of hypocalcemia? *(D3HYPOCA)* ☐ 1 - Yes ☐ 2 - No

a. Specify symptoms: *(D3DCASYP)*

1-1 - Transient numbness or tingling
2-2 - Persistent, moderate numbness or tingling
3-3 - Severe numbness or tingling
4-4 - Tetany

Donor Post-Apheresis Hematology

57. Date of sample collection: *(DPAHEMDT)* *(mm/dd/yyyy)*
58. WBC: *(DPAWBC)* *(xx.x)* x 10^9/L
59. Platelets: *(DPAPLATE)* *(xxx)* x 10^9/L
60. Hematocrit: *(DPAHEMAT)* *(xx.x)* %
61. Hemoglobin: *(DPAHEMOG)* *(xx.x)* g/dL

Comments: *(DTXCOMM1)*

Blood and Marrow Transplant Clinical Trials Network

0202A (ENR)

Web Version: 1.0; 3.00; 08-20-09

Follicular Lymphoma Enrollment Form - Segment A

1. Record date patient informed consent form was signed: *(CNSNTDT)* _____ *(mm/dd/yyyy)*

Note: All assessments must be made at the time of enrollment.

Treatment Arm

2. Record the biologically assigned treatment arm: *(RXARM)* ☐ 1 - Allogeneic HSCT ☐ 2 - Autologous HSCT + Rituximab
3. Record the number of living siblings that the patients has: *(NUMBSIBS)* _____ *(xx)*
4. Record the number of living siblings that were HLA typed: *(SIBTYPE)* _____ *(xx)*
5. Record the number of living HLA-identical siblings the patients has: *(ANYHLASB)* _____ *(xx)*

Patient Inclusion Criteria

6. Does the patient have histologically confirmed recurrent REAL classification follicle center lymphoma? *(FOLLYMPH)* ☐ 1 - Yes ☐ 2 - No
7. Record the patient's follicular grade: *(FLGRADE)* ☐ 1 - Grade I ☐ 2 - Grade II
8. Patient's birthdate: *(PTBRTHDT)* 03/26/1972 *(mm/dd/yyyy)*
9. How many prior regimens of chemotherapy (excluding monoclonal antibody therapy and involved field radiation therapy) has the patient received? *(PREVCHEM)*
   - 1-1 - One Prior Regimen
   - 2-2 - Two Prior Regimens
   - 3-3 - Three Prior Regimens
10. Indicate the patient's current follicular lymphoma status: *(FLSTATSA)*
    - 01-01 - First
    - 02-02 - Second
    - 03-03 - Third
    - 04-04 - Fourth
    - 05-05 - Fifth
    - *Additional Options Listed Below

    (FLSTATSB)
    - 1-1 - Relapse
    - 2-2 - PR
    - 3-3 - CR
11. What is the percentage of bone marrow involvement with lymphoma? *(BMPERCNT)* _____ *(xx.x)* %
12. Are all lymph nodes <3 cm in axial diameter? *(LYNODDIA)* ☐ 1 - Yes ☐ 2 - No
13. Has the estimated lymph node volume (measured as a product of bi-dimensional measurements) been reduced by >75%? *(LYNODVOL)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value	ULN For Your Institution	Date of Assessment
14. Left Ventricular Ejection Fraction at rest:	*(EJCTFRCT)* _____ *(xxx)*	N/A	*(EJCFRDT)* _____ *(mm/dd/yyyy)*
15. Bilirubin:	*(TOTBILI)* _____ *(xx.x)* mg/dL	*(BILIULN)* _____ *(xx.x)* mg/dL	*(BILITDT)* _____ *(mm/dd/yyyy)*
16. ALT:	*(ALT)* _____ *(xxx)* Units/L	*(ALT1ULN)* _____ *(xxx)* Units/L	*(ALT1STDT)* _____ *(mm/dd/yyyy)*
17. AST:	*(AST)* _____ *(xxx)* Units/L	*(AST1ULN)* _____ *(xxx)* Units/L	*(ASTTSTDT)* _____ *(mm/dd/yyyy)*
18. Creatinine Clearance:	*(CRCL)* _____ *(xxx)*	N/A	*(CRCLTSDT)* _____ *(mm/dd/yyyy)*
19. DLCO:	*(DLCO)* _____ *(xxx)*	N/A	*(DLCOTSDT)* _____ *(mm/dd/yyyy)*
20. FEV1:	*(FEV1)* _____ *(xxx)*	N/A	*(FEV1TDT)* _____ *(mm/dd/yyyy)*
21. FVC:	*(FVC)* _____ *(xxx)*	N/A	*(FVCTSDT)* _____ *(mm/dd/yyyy)*

22. Record start date of most recent cycle of salvage chemotherapy: *(LCHEMODT)* _____ *(mm/dd/yyyy)*

23. Record the proposed date of initiation of cyclophosphamide and rituximab mobilization chemotherapy: *(MBLCHMDT)* _____ *(mm/dd/yyyy)*

Patient Exclusion Criteria

24. Record the patient's Karnofsky performance score: *(PS)*

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

25. Does the patient's disease show histologic evidence of transformation? *(HSTTRANS)* ☐ 1 - Yes ☐ 2 - No

26. Does the patient have uncontrolled hypertension? *(HYPRTNSN)* ☐ 1 - Yes ☐ 2 - No

27. Does the patient have an uncontrolled viral, bacterial or fungal infection? *(INFECT)* ☐ 1 - Yes ☐ 2 - No

28. Does the patient have a history of any malignant disease other than follicular lymphoma, basal cell carcinoma or treated cervical carcinoma *in situ*? *(MALIGHX)*

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

29. Date confirmed by study chair: *(MMAPRVDT)* _____ *(mm/dd/yyyy)*

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

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

32. Is the patient willing to use contraceptive techniques during treatment? *(CONTRA)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

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

Consent for Use of Biological Specimens for Research - Patient

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

The remainder of the form should be completed only if the patient has been registered on the Allogeneic arm.

Donor Inclusion Criteria

35. Record date donor informed consent was signed: *(CNSNTBDT)* _____ *(mm/dd/yyyy)*

36. Does the donor have adequate veins for leukapheresis or agree to placement of central venous catheter? *(VEINCATH)* ☐ 1 - Yes ☐ 2 - No

37. Record the donor's birthdate: *(DNRBRTDT)* _____ *(mm/dd/yyyy)*

Donor Exclusion Criteria

38. Are the donor and patient identical twins? *(IDENTICL)* ☐ 1 - Yes ☐ 2 - No

39. Is the donor pregnant (positive β-HCG) or breastfeeding? *(DNRPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

40. Is the donor HIV seropositive? *(DNHIVPOS)* ☐ 1 - Yes ☐ 2 - No

41. Is the donor hepatitis B surface antigen positive? *(HEPBSAGP)* ☐ 1 - Yes ☐ 2 - No

42. Is the donor hepatitis C positive? *(DNRHEPCP)* ☐ 1 - Yes ☐ 2 - No

43. Does the donor have a known allergy to G-CSF? *(DALLGCSF)* ☐ 1 - Yes ☐ 2 - No

44. Does the donor currently have a serious systemic illness? *(DNRSYSIL)* ☐ 1 - Yes ☐ 2 - No

45. Does the donor have an uncontrolled viral, bacterial or fungal infection? *(DNRUNINF)* ☐ 1 - Yes ☐ 2 - No

46. Is the donor currently receiving experimental therapy or an investigational drug? *(DNREXTHR)* ☐ 1 - Yes ☐ 2 - No

47. Does the donor have a history of any malignant disease other than treated basal cell carcinoma or cervical carcinoma in situ? *(DNCCANCR)*

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

48. Date confirmed by study chair: *(DREVWDTB)* _____ *(mm/dd/yyyy)*

Consent for use of Biological Samples for Research - Donor

49. Did the donor agree to provide blood and stem cells for future research? *(DSMPRESB)* ☐ 1 - Yes ☐ 2 - No

HLA Typing

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

DNA_HIGH-High Level DNA
DNA_LOW -Low Level DNA
SEROLOGY-Serologic
AB_SEROLOGY_DRB1_DNA_LOW -Loci A,B: Serologic, Locus DRB1: Low Level DNA
AB_DNA_LOW _DRB1_DNA_HIGH-Loci A,B: Low Level DNA, Locus DRB1: High Level DNA
*Additional Options Listed Below

50. Recipient HLA Typing

HLA-A

Typing method: *(RHLAAMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided: *(RHLAANUM)*

1-1 -One
2-2 -Two

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

HLA-B

Typing method: *(RHLABMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided: *(RHLABNUM)*

1-1 -One
2-2 -Two

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

HLA-DRB1

Typing method: *(RHLADMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided: *(RHLADNUM)*

1-1 -One
2-2 -Two

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

51. Donor HLA Typing

HLA-A

Typing method: *(DHLAAMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided: *(DHLAANUM)*

1-1 -One
2-2 -Two

1st:	*(DHLAA11X)*		*(DHLAA12X)* /		*(DHLAA13X)* /		*(DHLAA14X)* /
	(DHLAA15X)		*(DHLAA16X)* /		*(DHLAA17X)* /		*(DHLAA18X)* /
2nd:	*(DHLAA21X)*		*(DHLAA22X)* /		*(DHLAA23X)* /		*(DHLAA24X)* /
	(DHLAA25X)		*(DHLAA26X)* /		*(DHLAA27X)* /		*(DHLAA28X)* /

HLA-B

Typing method: *(DHLABMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided: *(DHLABNUM)*

1-1 - One
2-2 - Two

1st:	*(DHLAB11X)*		*(DHLAB12X)* /		*(DHLAB13X)* /		*(DHLAB14X)* /	
	(DHLAB15X)		*(DHLAB16X)* /		*(DHLAB17X)* /		*(DHLAB18X)* /	
2nd:	*(DHLAB21X)*		*(DHLAB22X)* /		*(DHLAB23X)* /		*(DHLAB24X)* /	
	(DHLAB25X)		*(DHLAB26X)* /		*(DHLAB27X)* /		*(DHLAB28X)* /	

HLA-DRB1

Typing method: *(DHLADMET)*

1-1 - DNA Technology
2-2 - Serology

Antigens/alleles provided: *(DHLADNUM)*

1-1 - One
2-2 - Two

1st:	*(DHLAD11X)*		*(DHLAD12X)* /		*(DHLAD13X)* /		*(DHLAD14X)* /	
	(DHLAD15X)		*(DHLAD16X)* /		*(DHLAD17X)* /		*(DHLAD18X)* /	
2nd:	*(DHLAD21X)*		*(DHLAD22X)* /		*(DHLAD23X)* /		*(DHLAD24X)* /	
	(DHLAD25X)		*(DHLAD26X)* /		*(DHLAD27X)* /		*(DHLAD28X)* /	

Locus-A calculated HLA Match Score *(SCORE_A)*

Locus-B calculated HLA Match Score *(SCORE_B)*

Locus-DRB1 calculated HLA Match Score *(SCORE_D)*

Total calculated HLA Match Score *(HLASCORE)*

Do you agree with the calculated HLA Match Score? *(HLAAGREE)* ☐ 1 - Yes ☐ 2 - No

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

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

Comments *(COMMENTS)*

Additional Selection Options for ENR

Indicate the patient's current follicular lymphoma status:
06-06 - Sixth
07-07 - Seventh
08-08 - Eighth
09-09 - Ninth
10-10 - Tenth

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

Type of HLA Match required by this protocol:
AB_SEROLOGY_DRB1_DNA_HIGH-Loci A, B: Serologic, Locus DRB1: High Level DNA
ABC_DNA_LOW_DRB1_DNA_HIGH-Loci A, B, C: Low Level DNA, Locus DRB1: High Level DNA
ABCDQ_DNA_LOW_DRB1_DNA_HIGH-Loci A, B, C, DQ: Low Level DNA, Locus DRB1: High Level DNA

Indicate your institution's HLA Match Score for this participant:
5/6-5/6
6/6-6/6
0/8-0/8
1/8-1/8
2/8-2/8
3/8-3/8
4/8-4/8
5/8-5/8
6/8-6/8
7/8-7/8
8/8-8/8

Blood and Marrow Transplant Clinical Trials Network

FACT-BMT (Version 4) (FCT)

Web Version: 1.0; 3.04; 11-02-11

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

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer each question by selecting the best choice. If you are unsure about how to answer a questions, please give the best answer you can.

Date of Evaluation: *(FACTDATE)* _____ *(mm/dd/yyyy)*

Physical Well-Being

1. I have a lack of energy *(LCKENRG)*
2. I have nausea *(NAUSEA)*
3. Because of my physical condition, I have trouble meeting the needs of my family *(FMLYNEED)*
4. I have pain *(PAIN)*
5. I am bothered by the side effects of treatment *(SIDEFFCT)*
6. I feel ill *(FEELILL)*
7. I am forced to spend time in bed *(TIMINBED)*

For each of the above:

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

Social/Family Well-Being

8. I feel close to my friends *(CLSFRNDS)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

9. I get emotional support from my family *(FAMSPPRT)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

10. I get support from my friends *(FRNDSPRT)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

11. My family has accepted my illness *(ACPTILNS)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

12. I am satisfied with family communication about my illness *(SFAMCOMN)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

13. I feel close to my partner (or the person who is my main support) *(PRTNRSPT)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

Did the patient answer the following question? (CHECKBOX)

☐ 1 - Yes ☐ 2 - No

14. I am satisfied with my sex life *(SEXLIFE)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

Emotional Well-Being

15. I feel sad *(FEELSAD)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

16. I am satisfied with how I am coping with my illness *(COPING)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

17. I am losing hope in the fight against my illness *(LOSEHOPE)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

18. I feel nervous *(NERVOUS)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

19. I worry about dying *(WORRYDIE)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

20. I worry that my condition will get worse *(WORSEN)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

Functional Well-Being

21. I am able to work (include work at home) *(WORK)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

22. My work (include work at home) is fulfilling *(FULFILL)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

23. I am able to enjoy life *(ENJYLIFE)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

24. I have accepted my illness *(ACCEPTED)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

25. I am sleeping well *(SLEEPWEL)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

26. I am enjoying the things I usually do for fun *(FUN)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

27. I am content with the quality of my life right now *(QOL)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

Additional Concerns

28. I am concerned about keeping my job (include work at home) *(JOB)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

29. I feel distant from other people *(DISTANT)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

30. I worry that the transplant will not work *(TRNSPWRY)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

31. The effects of treatment are worse than I had imagined *(TXEFFX)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

32. I have a good appetite *(APPETITE)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

33. I like the appearance of my body *(BDYAPRNC)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

34. I am able to get around myself *(GETARND)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

35. I get tired easily *(GETTIRED)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

36. I am interested in sex *(SEXINTRS)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

37. I have concerns about my ability to have children *(FERTILTY)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

38. I have confidence in my nurse(s) *(NURSE)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

39. I regret having the bone marrow transplant *(BMTREGRT)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

40. I can remember things *(MEMORY)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

41. I am able to concentrate (e.g., reading) *(CNCTRATE)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

42. I have frequent colds/infections *(COLDS)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

43. My eyesight is blurry *(EYESIGHT)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

44. I am bothered by a change in the way food tastes *(GUSTATOR)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

45. I have tremors *(TREMORS)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

46. I have been short of breath *(SHRTBRTH)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

47. I am bothered by skin problems (e.g., rash, itching) *(SKINPROB)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

48. I have problems with my bowels *(BOWELS)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

49. My illness is a personal hardship for my close family members *(HARDSHIP)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

50. The cost of my treatment is a burden on me or my family *(COSTOFTX)*

0-0 - Not at all
1-1 - A little bit
2-2 - Somewhat
3-3 - Quite a bit
4-4 - Very much
*Additional Options Listed Below

English (Universal)

16 November 2007

Additional Selection Options for FCT

I have a lack of energy
9-9 - Subject did not complete

Blood and Marrow Transplant Clinical Trials Network

Medication Form - 0202 (FMD)

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

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

For Autologous HSCT patients only, record the date and dose of Rituximab maintenance therapy received.

	Date Rituximab Maintenance Therapy Received	Dose Rituximab Maintenance Therapy Received
1. 1st weekly dose:	*(RTX1DSDT)* *(mm/dd/yyyy)*	*(DOSE1RTX)* *(xxx)* mg/m^2 IV
2. 2nd weekly dose:	*(RTX2DSDT)* *(mm/dd/yyyy)*	*(DOSE2RTX)* *(xxx)* mg/m^2 IV
3. 3rd weekly dose:	*(RTX3DSDT)* *(mm/dd/yyyy)*	*(DOSE3RTX)* *(xxx)* mg/m^2 IV
4. 4th weekly dose:	*(RTX4DSDT)* *(mm/dd/yyyy)*	*(DOSE4RTX)* *(xxx)* mg/m^2 IV

Comments: *(FMDCOMM1)*

Blood and Marrow Transplant Clinical Trials Network

Follow Up Status Form (FUS)

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

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

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

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

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

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

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

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

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

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

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

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

Specify other treatment: *(FUS1SPEC)* _____

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

10. Has the patient experienced secondary graft failure? *(SECGRFAL)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Secondary Graft Failure Form must be submitted.

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

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

13.

14. Indicate the patient's current follicular lymphoma disease status: *(CURFLSTA)*

1-1 - Complete Remission
2-2 - Partial Remission
3-3 - Stable Disease
4-4 - Relapsed Disease
5-5 - Progressive Disease

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

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

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

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

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

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

Comments: *(FUS1COMM)*

Additional Selection Options for FUS

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

Blood and Marrow Transplant Clinical Trials Network

Acute GVHD Form (GVH)

Web Version: 1.0; 10.04; 06-09-11

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

1. Date of staging: *(STAGEDT)* *(mm/dd/yyyy)*
   Start of GVHD Assessment Period: *(GVASSTDT)* *(mm/dd/yyyy)*
   End of GVHD Assessment Period: *(GVASENDT)* *(mm/dd/yyyy)*

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

2. Immunosuppressant (prophylaxis) received: *(IMMUNORC)*

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

3. Record most recent blood level of immunosuppressant (prophylaxis): *(TROUGHLV)* *(xxxx.x)* ng/mL
4. Record date blood sample obtained: *(TROUGHDT)* *(mm/dd/yyyy)* ?

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

5. Skin abnormalities: *(GVHSKINA)*

   0-0 - No Rash
   1-1 - Maculopapular Rash, < 25% of Body Surface
   2-2 - Maculopapular Rash, 25-50% of Body Surface
   3-3 - Generalized Erythroderma
   4-4 - Generalized Erythroderma with Bullus Formation and Desquamation

   ?

6. Skin etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SETGVHD) ☐ 1 - Yes ☐ 2 - No ?	*(SETDRGRX)* ☐ 1 - Yes ☐ 2 - No	*(SETCRTOX)* ☐ 1 - Yes ☐ 2 - No
Infection	**Other**	
(SETINFCT) ☐ 1 - Yes ☐ 2 - No	*(SETOTHER)* ☐ 1 - Yes ☐ 2 - No	

Specify other skin etiologies: *(GVHSKNSP)*

7. Skin biopsy for GVHD: *(GVHSKINB)*

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

8. Upper GI abnormalities: *(GVHUPGIA)*

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

9. Upper intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(UGIETGVH) ☐ 1 - Yes ☐ 2 - No	*(UGIETDRG)* ☐ 1 - Yes ☐ 2 - No	*(UGIETCON)* ☐ 1 - Yes ☐ 2 - No
TPN	**Infection**	**Other**
(UGIETTPN) ☐ 1 - Yes ☐ 2 - No	*(UGIETINF)* ☐ 1 - Yes ☐ 2 - No	*(UGIETOTH)* ☐ 1 - Yes ☐ 2 - No

Specify other upper intestinal tract etiologies: *(UGIETSPC)*

10. Upper intestinal tract biopsy for GVHD: *(UGIBIORS)*

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

11. Lower GI abnormalities: *(GVHINTA)*

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

?

Use mL/day for adult patients and mL/m^2 for pediatric patients

12. Lower intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(LGIETGVH) ☐ 1 - Yes ☐ 2 - No	*(LGIETDRG)* ☐ 1 - Yes ☐ 2 - No	*(LGIETCON)* ☐ 1 - Yes ☐ 2 - No
TPN	**Infection**	**Other**
(LGIETTPN) ☐ 1 - Yes ☐ 2 - No	*(LGIETINF)* ☐ 1 - Yes ☐ 2 - No	*(LGIETOTH)* ☐ 1 - Yes ☐ 2 - No

Specify other lower intestinal tract etiologies: *(LGIETSPC)*

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

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

14. Liver abnormalities: *(GVHLIVRA)*

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

15. Liver etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity	TPN
(LIVETGVH) ☐ 1 - Yes ☐ 2 - No	*(LIVETDRG)* ☐ 1 - Yes ☐ 2 - No	*(LIVETCND)* ☐ 1 - Yes ☐ 2 - No	*(LIVETTPN)* ☐ 1 - Yes ☐ 2 - No
Infection	**VOD**	**Other**	
(LIVETINF) ☐ 1 - Yes ☐ 2 - No	*(LIVETVOD)* ☐ 1 - Yes ☐ 2 - No	*(LIVETOTH)* ☐ 1 - Yes ☐ 2 - No	

Specify other liver etiologies: *(GVHLIVRS)*

16. Liver biopsy for GVHD: *(GVHLIVRB)*

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

') }

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

17. If yes, specify agent name: *(GVHAGENT)*

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

Specify other agent: *(GVHAGNSP)*

18. Indicate treatment modification: *(GVHTRMOD)*

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

Comments: *(GVHCOMM)*

Additional Selection Options for GVH

Lower GI abnormalities:
5-5 - Severe Abdominal Pain with or without Ileus, or Stool with Frank Blood or Melena

If yes, specify agent name:
6-6 - MMF
7-7 - Daclizumab
8-8 - Methylprednisolone
9-9 - Other

Blood and Marrow Transplant Clinical Trials Network

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

2. Organism I: *(ORGN01)*

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

?

If other specify: *(INFSPEC1)*

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

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

4. Severity of infection: *(SVRTY01)*

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

INFECTION II

5. Type of infection: *(INFTYP02)*

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

6. Organism II: *(ORGN02)*

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

If other specify: *(INFSPEC2)*

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

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

8. Severity of infection: *(SVRTY02)*

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

INFECTION III

9. Type of infection: *(INFTYP03)*

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

10. Organism III: *(ORGN03)*

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

If other specify: *(INFSPEC3)*

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

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

12. Severity of infection: *(SVRTY03)*

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

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

Provide agent(s) administered for this infectious period:

14. 1st agent: *(AGENT1)*

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

If other specify: *(AGTSPEC1)*

15. 2nd agent: *(AGENT2)*

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

If other specify: *(AGTSPEC2)*

16. 3rd agent: *(AGENT3)*

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

If other specify: *(AGTSPEC3)*

17. Were additional agents administered for this infectious period? *(ADDAGENT)* ☐ 1 - Yes ☐ 2 - No

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

Comments: *(INFCOM)*

Additional Selection Options for INF

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

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

NST Hematopoiesis Form (NHM)

Web Version: 1.0; 7.00; 05-24-11

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

1. Did the patient's ANC drop below 500/mm^3 after the initiation of the conditioning regimen? *(ANCDROP)* ☐ 1 - Yes ☐ 2 - No
   2. Record date ANC dropped below 500/mm^3: *(ANCDRPDT)* _____ *(mm/dd/yyyy)*
3. Did the patient's ANC recover to ≥500/mm^3? *(MDNRPRCN)* ☐ 1 - Yes ☐ 2 - No
   4. Record first day ANC ≥500/mm^3: *(ANC500DT)* _____ *(mm/dd/yyyy)*
   5. Record ANC: *(ANC500LV)* _____ *(xxxx)* /mm^3

Record Chimerism Assay Data for Marrow and/or Blood

Please upload source documents for all chimerism results during the assessment period.

Marrow:

6. Was a chimerism assay performed on a marrow sample during this assessment period? *(MRWCHMRS)* ☐ 1 - Yes ☐ 2 - No
   7. Record date specimen collected: *(MRWCOLDT)* _____ *(mm/dd/yyyy)*
   8. Record method of evaluation: *(MRWEVALM)*

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

   Specify other method of evaluation: *(NHMSPEC1)* _____
   9. Record marrow chimerism cell type: *(CELLTYPE)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes
   10. Record marrow assay results: *(ASSYRSLT)*

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

   11. Record % donor: *(MDNRPRCT)* _____ *(xx)* %

Blood:

12. Was a chimerism assay performed on a blood sample during this assessment period? *(BLDCHMRS)* ☐ 1 - Yes ☐ 2 - No
   13. Record date specimen collected: *(BLDCHMDT)* _____ *(mm/dd/yyyy)*
   14. Record method of evaluation: *(BLDEVALM)*

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

   Specify other method of evaluation: *(NHMSPEC2)* _____
   15. Record blood chimerism cell type: *(BLDCLTYP)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes
   16. Record blood assay results: *(BLDARSLT)*

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

   17. Record % donor: *(BDNRPRCT)* _____ *(xx)*

T Cell:

18. Was a chimerism assay performed on a T cell sample during this assessment period? *(TCLCHRSM)* ☐ 1 - Yes ☐ 2 - No
   19. Record the type of T cell sample: *(SMPLTYPE)* ☐ 1 - Blood ☐ 2 - Marrow
   20. Record date specimen collected: *(TCLSPCDT)* _____ *(mm/dd/yyyy)*

21. Record method of evaluation: *(TCLEVALM)*

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

Specify other method of evaluation: *(NHMSPEC3)*

22. Record T cell assay results: *(TCLRSLTS)*

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

23. Record % donor: *(TCLDNRPC)*

(xx)

Comments: *(NHMCOMM1)*

Additional Selection Options for NHM

Record method of evaluation:
9-9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Pre-HSCT Checklist (PHC)

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

1. Treatment arm: *(RXBARM)* ☐ 1 - Allogeneic HSCT ☐ 2 - Autologous HSCT + Rituximab

2. Record the patient's weight: *(PTIENTWT)* _____ *(xxx.x)* kg

3. Record the date patient's weight was assessed: *(WEIGHTDT)* _____ *(mm/dd/yyyy)*

4. Record the total number of $CD34^+$ cells or $CD34^+$ cells/kg in the allogeneic or autologous graft: *(FLGRAFT)*

_____ *(xxxx.x)* Unit: *(GRFTUNIT)*

1 - 1 - x 10^6 CD34+ Cells
2 - 2 - x 10^6 CD34+ Cells/Kg

After Cytoxan / Rituximab Therapy

5. Record the date patient's ANC >1000/mm^3: *(FLANCRDT)* _____ *(mm/dd/yyyy)*

ANC: *(FLANCVAL)* _____ *(xxxxx)* /mm^3

6. Record the date patient's platelet count >100x10^9 cells/L: *(FLPLTRDT)* _____ *(mm/dd/yyyy)*

Platelet Count: *(FLPLTVAL)* _____ *(xxx)* x10^9 cells/L

7. Record the date cytoxan / rituximab mobilization chemotherapy began: *(MBLSTTDT)* _____ *(mm/dd/yyyy)*

8. Record the proposed date of initiation of pre-transplant conditioning (e.g. rituximab for allogeneic arm or BCNU or TBI for autologous arm): *(PRTXCOND)* _____ *(mm/dd/yyyy)*

Comments: *(COMMPHC)*

Blood and Marrow Transplant Clinical Trials Network

Pre-Rituximab Checklist (PRC)

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

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

Complete this form for Autologous HSCT patients only.

1. Record the proposed date of initiation of rituximab maintenance therapy: *(PRPRTXDT)* *(mm/dd/yyyy)*

	Most Recent Value	ULN for your Institution	Date Sample Obtained
2. Bilirubin:	*(BILIPRC)* *(xx.x)* mg/dL	*(BILULPRC)* *(xx.x)* mg/dL	*(BILDTPRC)* *(mm/dd/yyyy)*
3. ALT:	*(ALTPRC)* *(xxx)* Units/L	*(ALTULPRC)* *(xxx)* Units/L	*(ALTDTPRC)* *(mm/dd/yyyy)*
4. AST:	*(ASTPRC)* *(xxx)* Units/L	*(ASTULPRC)* *(xxx)* Units/L	*(ASTDTPRC)* *(mm/dd/yyyy)*

5. Record creatinine clearance: *(CRCLPRC)* *(xxx)* ml/min
6. Record date creatinine clearance sample obtained: *(CCLDTPRC)* *(mm/dd/yyyy)*
7. Is the patient currently taking intravenous antibiotics? *(IVANTPRC)* ☐ 1 - Yes ☐ 2 - No
8. Is the patient currently taking any amphotericin B formulations or voriconazole for a proven, probable or possible fungal infection? *(AMPHOPRC)* ☐ 1 - Yes ☐ 2 - No
9. Did the patient develop a CMV infection post-autologous HSCT? *(CMVPOSTA)* ☐ 1 - Yes ☐ 2 - No
10. Was the patient treated with ganciclovir, valganciclovir or foscarnet per institutional guidelines? *(CMVTREAT)* ☐ 1 - Yes ☐ 2 - No
11. Does the patient currently have an active CMV infection? *(ACTIVCMV)* ☐ 1 - Yes ☐ 2 - No
12. Is the patient CMV antigenemia negative? *(CMVNEG)* ☐ 1 - Yes ☐ 2 - No
13. Has mucositis resolved? *(MUCRSPRC)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
14. Is the patient currently receiving hyperalimentation? *(RVHYPPRC)* ☐ 1 - Yes ☐ 2 - No

Comments: *(PRCCOMM)*

(_4FOCUS)

This form is for Autologous HSCT patients only. Please return to the Data Entry Main screen.

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

Specimen Acquisition Form - 0202 (SAF)

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

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

Peripheral Blood Samples for t(14;18) PCR Testing

1. Was a PCR sample for t(14;18) testing drawn during this assessment period? *(PCRSAMPL)* ☐ 1 - Yes ☐ 2 - No
2. Was a PCR sample for t(14;18) testing drawn during this assessment period? *(PCRSAMP2)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Required
3. If yes, record the date the PCR sample was obtained: *(PCRSMPDT)* _____ *(mm/dd/yyyy)*
4. If yes, record the date the PCR sample was obtained: *(PCRSPDT2)* _____ *(mm/dd/yyyy)*
5. What was the PCR sample result? *(PCRRESLT)* ☐ 1 - Positive ☐ 2 - Negative

Patient Future Testing Sample - Nucleated Cells from Peripheral Blood

6. Was a peripheral blood sample drawn from the patient for future testing? *(PBFTSMPP)* ☐ 1 - Yes ☐ 2 - No
7. If yes, record the date the peripheral blood sample was obtained: *(PBFTSPDT)* _____ *(mm/dd/yyyy)*

Donor Future Testing Samples - Allograft and Peripheral Blood Nucleated Cells

8. Was a peripheral blood sample drawn from the donor for future testing? *(PBFTSMPD)* ☐ 1 - Yes ☐ 2 - No
9. If yes, record the date the peripheral blood sample was obtained: *(PBFTSDDT)* _____ *(mm/dd/yyyy)*
10. Was a sample taken from the allogeneic donor HSC product for future testing? *(DNRALLOS)* ☐ 1 - Yes ☐ 2 - No
11. If yes, record the date the sample from the allogeneic donor HSC product was obtained: *(DNRALLDT)* _____ *(mm/dd/yyyy)*

Comments: *(SAFCOMM1)*

Blood and Marrow Transplant Clinical Trials Network

SF36 Quality of Life (SFH)

Web Version: 1.0; 3.04; 11-02-11

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

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer each question by selecting the best choice. If you are unsure about how to answer a question, please give the best answer you can.

Date of Evaluation: *(SF36DATE)* _____ *(mm/dd/yyyy)*

1. In general, would you say your health is: *(GENHLTH)*

1-1 - Excellent
2-2 - Very Good
3-3 - Good
4-4 - Fair
5-5 - Poor
*Additional Options Listed Below

2. Compared to one year ago, how would you rate your health in general now? *(COMPARE)*

1-1 - Much better now than one year ago
2-2 - Somewhat better now than one year ago
3-3 - About the same as one year ago
4-4 - Somewhat worse than one year ago
5-5 - Much worse than one year ago
*Additional Options Listed Below

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Activities	Amount of Limitation
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	*(VIGOROUS)* 1-1 - Yes, limited a lot; 2-2 - Yes, limited a little; 3-3 - No, not limited at all; 9-9 - Subject did not complete
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	*(MODERATE)* 1-1 - Yes, limited a lot; 2-2 - Yes, limited a little; 3-3 - No, not limited at all; 9-9 - Subject did not complete
c. Lifting or carrying groceries	*(LIFTING)* 1-1 - Yes, limited a lot; 2-2 - Yes, limited a little; 3-3 - No, not limited at all; 9-9 - Subject did not complete
d. Climbing several flights of stairs	*(CLINBSEV)* 1-1 - Yes, limited a lot; 2-2 - Yes, limited a little; 3-3 - No, not limited at all; 9-9 - Subject did not complete
e. Climbing one flight of stairs	*(CLIMBONE)* 1-1 - Yes, limited a lot; 2-2 - Yes, limited a little; 3-3 - No, not limited at all; 9-9 - Subject did not complete
f. Bending, kneeling, or stooping	*(BENDING)* 1-1 - Yes, limited a lot; 2-2 - Yes, limited a little; 3-3 - No, not limited at all; 9-9 - Subject did not complete

g. Walking more than one mile

(WALKMILE)

1-1 -Yes, limited a lot
2-2 -Yes, limited a little
3-3 -No, not limited at all
9-9 -Subject did not complete

h. Walking several hundred yards

(WALKSBLK)

1-1 -Yes, limited a lot
2-2 -Yes, limited a little
3-3 -No, not limited at all
9-9 -Subject did not complete

i. Walking one hundred yards

(WALK1BLK)

1-1 -Yes, limited a lot
2-2 -Yes, limited a little
3-3 -No, not limited at all
9-9 -Subject did not complete

j. Bathing or dressing yourself

(BATHING)

1-1 -Yes, limited a lot
2-2 -Yes, limited a little
3-3 -No, not limited at all
9-9 -Subject did not complete

4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Cut down on the amount of time you spent on work or other activities *(CUTDOWN)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

b. Accomplished less than you would like *(ACCOMPL)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

c. Were limited in the kind of work or other activities *(LIMITED)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

d. Had difficulty performing the work or other activities (for example, it took extra effort) *(DIFFPERF)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems? (such as feeling depressed or anxious)

a. Cut down on the amount of time you spend on work or other activities *(EMOCUT)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

b. Accomplished less than you would like *(EMOACC)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

c. Did work or other activities less carefully than usual *(EMOLESS)* ☐ 1 - Yes ☐ 2 - No ☐ 9 - Subject did not complete

6. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

a. Cut down on the amount of time you spent on work or other activities

(CUTTIME)

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

b. Accomplished less than you would like

(LESSACC)

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

c. Were limited in the kind of work or other activities

(WORKLMT)

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

d. Had difficulty performing the work or other activities (for example, it took extra effort)

(PRFMDIFF)

1-1 - All of the time
2-2 - Most of the time
3-3 - Some of the time
4-4 - A little of the time
5-5 - None of the time
*Additional Options Listed Below

7. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

a. Cut down on the amount of time you spent on work or other activities

(ECUTTIME)

1-1 - All of the time
2-2 - Most of the time
3-3 - Some of the time
4-4 - A little of the time
5-5 - None of the time
*Additional Options Listed Below

b. Accomplished less than you would like

(ELESSACC)

1-1 - All of the time
2-2 - Most of the time
3-3 - Some of the time
4-4 - A little of the time
5-5 - None of the time
*Additional Options Listed Below

c. Did work or other activities less carefully than usual

(ECARELES)

1-1 - All of the time
2-2 - Most of the time
3-3 - Some of the time
4-4 - A little of the time
5-5 - None of the time
*Additional Options Listed Below

8. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(INTERFER)*

1-1 - Not at all
2-2 - Slightly
3-3 - Moderately
4-4 - Quite a bit
5-5 - Extremely
*Additional Options Listed Below

9. How much bodily pain have you had during the **past 4 weeks**? *(BODYPAIN)*

1-1 - None
2-2 - Very mild
3-3 - Mild
4-4 - Moderate
5-5 - Severe
*Additional Options Listed Below

10. During the **past 4 weeks**, how much did pain interfere with your normal work? (including both work outside the home and housework) *(WORKPAIN)*

1-1 - Not at all
2-2 - A little bit
3-3 - Moderately
4-4 - Quite a bit
5-5 - Extremely
*Additional Options Listed Below

11. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks**:

a. Did you feel full of pep?

(FULLPEP)

1-1 - All of the time
2-2 - Most of the time
3-3 - A good bit of the time
4-4 - Some of the time
5-5 - A little of the time
*Additional Options Listed Below

b. Have you been a very nervous person?

1-1 -All of the time
2-2 -Most of the time
3-3 -A good bit of the time
4-4 -Some of the time
5-5 -A little of the time
*Additional Options Listed Below

(NERVOUS)

c. Have you felt so down in the dumps that nothing could cheer you up?

1-1 -All of the time
2-2 -Most of the time
3-3 -A good bit of the time
4-4 -Some of the time
5-5 -A little of the time
*Additional Options Listed Below

(DUMPS)

d. Have you felt calm and peaceful?

1-1 -All of the time
2-2 -Most of the time
3-3 -A good bit of the time
4-4 -Some of the time
5-5 -A little of the time
*Additional Options Listed Below

(CALM)

e. Did you have a lot of energy?

1-1 -All of the time
2-2 -Most of the time
3-3 -A good bit of the time
4-4 -Some of the time
5-5 -A little of the time
*Additional Options Listed Below

(LOTSNRG)

f. Have you felt downhearted and blue?

1-1 -All of the time
2-2 -Most of the time
3-3 -A good bit of the time
4-4 -Some of the time
5-5 -A little of the time
*Additional Options Listed Below

(BLUE)

g. Did you feel worn out?

1-1 -All of the time
2-2 -Most of the time
3-3 -A good bit of the time
4-4 -Some of the time
5-5 -A little of the time
*Additional Options Listed Below

(WORNOUT)

h. Have you been a happy person?

1-1 -All of the time
2-2 -Most of the time
3-3 -A good bit of the time
4-4 -Some of the time
5-5 -A little of the time
*Additional Options Listed Below

(HAPPY)

i. Did you feel tired?

1-1 -All of the time
2-2 -Most of the time
3-3 -A good bit of the time
4-4 -Some of the time
5-5 -A little of the time
*Additional Options Listed Below

(TIRED)

j. Did you feel full of life?

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

(FULLLIFE)

k. Have you been very nervous?

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

(FEELNERV)

l. Have you felt so down in the dumps that nothing could cheer you up?

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

(FEELDOWN)

m. Have you felt calm and peaceful?

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

(FEELCALM)

n. Did you have a lot of energy?

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

(FLENERGY)

o. Have you felt downhearted and depressed?

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

(FEELDEPR)

p. Did you feel worn out?

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

(FEELWORN)

q. Have you been happy?

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

(FEELHAP)

r. Did you feel tired?

1-1 -All of the time
2-2 -Most of the time
3-3 -Some of the time
4-4 -A little of the time
5-5 -None of the time
*Additional Options Listed Below

(FEELTIR)

12. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities? (like visiting friends, relatives, etc.) *(EMOTINT)*

1-1 -All of the time
2-2 -Most of the time
3-3 -A good bit of the time
4-4 -Some of the time
5-5 -A little of the time
*Additional Options Listed Below

13. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)? *(INSOCIAL)*

1-1 - All of the time
2-2 - Most of the time
3-3 - Some of the time
4-4 - A little of the time
5-5 - None of the time
*Additional Options Listed Below

14. How TRUE or FALSE is each of the following statements is for you?

a. I seem to get sick a little easier than other people *(SICKEASY)*

1-1 - Definitely true
2-2 - Mostly true
3-3 - Don't know
4-4 - Mostly false
5-5 - Definitely false
*Additional Options Listed Below

b. I am as healthy as anybody I know *(HEALTHY)*

1-1 - Definitely true
2-2 - Mostly true
3-3 - Don't know
4-4 - Mostly false
5-5 - Definitely false
*Additional Options Listed Below

c. I expect my health to get worse *(WORSE)*

1-1 - Definitely true
2-2 - Mostly true
3-3 - Don't know
4-4 - Mostly false
5-5 - Definitely false
*Additional Options Listed Below

d. My health is excellent *(EXCLNT)*

1-1 - Definitely true
2-2 - Mostly true
3-3 - Don't know
4-4 - Mostly false
5-5 - Definitely false
*Additional Options Listed Below

Additional Selection Options for SFH

In general, would you say your health is:
9-9 - Subject did not complete

Compared to one year ago, how would you rate your health in general now?
9-9 - Subject did not complete

4a. Time cut down
9-9 - Subject did not complete

During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
9-9 - Subject did not complete

How much bodily pain have you had during the past 4 weeks?
6-6 - Very severe
9-9 - Subject did not complete

During the past 4 weeks, how much did pain interfere with your normal work? (including both work outside the home and housework)
9-9 - Subject did not complete

9a. Full of pep
6-6 - None of the time
9-9 - Subject did not complete

I seem to get sick a little easier than other people
9-9 - Subject did not complete

Blood and Marrow Transplant Clinical Trials Network

Secondary Graft Failure Form (SGF)

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

Segment *(PROTSEG)*:

1. Did the patient achieve engraftment, defined as >5% donor chimerism by Day 56 post HSCT? *(PREVENGR)* ☐ 1 - Yes ☐ 2 - No
2. Did the patient subsequently experience secondary graft failure, defined as <5% donor chimerism? *(LOSTGRFT)* ☐ 1 - Yes ☐ 2 - No
3. Record date of collection of the sample indicating secondary graft failure: *(TCCHIMDT)* _____ *(mm/dd/yyyy)*
4. Record type of sample: *(CHSAMTYP)* ☐ 1 - Blood ☐ 2 - Marrow
5. Record method of evaluation: *(TCMETSFG)*

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

6. Specify other method of evaluation: *(TCMETSPE)* _____
7. Record percent donor cell: *(TCPERDNR)* _____ *(x)* %

Comments: *(SGFCOMM)*

Additional Selection Options for SGF

Record method of evaluation:
9-9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Sibling Information Form (SIB)

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

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

1. Number of living siblings patient has: *(LIVSIBS)* ____ *(xx)*
2. Number of living siblings that were HLA typed: *(SIBTYPED)* ____ *(xx)*
3. Number of living HLA-identical siblings patient has: *(ANYHLAS1)* ____ *(xx)*

For each living sibling who was NOT HLA typed, indicate the reason why:

4. 1st sibling that was not HLA typed: *(RNOTYPE1)*

```
01-01 - Sibling Refused
02-02 - Sibling Did Not Fall Within the Age Limits
03-03 - Sibling and Patient are Identical Twins
04-04 - Sibling is Pregnant or Breastfeeding
05-05 - Sibling Has History of Infectious Disease as Listed in Protocol Exclusion Criteria
*Additional Options Listed Below
```

Specify other reason: *(SIB1SPEC)*

5. 2nd sibling that was not HLA typed: *(RNOTYPE2)*

```
01-01 - Sibling Refused
02-02 - Sibling Did Not Fall Within the Age Limits
03-03 - Sibling and Patient are Identical Twins
04-04 - Sibling is Pregnant or Breastfeeding
05-05 - Sibling Has History of Infectious Disease as Listed in Protocol Exclusion Criteria
*Additional Options Listed Below
```

Specify other reason: *(SIB2SPEC)*

6. 3rd sibling that was not HLA typed: *(RNOTYPE3)*

```
01-01 - Sibling Refused
02-02 - Sibling Did Not Fall Within the Age Limits
03-03 - Sibling and Patient are Identical Twins
04-04 - Sibling is Pregnant or Breastfeeding
05-05 - Sibling Has History of Infectious Disease as Listed in Protocol Exclusion Criteria
*Additional Options Listed Below
```

Specify other reason: *(SIB3SPEC)*

For each HLA-identical sibling who did NOT donate peripheral blood stem cells to the patient, answer the following questions:

1st HLA-identical sibling:

7. Did the sibling consent to take part in the study? *(SIB1CONS)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Approached
8. Record the sibling's birthdate: *(SIB1BDAY)* ____ *(mm/dd/yyyy)*
9. Are the sibling and patient identical twins? *(IDENT1TW)* ☐ 1 - Yes ☐ 2 - No
10. Is the sibling pregnant (positive β-HCG) or breastfeeding? *(SIB1PREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
11. Is the sibling HIV seropositive? *(SIB1HIVP)* ☐ 1 - Yes ☐ 2 - No
12. Is the sibling hepatitis B surface antigen positive? *(SIB1HEPB)* ☐ 1 - Yes ☐ 2 - No
13. Is the sibling hepatitis C positive? *(SIB1HEPC)* ☐ 1 - Yes ☐ 2 - No
14. Does the sibling have a known allergy to G-CSF? *(SIB1GCSF)* ☐ 1 - Yes ☐ 2 - No
15. Does the sibling currently have a serious systemic illness? *(SIB1SYS)* ☐ 1 - Yes ☐ 2 - No
16. Does the sibling have an uncontrolled viral, bacterial or fungal infection? *(SIB1UINF)* ☐ 1 - Yes ☐ 2 - No
17. Is the sibling currently receiving experimental therapy or an investigational drug? *(SIB1EXTH)* ☐ 1 - Yes ☐ 2 - No
18. Does the sibling have a history of any malignant disease other than treated basal cell carcinoma or cervical carcinoma in situ? *(SIB1CNCR)*

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

19. Record reason sibling did not donate peripheral blood stem cells to patient? *(SIB1NSTD)* ____

2nd HLA-identical sibling:

20. Did the sibling consent to take part in the study? *(SIB2CONS)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Approached
21. Record the sibling's birthdate: *(SIB2BDAY)* _____ *(mm/dd/yyyy)*
22. Are the sibling and patient identical twins? *(IDENT2TW)* ☐ 1 - Yes ☐ 2 - No
23. Is the sibling pregnant (positive β-HCG) or breastfeeding? *(SIB2PREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
24. Is the sibling HIV seropositive? *(SIB2HIVP)* ☐ 1 - Yes ☐ 2 - No
25. Is the sibling hepatitis B surface antigen positive? *(SIB2HEPB)* ☐ 1 - Yes ☐ 2 - No
26. Is the sibling hepatitis C positive? *(SIB2HEPC)* ☐ 1 - Yes ☐ 2 - No
27. Does the sibling have a known allergy to G-CSF? *(SIB2GCSF)* ☐ 1 - Yes ☐ 2 - No
28. Does the sibling currently have a serious systemic illness? *(SIB2SYSI)* ☐ 1 - Yes ☐ 2 - No
29. Does the sibling have an uncontrolled viral, bacterial or fungal infection? *(SIB2UINF)* ☐ 1 - Yes ☐ 2 - No
30. Is the sibling currently receiving experimental therapy or an investigational drug? *(SIB2EXTH)* ☐ 1 - Yes ☐ 2 - No
31. Does the sibling have a history of any malignant disease other than treated basal cell carcinoma or cervical carcinoma in situ? *(SIB2CNCR)*

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

32. Record reason sibling did not donate peripheral blood stem cells to patient? *(SIB2NSTD)* _____

3rd HLA-identical sibling:

33. Did the sibling consent to take part in the study? *(SIB3CONS)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Approached
34. Record sibling's birthdate: *(SIB3BDAY)* _____ *(mm/dd/yyyy)*
35. Are the sibling and patient identical twins? *(IDENT3TW)* ☐ 1 - Yes ☐ 2 - No
36. Is the sibling pregnant (positive β-HCG) or breastfeeding? *(SIB3PREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
37. Is the sibling HIV seropositive? *(SIB3HIV)* ☐ 1 - Yes ☐ 2 - No
38. Is the sibling hepatitis B surface antigen positive? *(SIB3HEPB)* ☐ 1 - Yes ☐ 2 - No
39. Is the sibling hepatitis C positive? *(SIB3HEPC)* ☐ 1 - Yes ☐ 2 - No
40. Does the sibling have a known allergy to G-CSF? *(SIB3GCSF)* ☐ 1 - Yes ☐ 2 - No
41. Does the sibling currently have a serious systemic illness? *(SIB3SYSI)* ☐ 1 - Yes ☐ 2 - No
42. Does the sibling have an uncontrolled viral, bacterial or fungal infection? *(SIB3UINF)* ☐ 1 - Yes ☐ 2 - No
43. Is the sibling currently receiving experimental therapy or an investigational drug? *(SIB3EXTH)* ☐ 1 - Yes ☐ 2 - No
44. Does the sibling have a history of any malignant disease other than treated basal cell carcinoma or cervical carcinoma in situ? *(SIB3CNCR)*

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

45. Record reason sibling did not donate peripheral blood stem cells to patient? *(SIB3NSTD)* _____

Comments: *(SIB1COMM)*

Additional Selection Options for SIB

1st sibling that was not HLA typed:
06-06 - Sibling Has a Known Allergy to G-CSF
07-07 - Sibling Currently Has a Systemic Illness
08-08 - Sibling Has an Uncontrolled Infection
09-09 - Sibling is Currently Receiving an Experimental Therapy
10-10 - Sibling Has a History of Malignant Disease
99-99 - Other

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0202 (TX3)

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

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

1. Record date of evaluation: *(TX3EVLDT)* _____ *(mm/dd/yyyy)*

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

Blood/Bone Marrow Toxicity

2. Neutropenia: *(TX3NEUTR)*

0-0 - Grades 0-2
3-3 - <1000 - 500/mm^3;<1.0 - 0.5 x 10^9 L
4-4 - <500/mm^3;<0.5 x 10^9 L
5-5 - Death

GI Toxicity

3. Mucositis/Stomatitis (clinical exam): *(TX3MCSTS)*

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

Mouth pain or esophageal pain requiring IV hydration/narcotics.

Renal Toxicity

4. Did the patient experience renal failure severe enough to warrant dialysis? *(TX3RENAL)* ☐ 1 - Yes ☐ 2 - No
5. Did the patient receive dialysis? *(TX3DIALS)* ☐ 1 - Yes ☐ 2 - No
6. Did the patient's serum creatinine exceed 3.0 mg/dL? *(TX3CREAT)* ☐ 1 - Yes ☐ 2 - No
7. Record serum creatinine value: *(TX3CRVAL)* _____ *(xx.x)* mg/dL
8. Record date serum creatinine first exceeded 3.0 mg/dL: *(TX3CRDAT)* _____ *(mm/dd/yyyy)*

9. Hemorrhagic cystitis: *(TX3CYSTI)*

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

Hemorrhagic Toxicity

10. Hemorrhage: *(TX3HEMRG)*

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

Cardiovascular Toxicity

11. Hypotension: *(TX3HYPOT)*

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

12. Cardiac arrhythmia: *(TX3CRDAR)*

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

13. Left ventricular systolic dysfunction: *(TX3LVENT)*

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

Neurologic Toxicity

14. Somnolence: *(TX3SMNLN)*

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

15. Did the patient experience any seizures during this assessment period? *(TX3SEIZR)* ☐ 1 - Yes ☐ 2 - No

16. Record seizure toxicity grade: *(TX3SZGRD)*

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

Coagulation Toxicity

17. HUS/TTP/thrombotic microangiopathy: *(TX3DIC)*

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

Vascular Toxicity

18. Vascular leak syndrome: *(TX3VASLK)*

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

Pulmonary Toxicity

19. Hypoxia (for more than 24 hours): *(TX3HYPXI)*

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

20. Dyspnea: *(TX3DYSPN)*

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

21. Pneumonitis: *(TX3PNMTS)*

0-0 - Grades 0-2
3-3 - Symptomatic; Interfering With ADL; Oxygen Indicated
4-4 - Life-Threatening; Ventilatory Support Indicated
5-5 - Death

22. During this assessment period, was an FEV1 performed? *(TX3FEVDN)* ☐ 1 - Yes ☐ 2 - No

23. Record FEV1 value obtained: *(TX3FEVVL)* _____ *(xxx)* % of predicted value

24. During this assessment period, was an FVC performed? *(TX3FVCDN)* ☐ 1 - Yes ☐ 2 - No

25. Record FVC value obtained: *(TX3FVCVL)* _____ *(xxx)* % of predicted value

Hepatic Toxicity

26. Did the patient develop abnormal liver function during this assessment period? *(TX3ABNLF)* ☐ 1 - Yes ☐ 2 - No

27. ALT: *(TX3ALT)*

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

28. Alkaline Phosphatase: *(TX3ALKPH)*

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

29. Bilirubin: *(TX3BILI)*

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

	Peak Value During Interval	ULN for your Institution	Date Sample Obtained
30. ALT:	*(TX3ALTP)* _____ *(xxx)* Units/L	*(TX3ALTUL)* _____ *(xx)* Units/L	*(TX3ALTDT)* _____ *(mm/dd/yyyy)*

31. Alkaline Phosphatase:	*(TX3ALPHP)* ____ *(xxx)* Units/L	*(TX3ALPHU)* ____ *(xxx)* Units/L	*(TX3ALPHD)* ____ *(mm/dd/yyyy)*
32. Bilirubin:	*(TX3BILIP)* ____ *(xx.x)* mg/dL	N/A	*(TX3BILID)* ____ *(mm/dd/yyyy)*

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

33. Jaundice: *(TX3JANDC)* ☐ 1 - Yes ☐ 2 - No
34. Hepatomegaly: *(TX3HPTMG)* ☐ 1 - Yes ☐ 2 - No
35. Right upper quadrant pain: *(TX3QUADP)* ☐ 1 - Yes ☐ 2 - No
36. Weight gain (>5%) from baseline: *(TX3WGHTG)* ☐ 1 - Yes ☐ 2 - No
37. Other clinical signs/symptoms: *(TX3OTHAB)* ☐ 1 - Yes ☐ 2 - No

Specify other clinical signs/symptoms: *(TX3SPEC1)*

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

N/A	Etiology	Biopsy Results	Doppler Ultrasound Results
VOD:	*(TX3VODET)* 1-1 - Yes 2-2 - No	*(TX3VODBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - Not Done	*(TX3VODDP)* 1-1 - Confirmed 2-2 - Not Confirmed 3-3 - Not Done 4-4 - Inconclusive Under Doppler Ultrasound
GVHD:	*(TX3GVHET)* 1-1 - Yes 2-2 - No	*(TX3GVHBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - Not Done	*(TX3GVHDP)* 1-1 - Confirmed 2-2 - Not Confirmed 3-3 - Not Done 4-4 - Inconclusive Under Doppler Ultrasound
Infection:	*(TX3INFET)* 1-1 - Yes 2-2 - No	*(TX3INFBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - Not Done	*(TX3INFDP)* 1-1 - Confirmed 2-2 - Not Confirmed 3-3 - Not Done 4-4 - Inconclusive Under Doppler Ultrasound
Other:	*(TX3OTHET)* 1-1 - Yes 2-2 - No	*(TX3OTHBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - Not Done	*(TX3OTHDP)* 1-1 - Confirmed 2-2 - Not Confirmed 3-3 - Not Done 4-4 - Inconclusive Under Doppler Ultrasound
Unknown:	*(TX3UNKET)* 1-1 - Yes 2-2 - No	N/A	N/A

Specify other etiology: *(TX3SPEC2)*

Stem Cell Infusional Toxicities (Within 24 Hours of Infusion)

39. Allergic reaction/hypersensitivity: *(TX3ALRGY)*
0-0 - Grades 0-2
3-3 - Symptomatic Bronchospasm, with or without Urticaria; Parenteral Med(s) Indicated
4-4 - Anaphylaxis
5-5 - Death

40. Cardiac arrhythmia: *(TX3CARDC)*
0-0 - Grades 0-2
3-3 - Incompletely Controlled Medically, or Controlled with Device (e.g., Pacemaker)
4-4 - Life-Threatening; Disabling (e.g., Arrhythmia Associated with CHF, Syncope, Shock)
5-5 - Death

41. Hypertension: *(TX3HYPRT)*
0-0 - Grades 0-2
3-3 - Requiring More than One Drug or More Intensive Therapy than Previously
4-4 - Life-Threatening Consequences (e.g., Hypertensive Crisis)
5-5 - Death

42. Hypotension: *(TX3HYPO2)*
0-0 - Grades 0-2
3-3 - Sustained (>/=24 hrs) Therapy, Resolves w/o Persisting Physiologic Consequences
4-4 - Shock (e.g., Acidemia; Impairment of Vital Organ Function)
5-5 - Death

43. Fever: *(TX3FEVER)*
0-0 - Grades 0-1
2-2 - >39.0-40.0C (102.3-104.0F)
3-3 - >40C (>104.0F) for <24 hrs
4-4 - >40C (>104.0F) for >24 hrs
5-5 - Death

44. Rigors, chills: *(TX3RIGOR)*

0-0 - Grades 0-2
3-3 - Severe or Prolonged, not Responsive to Narcotics

45. Vomiting: *(TX3VOMIT)*

0-0 - Grades 0-1
2-2 - 2-5 Episodes in 24 hrs; IV Fluids Indicated < 24 hrs
3-3 - >/=6 Episodes in 24 hrs; IV Fluids, or TPN Indicated >/= 24 hrs
4-4 - Life-Threatening Consequences
5-5 - Death

46. Hypoxia: *(TX3HYPX2)*

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

Comments: *(TX3COMM)*

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

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

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

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

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

Comments: *(COMMTXP1)*