Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Web Version: 1.0; 5.00; 06-05-17

Segment *(PROTSEG)*: A

Date of Admission *(ADMITDT)*:

1. Date of discharge:*(DISCHDT)* _____ *(mm/dd/yyyy)*

2. Patient discharge status:*(DISCPTST)* ☐ 1 - Alive ☐ 2 - Dead
If Dead, a Death Form must be submitted.

3. Record PRIMARY discharge diagnosis:*(PHSPREAS)*
01 - GVHD
02 - Relapse/Progression
03 - Graft Failure
04 - Infection
05 - Fungal Infection
*Additional Options Listed Below
?

Specify organ:(ADM4SPEC)* _____

**Specify other:*(ADM1SPEC)* _____

4. Record secondary discharge diagnoses:

a. GVHD:*(REASGVHD)* ☐ 1 - Contributory ☐ 2 - Noncontributory ?

b. Relapse/progression:*(REASRLPS)* ☐ 1 - Contributory ☐ 2 - Noncontributory

c. Graft failure:*(REASGF)* ☐ 1 - Contributory ☐ 2 - Noncontributory

d. Infection:*(REASINF)* ☐ 1 - Contributory ☐ 2 - Noncontributory

e. Fever:*(REASFVR)* ☐ 1 - Contributory ☐ 2 - Noncontributory

f. Seizure:*(REASSZR)* ☐ 1 - Contributory ☐ 2 - Noncontributory

g. Bleeding/hemorrhage:*(REASGIBL)* ☐ 1 - Contributory ☐ 2 - Noncontributory

h. Diarrhea:*(REASDRH)* ☐ 1 - Contributory ☐ 2 - Noncontributory

i. Nausea/vomiting:*(REASNV)* ☐ 1 - Contributory ☐ 2 - Noncontributory

j. Organ failure:*(REASORGF)* ☐ 1 - Contributory ☐ 2 - Noncontributory

Specify organ:*(ADM3SPEC)* _____

k. Trauma:*(REASTRAM)* ☐ 1 - Contributory ☐ 2 - Noncontributory

l. Psychiatric:*(REASPSYC)* ☐ 1 - Contributory ☐ 2 - Noncontributory

m. Secondary malignancy:*(REASMALG)* ☐ 1 - Contributory ☐ 2 - Noncontributory

n. Scheduled procedure/treatment:*(REASPROC)* ☐ 1 - Contributory ☐ 2 - Noncontributory

o. Thrombosis/thrombus/embolism:*(REASTRMB)* ☐ 1 - Contributory ☐ 2 - Noncontributory

p. Other:*(REASOTHR)* ☐ 1 - Contributory ☐ 2 - Noncontributory

Specify other:*(ADM2SPEC)* _____

5. Record re-admission institution:*(ADMCENTR)*
1 - Original Transplant Center
2 - Other Transplant Center
3 - Other Hospital

Comments:*(ADMCOMM1)* _____

Additional Selection Options for ADM

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

Blood and Marrow Transplant Clinical Trials Network

Adverse Event Form (AE1)

Web Version: 1.0; 5.00; 01-28-16

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

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

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

12. Record the date of resolution:*(AVRESDT)* *(mm/dd/yyyy)* ?

13. Was this event associated with:*(AVASSOCI)*

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

?

Comments:*(AE1COMM)*

Additional Selection Options for AE1

What is the relationship to transplant:
88 - Not Applicable

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

Blood and Marrow Transplant Clinical Trials Network

AE Summary Form (AE2)

Web Version: 1.0; 3.12; 10-16-15

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

1. Report activation status:*(AVSTAT_A)*

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

Relevant Past Medical History

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

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

(SEMEDHX)

3. **Event Summary**

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

(SESUMM)

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

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

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AE Therapy Form (AE3)

Web Version: 1.0; 4.05; 10-16-15

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

1. Report activation status:*(AVSTAT_B)*

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

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

				1 - Treatment of adverse event 9 - Other
(CONMED5)	*(CM5STDT)*	*(CM5SPDT)*	*(CM5DOSE)*	*(CM5INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED6)	*(CM6STDT)*	*(CM6SPDT)*	*(CM6DOSE)*	*(CM6INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED7)	*(CM7STDT)*	*(CM7SPDT)*	*(CM7DOSE)*	*(CM7INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED8)	*(CM8STDT)*	*(CM8SPDT)*	*(CM8DOSE)*	*(CM8INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED9)	*(CM9STDT)*	*(CM9SPDT)*	*(CM9DOSE)*	*(CM9INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED10)	*(CM10STDT)*	*(CM10SPDT)*	*(CM10DOSE)*	*(CM10INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED11)	*(CM11STDT)*	*(CM11SPDT)*	*(CM11DOSE)*	*(CM11INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED12)	*(CM12STDT)*	*(CM12SPDT)*	*(CM12DOSE)*	*(CM12INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED13)	*(CM13STDT)*	*(CM13SPDT)*	*(CM13DOSE)*	*(CM13INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED14)	*(CM14STDT)*	*(CM14SPDT)*	*(CM14DOSE)*	*(CM14INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED15)	*(CM15STDT)*	*(CM15SPDT)*	*(CM15DOSE)*	*(CM15INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED16)	*(CM16STDT)*	*(CM16SPDT)*	*(CM16DOSE)*	*(CM16INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED17)	*(CM17STDT)*	*(CM17SPDT)*	*(CM17DOSE)*	*(CM17INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED18)	*(CM18STDT)*	*(CM18SPDT)*	*(CM18DOSE)*	*(CM18INDI)* 1 - Treatment of adverse event 9 - Other

(CONMED19)	*(CM19STDT)*	*(CM19SPDT)*	*(CM19DOSE)*	*(CM19INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED20)	*(CM20STDT)*	*(CM20SPDT)*	*(CM20DOSE)*	*(CM20INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED21)	*(CM21STDT)*	*(CM21SPDT)*	*(CM21DOSE)*	*(CM21INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED22)	*(CM22STDT)*	*(CM22SPDT)*	*(CM22DOSE)*	*(CM22INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED23)	*(CM23STDT)*	*(CM23SPDT)*	*(CM23DOSE)*	*(CM23INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED24)	*(CM24STDT)*	*(CM24SPDT)*	*(CM24DOSE)*	*(CM24INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED25)	*(CM25STDT)*	*(CM25SPDT)*	*(CM25DOSE)*	*(CM25INDI)* 1 - Treatment of adverse event 9 - Other

Comments:*(AE3COMM)*

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AE Laboratory/Diagnostics Form (AE4)

Web Version: 1.0; 3.12; 06-16-16

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

1. Report activation status:*(AVSTAT_C)*

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

Laboratory Test Results

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

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

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

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

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

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

Test	Date Performed *(mm/dd/yyyy)*	Results/Comments
(ADDTS1)	*(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)*

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AE Review Form (AE5)

Web Version: 1.0; 3.12; 10-16-15

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

1. Report activation status:*(AVSTAT_D)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason
2. Reviewed:*(AEREVIEW)* ☐ 1 - Yes ☐ 2 - No
3. Reviewed by:*(ARFREVBY)*
4. Review date:*(ARFREVDT)* *(mm/dd/yyyy)*
5. Comment 1 - For Distribution:*(ARCM1DIS)*
6. Comment 2 - All Other Reviewers/Data Coordinating Center*(ARCM2ALL)*

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AE Medical Monitor Reviewer Form (AE6)

Web Version: 1.0; 9.00; 03-06-17

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

1. Adverse event status:*(AVSTAT_E)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason
2. Has this event been determined to be an unexpected, grade 3-5 adverse event? *(AMDETER)*
   - ☐ 1 - Yes ☐ 2 - No
3. What is the relationship to transplant:*(AMRELTXP)*
   - 1 - Unrelated
   - 2 - Unlikely
   - 3 - Possible
   - 4 - Probable
   - 5 - Definite
   - *Additional Options Listed Below
4. What is the relationship to bortezomib:*(AMRELBOR)*
   - 1 - Unrelated
   - 2 - Unlikely
   - 3 - Possible
   - 4 - Probable
   - 5 - Definite
   - *Additional Options Listed Below
5. What is the relationship to maraviroc:*(AMRELMAR)*
   - 1 - Unrelated
   - 2 - Unlikely
   - 3 - Possible
   - 4 - Probable
   - 5 - Definite
   - *Additional Options Listed Below
6. Does this require expedited reporting to the FDA?*(AMEXPFDA)*
   - ☐ 1 - Yes ☐ 2 - No
7. Does this require expedited reporting to the DSMB?*(AMEXPDSM)*
   - ☐ 1 - Yes ☐ 2 - No
8. Do you recommend the patient be withdrawn from further protocol therapy? *(AMWITHDR)*
   - ☐ 1 - Yes ☐ 2 - No
9. Is the review complete?*(AMREVDNE)*
   - ☐ 1 - Yes ☐ 2 - No
10. If **No**, what additional information is required:*(AMREVINF)*
11. Medical Monitor event description:*(AMMMEVDS)*
12. Medical Monitor CTCAE grade of event:*(CTCAEGRD)*
    - 1 - Grade 1
    - 2 - Grade 2
    - 3 - Grade 3
    - 4 - Grade 4
    - 5 - Grade 5

Comments:*(AE6COMM)*

Additional Selection Options for AE6

What is the relationship to transplant:
88 - Not Applicable

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Bortezomib SAE Screening Form (BSS)

Web Version: 1.0; 1.02; 10-16-15

Segment *(PROTSEG)*: A
Date of Onset *(ADVDATE)*:
Event Description *(BRTADVDS)*:

1. Brief description of 'Other Adverse Event':*(BSSOTADV)*

2. Relationship to bortezomib:*(BSSRLBRT)*

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

3. Event was associated with:*(BSSEVASS)*

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

4. Has the event resolved?*(BSSEVRSL)*

☐ 1 - Yes ☐ 2 - No

5. Date of resolution:*(BSSRESDT)* *(mm/dd/yyyy)*

Comments:*(BSSCOMM)*

Additional Selection Options for BSS

Event Description *(BRTADVDS)* (key field):
1 - Neutropenia
2 - Thrombocytopenia
3 - Anemia
4 - Minor Bleeding Episodes (i.e. Epistaxis)
5 - Graft-Versus-Host Disease (GVHD)
6 - Graft Failure
7 - Hepatic Veno-Occlusive Disease (VOD)
8 - Thrombotic Microangiopathy (TMA)
9 - Other Adverse Event

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

Blood and Marrow Transplant Clinical Trials Network

CIBMTR Recipient ID (CID)

Web Version: 1.0; 1.06; 10-16-15

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

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

Comments:*(CIDCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Conditioning Regimen Form-1203 (DCR)

Web Version: 1.0; 2.02; 01-28-16

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

1. Patient's primary diagnosis:*(DCPRMDX)*
   - 01 - Acute Lymphoblastic Leukemia (ALL)
   - 02 - Acute Myelogenous Leukemia (AML)
   - 03 - Chronic Myelogenous Leukemia (CML)
   - 04 - Chronic Lymphocytic Leukemia (CLL)
   - 05 - Myelodysplastic Syndrome (MDS)
   - *Additional Options Listed Below

2. If the patient's primary diagnosis is acute leukemia (ALL or AML), record the disease status at study entry:*(DCALSTT)*
   - 1 - Primary Induction Failure
   - 2 - First Complete Remission
   - 3 - 2nd/Subsequent Complete Remission
   - 4 - First Relapse
   - 5 - 2nd/Subsequent Relapse
   - *Additional Options Listed Below

3. If the patient's primary diagnosis is chronic myelogenous leukemia (CML), record the disease status at study entry:*(DCCMSTT)*
   - 01 - First Chronic Phase
   - 02 - Hematologic Complete Remission
   - 03 - Accelerated Phase
   - 04 - Blast Crisis
   - 05 - Second or Greater Chronic Phase

4. If the patient's primary diagnosis is chronic lymphocytic leukemia (CLL), record the disease status at study entry:*(DCCLSTT)*
   - 1 - Never Treated
   - 2 - Complete Remission
   - 3 - Nodular Partial Remission
   - 4 - Partial Remission
   - 5 - No Response/Stable Disease
   - *Additional Options Listed Below

5. If the patient's primary diagnosis is myelodysplastic syndrome (MDS), record the disease status at study entry:*(DCMDSTT)*
   - 1 - Complete Remission
   - 2 - Hematologic Improvement
   - 3 - No Response/Stable Disease
   - 4 - Progression from Hematologic Improvement
   - 5 - Relapse from Complete Remission

6. If the patient's primary diagnosis is lymphoma, record the disease status at study entry:*(DCLYSTT)*
   - 1 - Disease Untreated
   - 2 - Partial Remission
   - 3 - First Complete Remission
   - 4 - 2nd/Subsequent Remission
   - 5 - First Relapse
   - *Additional Options Listed Below

7. Record the patient's HCT-Specific Comorbidity Index Score at study entry: *(DCHCTID)*

8. Record the patient's body surface area (BSA) used to calculate conditioning regimen chemotherapy doses:*(DCBSA)* *(x.xx)* m^2

9. Record the date the BSA was obtained:*(DCBSADT)* *(mm/dd/yyyy)*

10. Record the body weight type used to calculate the conditioning regimen chemotherapy doses:*(DCWTTYP)*
    - 1 - Actual body weight
    - 2 - Ideal body weight (IBW)
    - 3 - Adjusted ideal body weight (AIBW)

11. Record the patient's body weight:*(DCPTWT)* *(xxx.x)* kg

12. Record the date the weight was obtained:*(DCPTWDT)* *(mm/dd/yyyy)*

13. Record the conditioning regimen that the patient received:*(DCCONRG)*

1 - Fludarabine/Busulfan
2 - Fludarabine/Melphalan
3 - Fludarabine/Cyclophosphamide
4 - Fludarabine/TBI
5 - Fludarabine/Cyclophosphamide/TBI
*Additional Options Listed Below

14. GVHD prophylaxis regimen randomization assignment:*(DCGPHRAN)*

1 - Tacrolimus/Methotrexate/Bortezomib
2 - Tacrolimus/Methotrexate/Maraviroc
3 - Tacrolimus/MMF/Cyclophosphamide

15. Select the GVHD prophylaxis regimen the patient will receive:*(DCGPHXRC)*

1 - Tacrolimus/Methotrexate/Bortezomib
2 - Tacrolimus/Methotrexate/Maraviroc
3 - Tacrolimus/MMF/Cyclophosphamide

16. Record the dose and date of Flu/Bu administration:

	Fludarabine Dose	Date Given
Dose 1:	*(DCFL11D)* *(xxx)* mg	*(DCFL11DT)* *(mm/dd/yyyy)*
Dose 2:	*(DCFL12D)* *(xxx)* mg	*(DCFL12DT)* *(mm/dd/yyyy)*
Dose 3:	*(DCFL13D)* *(xxx)* mg	*(DCFL13DT)* *(mm/dd/yyyy)*
Dose 4:	*(DCFL14D)* *(xxx)* mg	*(DCFL14DT)* *(mm/dd/yyyy)*
Dose 5:	*(DCFL15D)* *(xxx)* mg	*(DCFL15DT)* *(mm/dd/yyyy)*
	Busulfan Dose	**Date Given**
Dose 1:	*(DCBU1D)* *(xxx)* mg	*(DCBUD1DT)* *(mm/dd/yyyy)*
Dose 2:	*(DCBU2D)* *(xxx)* mg	*(DCBUD2DT)* *(mm/dd/yyyy)*
Dose 3:	*(DCBU3D)* *(xxx)* mg	*(DCBUD3DT)* *(mm/dd/yyyy)*
Dose 4:	*(DCBU4D)* *(xxx)* mg	*(DCBUD4DT)* *(mm/dd/yyyy)*

17. Record the dose and date of Flu/Mel administration:

	Fludarabine Dose	Date Given
Dose 1:	*(DCFL21D)* *(xxx)* mg	*(DCFL21DT)* *(mm/dd/yyyy)*
Dose 2:	*(DCFL22D)* *(xxx)* mg	*(DCFL22DT)* *(mm/dd/yyyy)*
Dose 3:	*(DCFL23D)* *(xxx)* mg	*(DCFL23DT)* *(mm/dd/yyyy)*
Dose 4:	*(DCFL24D)* *(xxx)* mg	*(DCFL24DT)* *(mm/dd/yyyy)*
	Melphalan Dose	**Date Given**
Dose:	*(DCMELD)* *(xxx)* mg	*(DCMELDT)* *(mm/dd/yyyy)*

18. Record the dose and date of Flu/Cy administration:

	Fludarabine Dose	Date Given
Dose 1	*(DCF3D1)* *(xxx)* mg	*(DCF3D1DT)* *(mm/dd/yyyy)*
Dose 2	*(DCF3D2)* *(xxx)* mg	*(DCF3D2DT)* *(mm/dd/yyyy)*
Dose 3	*(DCF3D3)* *(xxx)* mg	*(DCF3D3DT)* *(mm/dd/yyyy)*
	Cyclophosphamide Dose	**Date Given**
Dose 1	*(DCC1D1)* *(xxxxx)* mg	*(DCC1D1DT)* *(mm/dd/yyyy)*
Dose 2	*(DCC1D2)* *(xxxxx)* mg	*(DCC1D2DT)* *(mm/dd/yyyy)*
Dose 3	*(DCC1D3)* *(xxxxx)* mg	*(DCC1D3DT)* *(mm/dd/yyyy)*

19. Record the dose and date of Flu/TBI administration:

	Fludarabine Dose	Date Given
Dose 1	*(DCF4D1)* *(xxx)* mg	*(DCF4D1DT)* *(mm/dd/yyyy)*
Dose 2	*(DCF4D2)* *(xxx)* mg	*(DCF4D2DT)* *(mm/dd/yyyy)*
Dose 3	*(DCF4D3)* *(xxx)* mg	*(DCF4D3DT)* *(mm/dd/yyyy)*
	TBI Dose	**Date Given**
Dose 1	*(DCTBI1)* *(xxx)* cGy	*(DCTBI1DT)* *(mm/dd/yyyy)*

20. Record the dose and date of Flu/Cy/TBI administration:

	Cyclophosphamide Dose	Date Given
Dose 1	*(DCC2D1)* *(xxxx)* mg	*(DCC2D1DT)* *(mm/dd/yyyy)*
Dose 2	*(DCC2D2)* *(xxxx)* mg	*(DCC2D2DT)* *(mm/dd/yyyy)*
	Fludarabine Dose	**Date Given**
Dose 1	*(DCF5D1)* *(xxx)* mg	*(DCF5D1DT)* *(mm/dd/yyyy)*
Dose 2	*(DCF5D2)* *(xxx)* mg	*(DCF5D2DT)* *(mm/dd/yyyy)*
Dose 3	*(DCF5D3)* *(xxx)* mg	*(DCF5D3DT)* *(mm/dd/yyyy)*
Dose 4	*(DCF5D4)* *(xxx)* mg	*(DCF5D4DT)* *(mm/dd/yyyy)*
Dose 5	*(DCF5D5)* *(xxx)* mg	*(DCF5D5DT)* *(mm/dd/yyyy)*
	TBI Dose	**Date Given**
Dose 1	*(DCTBI2)* *(xxx)* cGy	*(DCTBI2DT)* *(mm/dd/yyyy)*

21. Record the dose and date of the other conditioning regimen administration:

All agents and doses should be recorded. If the same agent is administered on more than one day, each date and dose should be recorded.

Agent	Date	Other Agent	Specify Other Agent	Total Dose	Unit
1.	*(DC1DT)* *(mm/dd/yyyy)*	*(DC1AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Melphalan 4 - Cyclophosphamide 5 - TBI *Additional Options Listed Below	*(DC1OTHSP)*	*(DC1DOSE)* *(xxxxx)*	*(DC1UNIT)* 1 - mg 2 - cGy
2.	*(DC2DT)* *(mm/dd/yyyy)*	*(DC2AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Melphalan 4 - Cyclophosphamide 5 - TBI *Additional Options Listed Below	*(DC2OTHSP)*	*(DC2DOSE)* *(xxxxx)*	*(DC2UNIT)* 1 - mg 2 - cGy
3.	*(DC3DT)* *(mm/dd/yyyy)*	*(DC3AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Melphalan 4 - Cyclophosphamide 5 - TBI *Additional Options Listed Below	*(DC3OTHSP)*	*(DC3DOSE)* *(xxxxx)*	*(DC3UNIT)* 1 - mg 2 - cGy
4.	*(DC4DT)* *(mm/dd/yyyy)*	*(DC4AGENT)*	*(DC4OTHSP)*	*(DC4DOSE)* *(xxxxx)*	*(DC4UNIT)* 1 - mg 2 - cGy

		1 - Busulfan 2 - Fludarabine 3 - Melphalan 4 - Cyclophosphamide 5 - TBI *Additional Options Listed Below			
5.	*(DC5DT)* *(mm/dd/yyyy)*	*(DC5AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Melphalan 4 - Cyclophosphamide 5 - TBI *Additional Options Listed Below	*(DC5OTHSP)*	*(DC5DOSE)* *(xxxxx)*	*(DC5UNIT)* 1 - mg 2 - cGy
6.	*(DC6DT)* *(mm/dd/yyyy)*	*(DC6AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Melphalan 4 - Cyclophosphamide 5 - TBI *Additional Options Listed Below	*(DC6OTHSP)*	*(DC6DOSE)* *(xxxxx)*	*(DC6UNIT)* 1 - mg 2 - cGy
7.	*(DC7DT)* *(mm/dd/yyyy)*	*(DC7AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Melphalan 4 - Cyclophosphamide 5 - TBI *Additional Options Listed Below	*(DC7OTHSP)*	*(DC7DOSE)* *(xxxxx)*	*(DC7UNIT)* 1 - mg 2 - cGy
8.	*(DC8DT)* *(mm/dd/yyyy)*	*(DC8AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Melphalan 4 - Cyclophosphamide 5 - TBI *Additional Options Listed Below	*(DC8OTHSP)*	*(DC8DOSE)* *(xxxxx)*	*(DC8UNIT)* 1 - mg 2 - cGy
9.	*(DC9DT)* *(mm/dd/yyyy)*	*(DC9AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Melphalan 4 - Cyclophosphamide 5 - TBI *Additional Options Listed Below	*(DC9OTHSP)*	*(DC9DOSE)* *(xxxxx)*	*(DC9UNIT)* 1 - mg 2 - cGy

Comments: *(DCCOMM)*

Additional Selection Options for DCR

Patient's primary diagnosis:
06 - Small Lymphocytic Lymphoma (SLL)
07 - Follicular Lymphoma
08 - Marginal Zone Lymphoma
09 - Diffuse Large B-Cell Lymphoma (DLBL)
10 - Mantle Cell Lymphoma
11 - Hodgkin's Lymphoma

If the patient's primary diagnosis is acute leukemia (ALL or AML), record the disease status at study entry:
6 - No Treatment

If the patient's primary diagnosis is chronic lymphocytic leukemia (CLL), record the disease status at study entry:
6 - Progression
7 - Relapse (untreated)

If the patient's primary diagnosis is lymphoma, record the disease status at study entry:
6 - 2nd/Subsequent Relapse

Record the conditioning regimen that the patient received:
6 - Other reduced-intensity conditioning regimen

CR Agent 1
6 - Other agent

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 6.02; 12-02-15

1. Name Code:*(NAMECODE)*
2. IUBMID # (if available):*(IUBMID)*
3. Gender:*(GENDER)* ☐ 1 - Male ☐ 2 - Female
4. Date of Birth:*(DOB)* *(mm/dd/yyyy)*
5. Ethnicity:*(ETHNIC)*
   - 1- Hispanic or Latino
   - 2- Not Hispanic or Latino
   - 8- Unknown
   - 9- Not Answered
6. Race:*(RACE)*
   - White
   - 10 - White (Not Otherwise Specified)
   - 11 - European (Not Otherwise Specified)
   - 13 - Mediterranean
   - 14 - White North American
   - *Additional Options Listed Below

   Specify race:*(RACESP)*
7. Secondary Race:*(RACE2)*
   - White
   - 10 - White (Not Otherwise Specified)
   - 11 - European (Not Otherwise Specified)
   - 13 - Mediterranean
   - 14 - White North American
   - *Additional Options Listed Below

   Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

Web Version: 1.0; 4.16; 06-16-17

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

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

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

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

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

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

?

Specify other:*(DTHSPEC1)*

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

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

Specify other:*(DTHSPEC2)*

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

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

Specify other:*(DTHSPEC3)*

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

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

Specify other:*(DTHSPEC4)*

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

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

Specify other:*(DTHSPEC5)*

Comments:*(DTCMMNTS)*

Additional Selection Options for DTH

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

Blood and Marrow Transplant Clinical Trials Network

1203A (ENR)

Web Version: 1.0; 2.02; 01-28-16

GVHD Prophylaxis Enrollment Form: Segment A

1. Donor Type selected on Segment 0 Enrollment form:*(GV0DRTYP)*
   1 - Related Donor
   2 - Unrelated Donor
2. Record HLA Match and Donor Type:*(GVDNRMAT)*
   1 - Matched Sibling
   2 - Matched Unrelated
   3 - Mismatched Unrelated
3. Record the proposed start date of the conditioning regimen:*(GVSCNDDT)* *(mm/dd/yyyy)*
4. Record the planned reduced intensity conditioning (RIC) regimen:*(GVCNDREG)*
   1 - Fludarabine/Busulfan
   2 - Fludarabine/Melphalan
   3 - Fludarabine/Cyclophosphamide
   4 - Fludarabine/TBI
   5 - Fludarabine/Cyclophosphamide/TBI
   *Additional Options Listed Below
   5. If 'Other,' specify conditioning regimen:*(GVOTRGSP)*
   6. Date 'Other' regimen approved by protocol chairs:*(GVRGOKDT)* *(mm/dd/yyyy)*

Inclusion Criteria

7. Patient's primary diagnosis pre-transplant:*(GVPTXDX)*
   01 - Acute Lymphoblastic Leukemia (ALL)
   02 - Acute Myelogenous Leukemia (AML)
   03 - Chronic Myelogenous Leukemia (CML)
   04 - Chronic Lymphocytic Leukemia (CLL)
   05 - Myelodysplastic Syndrome (MDS)
   *Additional Options Listed Below
   8. If the patient's primary diagnosis is acute leukemia, CML, or MDS, record date bone marrow assessment was performed:*(GVBMDT)* *(mm/dd/yyyy)*
   9. Were there myeloblasts in the marrow?*(GVBMBLST)* ☐ 1 - Yes ☐ 2 - No
      10. If yes, record the percentage of myeloblasts:*(GVBMPCT)* *(xxx.x)* %
   11. If the patient's primary diagnosis is acute leukemia, CML, or MDS, record date peripheral blood assessment was performed:*(GVPBDT)* *(mm/dd/yyyy)*
   12. Were there myeloblasts in the peripheral blood (i.e., circulating blasts)? *(GVPBBLST)* ☐ 1 - Yes ☐ 2 - No
   13. If the patient's primary diagnosis is CLL or lymphoma, does the patient have chemosensitive disease at the time of enrollment?*(GVSENDIS)* ☐ 1 - Yes ☐ 2 - No
   14. If the patient's primary diagnosis is lymphoma, record date imaging study was performed:*(GVLYMPDT)* *(mm/dd/yyyy)*
15. Record left ventricular ejection fraction at rest:*(GVEFPCT)* *(xxx)* %
   16. Record date of left ventricular ejection fraction:*(GVEFDT)* *(mm/dd/yyyy)*

	Most Recent Value Prior to Enrollment	Date of Assessment
17. DLCO % (Adjusted for Hgb)	*(GVDLCPCT)* *(xxx)*	*(GVDLCODT)* *(mm/dd/yyyy)*
18. FEV1 %	*(GVFEVPCT)* *(xxx)*	*(GVFEVDT)* *(mm/dd/yyyy)*

19. Does the patient have Gilbert's Syndrome?*(GVGSBILI)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value Prior to Enrollment	ULN at Your Institution	Date Sample Obtained

20. Total Bilirubin (mg/dL)	*(GVBILVAL)* *(xx.x)*	*(GVBILULN)* *(xx.x)*	*(GVBILIDT)* *(mm/dd/yyyy)*
21. ALT (IU)	*(GVALTVAL)* *(xxx)*	*(GVALTULN)* *(xxx)*	*(GVALTDT)* *(mm/dd/yyyy)*
22. AST (IU)	*(GVASTVAL)* *(xxx)*	*(GVASTULN)* *(xxx)*	*(GVASTDT)* *(mm/dd/yyyy)*
23. Estimated Creatinine Clearance (mL/min)	*(GVCRCL)* *(xxx.x)*	N/A	*(GVCRCLDT)* *(mm/dd/yyyy)*

Exclusion Criteria

24. Has the patient had a prior allogeneic transplant?*(GVPRIRTX)* ☐ 1 - Yes ☐ 2 - No

25. Record the patient's Karnofsky performance score:*(GVKARNPS)*

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

26. Does the patient currently have leukemia involvement in the CNS?*(GVLEUCNS)* ☐ 1 - Yes ☐ 2 - No

27. Does the patient have a current uncontrolled bacterial, viral, or fungal infection (taking medication and with progression or no clinical improvement)?*(GVINFECT)* ☐ 1 - Yes ☐ 2 - No

28. Does the patient have a presence of fluid collection (ascites, pleural or pericardial effusion) that interferes with methotrexate clearance or makes methotrexate use contraindicated?*(GVFLUCOL)* ☐ 1 - Yes ☐ 2 - No

29. Does the patient have transformed lymphoma (e.g., Richters transformation arising in follicular lymphoma or chronic lymphocytic leukemia)?*(GVTRFLYM)* ☐ 1 - Yes ☐ 2 - No

30. Is the patient seropositive for the human immunodeficiency virus (HIV)? *(GVHIVPOS)* ☐ 1 - Yes ☐ 2 - No

31. Does the patient have active Hepatitis B or C, determined by serology and/or NAAT?*(GVHEPBC)* ☐ 1 - Yes ☐ 2 - No

32. Does the patient have hypersensitivity to bortezomib, boron, or mannitol? *(GVDRGSEN)* ☐ 1 - Yes ☐ 2 - No

33. Does the patient have ≥ Grade 2 sensory peripheral neuropathy?*(GVGD2SPN)* ☐ 1 - Yes ☐ 2 - No

34. Has the patient had a myocardial infarction within 6 months prior to enrollment or New York Heart Association (NYHA) Class III or IV heart failure, uncontrolled angina, severe uncontrolled ventricular arrhythmias, electrocardiographic evidence of acute ischemia, or active conduction system abnormalities?*(GVCARDIS)* ☐ 1 - Yes ☐ 2 - No

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

36. Is the patient pregnant (positive beta-HCG) or breastfeeding?*(GVPREG)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

37. Is the patient (all males and females of childbearing potential) willing to use contraceptive techniques during, and for 12 months following treatment? *(GVCONTOK)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

38. Does the patient have a serious medical or psychiatric illness likely to interfere with participation in this clinical study?*(GVSERPRB)* ☐ 1 - Yes ☐ 2 - No

39. Does the patient have any prior malignancies, except resected basal cell carcinoma or treated cervical carcinoma in situ?*(GVPRMALG)* ☐ 1 - Yes ☐ 2 - No

40. Was the malignancy treated with curative intent ≥ 5 years prior to enrollment on this study?*(GVTRT5YR)* ☐ 1 - Yes ☐ 2 - No

41. If no, date approved by Protocol Officer or one of the Study Chairs: *(GVAPRVDT)* *(mm/dd/yyyy)*

42. Will ATG or alemtuzumab be used in this patient's conditioning regimen? *(GVATGCAM)* ☐ 1 - Yes ☐ 2 - No

43. Is post-transplant therapy (including use of TKIs) planned for this patient? *(GVPTXTRP)* ☐ 1 - Yes ☐ 2 - No

44. Is there planned use of any agent that interacts with hepatic cytochrome P450 enzymes (CYP3A4), or glutathione S-transferases (involved in bortezomib and/or busulfan metabolism) during day -5 through day +7?*(GVAGNINT)* ☐ 1 - Yes ☐ 2 - No

45. If yes, will these agents be withheld during day -5 through day +7 if the patient is randomized to receive bortezomib?*(GVAGIBWH)* ☐ 1 - Yes ☐ 2 - No

It is acceptable to use alternative non-interacting medications during this period, and then resume prior medications.

46. Does the patient have secondary acute myeloid leukemia arising from myeloproliferative disease (e.g. CMML) with evidence of active myeloproliferative features or myelofibrosis in the background?*(GVSECAML)* ☐ 1 - Yes ☐ 2 - No

Consent for Use of Biological Samples for Optional Future Research

47. Did the patient give consent to provide blood samples for optional future research purposes?*(GVFRBLD)* ☐ 1 - Yes ☐ 2 - No

Comments: *(GVACOMM)*

Additional Selection Options for ENR

Record the planned reduced intensity conditioning (RIC) regimen:
6 - Other reduced-intensity conditioning regimen

Patient's primary diagnosis pre-transplant:
06 - Small Lymphocytic Lymphoma (SLL)
07 - Follicular Lymphoma
08 - Marginal Zone Lymphoma
09 - Diffuse Large B-Cell Lymphoma (DLBL)
10 - Mantle Cell Lymphoma
11 - Hodgkin's Lymphoma

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

Blood and Marrow Transplant Clinical Trials Network

Follow Up Status Form - 1203 (F16)

Web Version: 1.0; 2.01; 01-28-16

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

1. Date of last contact:*(F16LSCTD)* _____ *(mm/dd/yyyy)*

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

2. Has the patient died?*(F16PTDTH)* ☐ 1 - Yes ☐ 2 - No
   If Yes, a Death Form must be submitted.
   3. Date of patient death:*(F16DTHDT)* _____ *(mm/dd/yyyy)*
4. Has the patient's underlying disease (e.g., malignancy) progressed or relapsed according to morphologic, cytogenetic, or radiologic evidence?*(F16PTRLP)* ☐ 1 - Yes ☐ 2 - No
   If Yes, a Relapse Form must be submitted.
   5. Date of relapse or disease progression:*(F16RLPDT)* _____ *(mm/dd/yyyy)*
6. Has the patient's underlying disease (e.g., malignancy) been treated for progression or relapse?*(F16TRRLP)* ☐ 1 - Yes ☐ 2 - No
   7. Date treatment administered:*(F16TRADM)* _____ *(mm/dd/yyyy)*
8. Has immunosuppressive therapy been withdrawn to treat disease progression or relapse?*(F16WDIMM)* ☐ 1 - Yes ☐ 2 - No
   9. Date of withdrawal from immunosuppressive therapy:*(F16IMMDT)* _____ *(mm/dd/yyyy)*
10. Was immunosuppressive therapy given to treat or control GVHD?*(F16ITXGV)* ☐ 1 - Yes ☐ 2 - No
    11. Date immunosuppressive therapy was given to treat or control GVHD:*(F16IMGDT)* _____ *(mm/dd/yyyy)*
12. Has a donor lymphocyte infusion (DLI) been given to treat disease progression or relapse?*(F16DLI)* ☐ 1 - Yes ☐ 2 - No
    13. Date of DLI:*(F16DLIDT)* _____ *(mm/dd/yyyy)*
14. Has the patient received a non-protocol specified transplant?*(F16NPTXP)* ☐ 1 - Yes ☐ 2 - No
    15. Date of non-protocol specified transplant:*(F16NPTDT)* _____ *(mm/dd/yyyy)*
16. Has the patient experienced secondary graft failure?*(F16SGF)* ☐ 1 - Yes ☐ 2 - No
    If Yes, a Secondary Graft Failure Form must be submitted.
    17. Date of secondary graft failure:*(F16SGFDT)* _____ *(mm/dd/yyyy)*
18. Has the patient experienced any new Grade 2-3 infections?*(F16PTINF)* ☐ 1 - Yes ☐ 2 - No
    If Yes, an Infection Form must be submitted.
    19. Date of infection:*(F16INFDT)* _____ *(mm/dd/yyyy)*
20. Has the patient been hospitalized?*(F16PTHSP)* ☐ 1 - Yes ☐ 2 - No
21. Has the patient been hospitalized (other than for transplant)?*(F16PTHSP)* ☐ 1 - Yes ☐ 2 - No
    If Yes, a Re-Admission Form must be submitted.
    22. Date of hospitalization:*(F16HSPDT)* _____ *(mm/dd/yyyy)*
23. Has the patient experienced any Unexpected, Grade 3-5 Adverse Events? *(F16PTSAE)* ☐ 1 - Yes ☐ 2 - No
    If Yes, an Unexpected, Grade 3 - 5 Adverse Event Form must be submitted.
    24. Date of onset of Unexpected, Grade 3-5 Adverse Event:*(F16SAEDT)* _____ *(mm/dd/yyyy)*
25. Is the patient on >10mg of prednisone or an equivalent dose of another corticosteroid medication?*(F16PCSDS)* ☐ 1 - Yes ☐ 2 - No
    26. Date prednisone (or equivalent corticosteroid medication) was discontinued or became ≤ 10mg?*(F16PCSDT)* _____ *(mm/dd/yyyy)*

Comments:*(F16COMM)* _____

Blood and Marrow Transplant Clinical Trials Network

Follow Up/Chronic GVHD Form (FGV)

Web Version: 1.0; 2.02; 01-30-17

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

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

Acute GVHD

3. Maximum overall grade of acute GVHD during this assessment period:*(FGGRAGVH)*
   - 0 - No Symptoms of Acute GVHD
   - 1 - I
   - 2 - II
   - 3 - III
   - 4 - IV

4. Did new clinical signs and/or symptoms of acute GVHD develop during this assessment period?*(FGAGVDVL)* ☐ 1 - Yes ☐ 2 - No

   Only report new clinical signs and/or symptoms of acute GVHD that developed during the assessment period at the top of the form.

5. Date of diagnosis of acute GVHD:*(FGAGDGDT)* _____ *(mm/dd/yyyy)*

   If the date is out of range because the diagnosis occurred before this assessment period, question 4 should be answered '2-No'.

Record the highest severity for the following organ systems at the time of maximum overall grade of acute GVHD.

6. Skin abnormalities:*(FGASKNAB)*
   - 0 - No Rash
   - 1 - Maculopapular Rash, <25% of Body Surface
   - 2 - Maculopapular Rash, 25-50% of Body Surface
   - 3 - Generalized Erythroderma
   - 4 - Generalized Erythroderma with Bullus Formation and Desquamation

7. Upper GI abnormalities:*(FGAUGIAB)*
   - 0 - No Protracted Nausea and Vomiting
   - 1 - Persistent Nausea, Vomiting or Anorexia

8. Lower GI abnormalities:*(FGALGIAB)*
   - 0 - No Diarrhea
   - 1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m^2
   - 2 - Diarrhea >500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m^2
   - 3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m^2
   - 4 - Diarrhea >1500 mL/day or >833 mL/m^2
   - *Additional Options Listed Below

9. Liver abnormalities:*(FGALVRAB)*
   - 0 - Bilirubin <2.0 mg/dL
   - 1 - Bilirubin 2.0-3.0 mg/dL
   - 2 - Bilirubin 3.1-6.0 mg/dL
   - 3 - Bilirubin 6.1-15.0 mg/dL
   - 4 - Bilirubin >15.0 mg/dL

10. Was prophylaxis for GVHD given during this assessment period?*(FGPROPIM)*
    - 1 - Yes
    - 2 - No
    - 3 - Discontinued During This Assessment Period

11. If yes or discontinued during assessment period, specify all immunosuppressants used for GVHD prophylaxis:
    - a. ATG:*(FGPRATG)* ☐ 1 - Yes ☐ 2 - No
    - b. Bortezomib:*(FGPRBORT)* ☐ 1 - Yes ☐ 2 - No
    - c. Campath:*(FGPRCAMP)* ☐ 1 - Yes ☐ 2 - No
    - d. Cyclophosphamide:*(FGPRCYPH)* ☐ 1 - Yes ☐ 2 - No
    - e. Cyclosporine:*(FGPRCYCL)* ☐ 1 - Yes ☐ 2 - No
    - f. MMF:*(FGPRMMF)* ☐ 1 - Yes ☐ 2 - No

g. Maraviroc:*(FGPRMRVR)* ☐ 1 - Yes ☐ 2 - No

h. Methotrexate:*(FGPRMTRX)* ☐ 1 - Yes ☐ 2 - No

i. Prednisone:*(FGPRPRED)* ☐ 1 - Yes ☐ 2 - No

j. Sirolimus:*(FGPRSIR)* ☐ 1 - Yes ☐ 2 - No

k. Tacrolimus:*(FGPRTAC)* ☐ 1 - Yes ☐ 2 - No

l. Other:*(FGPROTHR)* ☐ 1 - Yes ☐ 2 - No

Specify other agent used:*(FGPROTSP)*

12. If GVHD prophylaxis was discontinued during this assessment, record the date:*(FGPRDCDT)* *(mm/dd/yyyy)*

Chronic GVHD

13. Maximum overall severity of chronic GVHD during this assessment period:*(FGSVCGVH)*
    - 0 - No Chronic GVHD
    - 1 - Mild
    - 2 - Moderate
    - 3 - Severe

14. Did new clinical signs and/or symptoms of chronic GVHD develop during this assessment period?*(FGCGVDVL)* ☐ 1 - Yes ☐ 2 - No ?

Only initial diagnosis or onset of chronic GVHD should be reported.

15. Date of initial diagnosis/onset of chronic GVHD:*(FGCGDGDT)* *(mm/dd/yyyy)* ?

16. Minimum Karnofsky/Lansky Score at time of diagnosis: *(FGDGKNLN)*
    - 01 - 100 (Normal; No Complaints/Fully Active)
    - 02 - 90 (Normal Activity/Minor Restriction in Strenuous Play)
    - 03 - 80 (Normal Activity with Effort/Restricted in Strenuous Play)
    - 04 - 70 (Unable to Carry On Normal Activity/Less Time Spent in Play)
    - 05 - 60 (Requires Occasional Assistance/Minimal Active Play)
    - *Additional Options Listed Below

17. Minimum platelet count at time of diagnosis:*(FGDGPLT)* *(xxxxxx)* /mm^3

18. Alkaline phosphatase at time of diagnosis:*(FGDGALKP)* *(xxxx)* Units/L

19. Weight at time of diagnosis:*(FGDGWGT)* *(xxx.x)* kg

20. Total bilirubin at time of diagnosis:*(FGDGBILI)* *(xx.x)* mg/dL

21. Did the patient have an erythematous or maculopapular rash at the time of diagnosis?*(FGRSDIAG)* ☐ 1 - Yes ☐ 2 - No

22. Was diarrhea, nausea, vomiting or liver function abnormalities present at the time of diagnosis? *(FGDRDIAG)* ☐ 1 - Yes ☐ 2 - No

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

Skin/Hair

23. Extent of skin involvement:*(FGSKNINV)*
    - 0 - No Symptoms
    - 1 - <18% BSA with disease signs but NO sclerotic features
    - 2 - 19-50% BSA OR involvement with superficial sclerotic features not hidebound (able to pinch)
    - 3 - >50% BSA OR deep sclerotic features hidebound OR impaired mobility, ulceration, severe pruritis

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

a. Lichenoid:*(FGRSLICH)* ☐ 1 - Yes ☐ 2 - No

b. Maculopapular:*(FGRSMACU)* ☐ 1 - Yes ☐ 2 - No

c. Sclerodermatous:*(FGRSSCLR)* ☐ 1 - Yes ☐ 2 - No

d. Other:*(FGRSOTHR)* ☐ 1 - Yes ☐ 2 - No

Specify other rash:*(FGRSOTSP)*

Ocular

24. Xerophthalmia:*(FGXEROPH)*
    - 0 - No Symptoms
    - 1 - Dry Eyes but Not Requiring Therapy
    - 2 - Dryness of Eyes or Inflammation Requiring Therapy

Oral

25. Mucositis/ulcers (functional):*(FGMUCOS)*

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

Pulmonary

26. Bronchiolitis obliterans:*(FGBRNCH)*

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

27. FEV1:*(FGFEV1VL)* *(xxx)* %

Record the lowest value during this assessment period.

28. Date FEV1 obtained:*(FGFEV1DT)* *(mm/dd/yyyy)*

29. FVC:*(FGFVCVL)* *(xxx)* %

Record the value at the time of the lowest FEV1 measurement.

30. DLCO:*(FGDLCOVL)* *(xxx)* %

Record the value at the time of the lowest FEV1 measurement.

Gastrointestinal

31. Esophagus:*(FGESOPH)*

0 - No Symptoms
1 - Symptoms, Confirmed with Diagnostic Procedure

32. Nausea and vomiting:*(FGNAUSVM)*

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

33. Diarrhea:*(FGDIARH)*

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

Hepatic

Record the highest value during this assessment period for the following:

	Highest Value	Date Sample Obtained
34. Bilirubin:	*(FGBILI)* *(xx.x)* mg/dL	*(FGBILIDT)* *(mm/dd/yyyy)*
35. ALT:	*(FGALT)* *(xxxx)* Units/L	*(FGALTDT)* *(mm/dd/yyyy)*
36. AST:	*(FGAST)* *(xxxx)* Units/L	*(FGASTDT)* *(mm/dd/yyyy)*
37. Alkaline Phosphatase:	*(FGALKPH)* *(xxxx)* Units/L	*(FGAKPHDT)* *(mm/dd/yyyy)*

Genitourinary

38. Non-infective vaginitis:*(FGVAGNIT)*

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

Musculoskeletal

39. Contractures:*(FGCONTRC)*

0 - No Symptoms/Undefined
1 - Mild Joint Contractures
2 - Moderate Joint Contractures
3 - Severe Joint Contractures

40. Myositis:*(FGMYOSIT)*

☐ 1 - Yes ☐ 2 - No

Hematologic

41. Eosinophilia:*(FGEOSINP)* ☐ 1 - Yes ☐ 2 - No

Other

42. Serositis:*(FGSEROS)* ☐ 1 - Yes ☐ 2 - No

43. Fascitis:*(FGFASCIT)* ☐ 1 - Yes ☐ 2 - No

44. Was there any other organ involvement?*(FGOTORGN)* ☐ 1 - Yes ☐ 2 - No

Specify other organ involvement:*(FGOTORSP)*

Biopsies Performed During this Assessment Period

45. Were any biopsies performed during this assessment period for suspected GVHD?*(FGBIOPSY)* ☐ 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:
46. *(FGBIO1TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO1SP)*	*(FGBIO1DT)* *(mm/dd/yyyy)*	*(FGBIO1RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
47. *(FGBIO2TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO2SP)*	*(FGBIO2DT)* *(mm/dd/yyyy)*	*(FGBIO2RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
48. *(FGBIO3TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO3SP)*	*(FGBIO3DT)* *(mm/dd/yyyy)*	*(FGBIO3RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
49. *(FGBIO4TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO4SP)*	*(FGBIO4DT)* *(mm/dd/yyyy)*	*(FGBIO4RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
50. *(FGBIO5TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO5SP)*	*(FGBIO5DT)* *(mm/dd/yyyy)*	*(FGBIO5RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
51. *(FGBIO6TY)* 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	*(FGBIO6SP)*	*(FGBIO6DT)* *(mm/dd/yyyy)*	*(FGBIO6RS)* 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal

GVHD Therapy

52. Was a specific therapy used to **treat** chronic GVHD during this assessment period?*(FGCHRTRT)*

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

Therapies used for GVHD prophylaxis should not be recorded here. Only report therapies that were initiated during this assessment period.

Treatment is defined as increasing the dose of an ongoing agent or addition of a new agent. Adjusting a drug taper does not qualify as treatment.

53. Date chronic GVHD treatment initiated:*(FGCTRTDT)* *(mm/dd/yyyy)*

If the date is out of range because the therapy was initiated during a previous assessment period, it should be entered on the previous form.

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

a. ALS, ALG, ATS, ATG:*(FGTHATG)* 1 - Yes 2 - No

b. Azathioprine:*(FGTHAZAT)* 1 - Yes 2 - No

c. Cyclosporine:*(FGTHCYCL)* 1 - Yes 2 - No

d. Systemic Corticosteroids:*(FGTHSYCO)* 1 - Yes 2 - No

e. Topical Corticosteroids:*(FGTHTPCO)* 1 - Yes 2 - No

f. Thalidomide:*(FGTHTHAL)* 1 - Yes 2 - No

g. Tacrolimus (FK 506, Prograf):*(FGTHTAC)* 1 - Yes 2 - No

h. Mycophenolate Mofetil (MMF, Cellcept):*(FGTHMMF)* 1 - Yes 2 - No

i. PUVA (Psoralen and UVA):*(FGTHPUVA)* 1 - Yes 2 - No

j. ECP (Extra-corporeal Photopheresis):*(FGTHECP)* 1 - Yes 2 - No

k. Sirolimus (Rapamycin):*(FGTHSIR)* 1 - Yes 2 - No

l. Etretinate:*(FGTHETR)* 1 - Yes 2 - No

m. Lamprene:*(FGTHLAMP)* 1 - Yes 2 - No

n. Etanercept:*(FGTHETAN)* 1 - Yes 2 - No

o. Zenapax (Daclizumab):*(FGTHZENA)* 1 - Yes 2 - No

p. Chloroquine Phosphate:*(FGTHCHPH)* 1 - Yes 2 - No

q. In Vivo Anti T-lymphocyte Monoclonal Antibody:*(FGTHMAB)* 1 - Yes 2 - No

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

r. In Vivo Immunotoxin:*(FGTHIMM)* 1 - Yes 2 - No

Specify in vivo immunotoxin used:*(FGTHIMSP)*

s. Other:*(FGTHOTHR)* 1 - Yes 2 - No

Specify other agent used:*(FGTHOTSP)*

Comments:*(FGVCOMM)*

Additional Selection Options for FGV

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Acute GVHD Form (GVH)

Web Version: 1.0; 10.14; 12-09-16

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

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

   The assessment for which you are entering data must have taken place within the above dates. If the patient was not seen during the assessment period specified above, please exit the form and request an exception for this form.
2. Immunosuppressant (prophylaxis) received:*(IMMUNORC)*
   - 0 - Prednisone
   - 1 - Cyclosporine
   - 2 - Tacrolimus
   - 3 - Not taken during assessment
3. Record most recent blood level of immunosuppressant (prophylaxis): *(TROUGHLV)* _____ *(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 - No Rash
   - 1 - Maculopapular Rash, <25% of Body Surface
   - 2 - Maculopapular Rash, 25-50% of Body Surface
   - 3 - Generalized Erythroderma
   - 4 - Generalized Erythroderma with Bullus Formation and Desquamation
6. Skin etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SETGVHD) ☐ 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 - Positive
   - 2 - Negative
   - 3 - Equivocal
   - 4 - Not Done
8. Upper GI abnormalities:*(GVHUPGIA)*
   - 0 - No Protracted Nausea and Vomiting
   - 1 - Persistent Nausea, Vomiting or Anorexia
9. Upper intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(UGIETGVH) ☐ 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 - Positive
2 - Negative
3 - Equivocal
4 - Not Done

11. Lower GI abnormalities:*(GVHINTA)*

0 - No Diarrhea
1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m^2
2 - Diarrhea >500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m^2
3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m^2
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 - Positive
2 - Negative
3 - Equivocal
4 - Not Done

14. Liver abnormalities:*(GVHLIVRA)*

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

15. Liver etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity	TPN
(LIVETGVH) ☐ 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 - Positive
2 - Negative
3 - Equivocal
4 - Not Done

17. Was any treatment of GVHD modified during this assessment period? ☐ 1 - Yes ☐ 2 - No
(GVHTHERP)

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

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

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

Specify other agent:*(GVHAGNSP)*

19. Indicate treatment modification:*(GVHTRMOD)*

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

Comments:*(GVHCOMM)*

Additional Selection Options for GVH

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

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

Blood and Marrow Transplant Clinical Trials Network

Hematopoiesis Form - 1203 (HF4)

Web Version: 1.0; 2.00; 10-16-15

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

1. Did the patient receive G-CSF during this assessment period?*(GCSFREC)* ☐ 1 - Yes ☐ 2 - No
   2. If 'Yes', was G-CSF initiated during this assessment period?*(GCSFIN)* ☐ 1 - Yes ☐ 2 - No
      3. Date G-CSF was initiated:*(GCSFDT)* _____ *(mm/dd/yyyy)*

4. Did the patient's ANC drop below 500/mm^3 after the initiation of the conditioning regimen?*(ANCDRP)* ☐ 1 - Yes ☐ 2 - No
   5. Did the patient achieve ANC $\geq$ 500/mm^3 for three consecutive measurements obtained on different days?*(ANCREC)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Previously Reported
      6. Record absolute neutrophil counts and dates obtained:

Day 1:	*(D1ANC)* _____ *(xxxxx)* /mm^3	*(D1ANCDT)* _____ *(mm/dd/yyyy)*
Day 2:	*(D2ANC)* _____ *(xxxxx)* /mm^3	*(D2ANCDT)* _____ *(mm/dd/yyyy)*
Day 3:	*(D3ANC)* _____ *(xxxxx)* /mm^3	*(D3ANCDT)* _____ *(mm/dd/yyyy)*

7. If 'No', record the most recent absolute neutrophil count:*(RECNTANC)* _____ *(xxxxx)* /mm^3
8. Date most recent absolute neutrophil count obtained:*(RCTANCDT)* _____ *(mm/dd/yyyy)*

Record Chimerism Assay Data for Marrow and/or Blood

Upload source documents for all chimerism results during the assessment period.

Marrow:

9. Was a chimerism assay performed on a marrow sample during this assessment period?*(MRWCHIM)* ☐ 1 - Yes ☐ 2 - No
10. Record date specimen collected:*(MRWCHIDT)* _____ *(mm/dd/yyyy)*
11. Record method of evaluation:*(MRWMTHD)*
    - 1 - Standard Cytogenetics
    - 2 - Fluorescent In Situ Hybridization (FISH)
    - 3 - Restriction Fragment-Length Polymorphisms (RFLP)
    - 4 - Polymerase Chain Reaction (PCR) [VNTR, STR, micro or mini satellite]
    - 5 - HLA Serotyping
    - *Additional Options Listed Below
12. Specify other method of evaluation:*(MRWMTHSP)* _____
13. Record marrow chimerism cell type:*(MRWTYPE)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes
14. Record marrow assay results:*(MRWRSLT)*
    - 1 - All Host Cells
    - 2 - All Donor Cells
    - 3 - Host and Donor
15. % Donor:*(MRWPCTD)* _____ *(xx)* %

Blood:

16. Was a chimerism assay performed on a blood sample during this assessment period?*(BLDCHIM)* ☐ 1 - Yes ☐ 2 - No
17. Record date specimen collected:*(BLDCHIDT)* _____ *(mm/dd/yyyy)*

18. Record method of evaluation:*(BLDMTHD)*

1 - Standard Cytogenetics
2 - Fluorescent In Situ Hybridization (FISH)
3 - Restriction Fragment-Length Polymorphisms (RFLP)
4 - Polymerase Chain Reaction (PCR) [VNTR, STR, micro or mini satellite]
5 - HLA Serotyping
*Additional Options Listed Below

19. Specify other method of evaluation:*(BLDMTHSP)*

20. Record blood chimerism cell type:*(BLDTYPE)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes

21. Record blood assay results:*(BLDRSLT)*

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

22. % Donor:*(BLDPCTD)* *(xx)* %

T Cell (CD3+):

23. Was a chimerism assay performed on a T cell sample during this assessment period?*(TCLCHIM)* ☐ 1 - Yes ☐ 2 - No

24. Record date specimen collected:*(TCLCHIDT)* *(mm/dd/yyyy)*

25. Record method of evaluation:*(TCLMTHD)*

1 - Standard Cytogenetics
2 - Fluorescent In Situ Hybridization (FISH)
3 - Restriction Fragment-Length Polymorphisms (RFLP)
4 - Polymerase Chain Reaction (PCR) [VNTR, STR, micro or mini satellite]
5 - HLA Serotyping
*Additional Options Listed Below

26. Specify other method of evaluation:*(TCLMTHSP)*

27. Record the type of T cell sample:*(TCLTYPE)* ☐ 1 - Blood ☐ 2 - Marrow

28. Record T cell assay results:*(TCLRSLT)*

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

29. % Donor:*(TCLPCTD)* *(xx)* %

Comments:*(HF4COMM)*

Additional Selection Options for HF4

Record method of evaluation:
9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Infection Form (IFN)

Web Version: 1.0; 3.00; 06-05-17

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

INFECTION I

1. Is Infection I a nonmicrobiologically defined infection?*(IFN1NMCR)* ☐ 1 - Yes ☐ 2 - No ?
   2. Did the patient have evidence of pneumonia or bronchopneumonia related to an infection?*(IFN1PTPN)* ☐ 1 - Yes ☐ 2 - No
      3. Did the patient require mechanical ventilation?*(IFN1PTVT)* ☐ 1 - Yes ☐ 2 - No
   4. Did the patient have typhlitis?*(IFN1PTTY)* ☐ 1 - Yes ☐ 2 - No
   5. Did the patient have severe sepsis without an identified organism?*(IFN1PSEP)* ☐ 1 - Yes ☐ 2 - No
   6. Type of infection:*(IFN1TYPE)*
      B - Bacteria
      V - Viral
      F - Fungal
      P - Protozoal
      O - Other
   7. Organism I:*(IFN1ORGN)*
      B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
      B02 - Agrobacterium radiobacter
      B03 - Alcaligenes xylosoxidans
      B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
      B05 - Bacillus (cereus, other species)
      *Additional Options Listed Below
      Specify other organism:*(IFN1OTSP)*
   8. Severity of infection:*(IFN1SVRT)*
      2 - Grade 2
      3 - Grade 3
9. Was there evidence of sepsis?*(IFN1EVSP)* ☐ 1 - Yes ☐ 2 - No
10. Was there evidence of new or worsening infiltrates at the time of the infection? *(IFN1EVIN)* ☐ 1 - Yes ☐ 2 - No

INFECTION II

11. Is Infection II a nonmicrobiologically defined infection?*(IFN2NMCR)* ☐ 1 - Yes ☐ 2 - No ?
    12. Did the patient have evidence of pneumonia or bronchopneumonia related to an infection?*(IFN2PTPN)* ☐ 1 - Yes ☐ 2 - No
        13. Did the patient require mechanical ventilation?*(IFN2PTVT)* ☐ 1 - Yes ☐ 2 - No
    14. Did the patient have typhlitis?*(IFN2PTTY)* ☐ 1 - Yes ☐ 2 - No
    15. Did the patient have severe sepsis without an identified organism?*(IFN2PSEP)* ☐ 1 - Yes ☐ 2 - No
    16. Type of infection:*(IFN2TYPE)*
        B - Bacteria
        V - Viral
        F - Fungal
        P - Protozoal
        O - Other
    17. Organism II:*(IFN2ORGN)*
        B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
        B02 - Agrobacterium radiobacter
        B03 - Alcaligenes xylosoxidans
        B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
        B05 - Bacillus (cereus, other species)
        *Additional Options Listed Below
        Specify other organism:*(IFN2OTSP)*

18. Severity of infection:*(IFN2SVRT)*

2 - Grade 2
3 - Grade 3

19. Was there evidence of sepsis?*(IFN2EVSP)* ☐ 1 - Yes ☐ 2 - No

20. Was there evidence of new or worsening infiltrates at the time of the infection? *(IFN2EVIN)* ☐ 1 - Yes ☐ 2 - No

INFECTION III

21. Is Infection III a nonmicrobiologically defined infection?*(IFN3NMCR)* ☐ 1 - Yes ☐ 2 - No ?

22. Did the patient have evidence of pneumonia or bronchopneumonia related to an infection?*(IFN3PTPN)* ☐ 1 - Yes ☐ 2 - No

23. Did the patient require mechanical ventilation?*(IFN3PTVT)* ☐ 1 - Yes ☐ 2 - No

24. Did the patient have typhlitis?*(IFN3PTTY)* ☐ 1 - Yes ☐ 2 - No

25. Did the patient have severe sepsis without an identified organism?*(IFN3PSEP)* ☐ 1 - Yes ☐ 2 - No

26. Type of infection:*(IFN3TYPE)*

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

27. Organism III:*(IFN3ORGN)*

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

Specify other organism:*(IFN3OTSP)*

28. Severity of infection:*(IFN3SVRT)*

2 - Grade 2
3 - Grade 3

29. Was there evidence of sepsis?*(IFN3EVSP)* ☐ 1 - Yes ☐ 2 - No

30. Was there evidence of new or worsening infiltrates at the time of the infection? *(IFN3EVIN)* ☐ 1 - Yes ☐ 2 - No

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

Provide agent(s) administered for the infection(s):

Agents administered for prophylaxis should not be reported.

32. 1st agent:*(IFN1AGNT)*

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

Specify other agent:*(IFN1AGSP)*

33. 2nd agent:*(IFN2AGNT)*

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

Specify other agent:*(IFN2AGSP)*

34. 3rd agent:*(IFN3AGNT)*

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

Specify other agent:*(IFN3AGSP)*

35. Were additional agents administered for the infection(s)?*(IFNADDAG)* ☐ 1 - Yes ☐ 2 - No

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

Comments: *(IFNCOMM)*

Additional Selection Options for IFN

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

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Medication Form - 1203 (MD7)

Web Version: 1.0; 1.00; 10-16-15

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

1. GVHD prophylaxis regimen received:*(MD7RXRCD)*

1 - Tacrolimus/Methotrexate/Bortezomib
2 - Tacrolimus/Methotrexate/Maraviroc
3 - Tacrolimus/MMF/Cyclophosphamide

Tacrolimus/Methotrexate/Bortezomib

2. Tacrolimus start date:*(MD7T1SDT)* *(mm/dd/yyyy)*

Record actual dose given and date given for methotrexate and bortezomib:

3.

	Methotrexate Dose	Date Given
Dose 1	*(MD71MX1)* *(xx.xx)* mg	*(MD71M1DT)* *(mm/dd/yyyy)*
Dose 2	*(MD71MX2)* *(xx.xx)* mg	*(MD71M2DT)* *(mm/dd/yyyy)*
Dose 3	*(MD71MX3)* *(xx.xx)* mg	*(MD71M3DT)* *(mm/dd/yyyy)*
Dose 4	*(MD71MX4)* *(xx.xx)* mg	*(MD71M4DT)* *(mm/dd/yyyy)*
	Bortezomib Dose	**Date Given**
Dose 1	*(MD7BRT1)* *(xx.xx)* mg	*(MD7BR1DT)* *(mm/dd/yyyy)*
Dose 2	*(MD7BRT2)* *(xx.xx)* mg	*(MD7BR2DT)* *(mm/dd/yyyy)*
Dose 3	*(MD7BRT3)* *(xx.xx)* mg	*(MD7BR3DT)* *(mm/dd/yyyy)*

Tacrolimus/Methotrexate/Maraviroc

4. Tacrolimus start date:*(MD7T2SDT)* *(mm/dd/yyyy)*

Record actual dose given and date given for methotrexate:

5.

	Methotrexate Dose	Date Given
Dose 1	*(MD72MX1)* *(xx.xx)* mg	*(MD72M1DT)* *(mm/dd/yyyy)*
Dose 2	*(MD72MX2)* *(xx.xx)* mg	*(MD72M2DT)* *(mm/dd/yyyy)*
Dose 3	*(MD72MX3)* *(xx.xx)* mg	*(MD72M3DT)* *(mm/dd/yyyy)*
Dose 4	*(MD72MX4)* *(xx.xx)* mg	*(MD72M4DT)* *(mm/dd/yyyy)*

6. Maraviroc start date:*(MD7MSTDT)* *(mm/dd/yyyy)*
7. Maraviroc end date:*(MD7MENDT)* *(mm/dd/yyyy)*
8. Was maraviroc dose-modified at any time during the administration period? *(MD7DSMOD)* ☐ 1 - Yes ☐ 2 - No
9. Did patient receive all doses of maraviroc as per protocol (2 times/day, Day -3 to Day 30 post-HSCT)?*(MD7MVALL)* ☐ 1 - Yes ☐ 2 - No
10. If no, how many doses of maraviroc were missed?*(MD7MVMS)* *(xx)*

11. Select reason for missed dose(s):*(MD7MVRS)*

1 - Hold, as specified in protocol
2 - Hold, not specified in protocol
3 - Patient non-compliance
4 - Medical staff error
5 - Other, specify

Specify other reason for missed dose(s):*(MD7MVRSP)*

Tacrolimus/Mycophenolate Mofetil/Cyclophosphamide

Record actual dose given and date given for cyclophosphamide:

12.

	Cyclophosphamide Dose	Date Given
Dose 1	*(MD7CY1)* *(xxxxx.x)* mg	*(MD7CY1DT)* *(mm/dd/yyyy)*
Dose 2	*(MD7CY2)* *(xxxxx.x)* mg	*(MD7CY2DT)* *(mm/dd/yyyy)*

13. Tacrolimus start date:*(MD7T3SDT)* *(mm/dd/yyyy)*

14. Mycophenolate mofetil (MMF) start date:*(MD7MFSDT)* *(mm/dd/yyyy)*

15. MMF end date:*(MD7MFEDT)* *(mm/dd/yyyy)*

16. Did patient receive all doses of MMF as per protocol (3 times/day, Day 5 to Day 35 post-HSCT)?*(MD7MFALL)* ☐ 1 - Yes ☐ 2 - No

17. If no, how many doses of MMF were missed?*(MD7MFMIS)* *(xxx)*

18. Select reason for missed dose(s):*(MD7MFRSN)*

1 - Toxicity
2 - Patient non-compliance
3 - Medical staff error
4 - Other, specify

Specify other reason for missed dose(s):*(MD7MFRSP)*

19. Was MMF continued after Day 35 post-HSCT?*(MD7MFP35)* ☐ 1 - Yes ☐ 2 - No

20. If Yes, select reason MMF was continued:*(MD7P35RS)*

1 - Active GVHD
2 - Administration error
3 - Other, specify

Specify other reason for continuation:*(MD7P35SP)*

Comments:*(MD7COMM)*

Blood and Marrow Transplant Clinical Trials Network

Chronic GVHD Provider Survey (PCG)

Web Version: 1.0; 1.04; 06-16-16

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

Instructions:

Please score a symptom only if you know or suspect it to be *related to chronic GVHD*. Subjective symptoms are acceptable. For example, joint tightness can be scored based on subjective findings despite the absence of objective limitations.

Please score symptoms present in the *last week*. Even if they may have resolved with treatment in the past week, if they were present recently and may possibly return, please score them.

1. Date of visit:*(PCGDATE)* _____ *(mm/dd/yyyy)*

		1	2	3
Skin Score	*(PCGSKIN)* ☐ No Symptoms	☐ <18% BSA with disease signs but NO sclerotic features	☐ 19-50% BSA OR involvement with superficial sclerotic features not hidebound (able to pinch)	☐ >50% BSA OR deep sclerotic feats. hidebound OR impaired mobility, ulceration or severe pruritis
Mouth Score	*(PCGMOUTH)* ☐ No Symptoms	☐ Mild symptoms with disease signs but not limiting oral intake significantly	☐ Moderate symptoms with signs with **partial** limitation of oral intake	☐ Severe symptoms with disease signs on examination with **major** limitation of oral intake
GI Tract Score	*(PCGGITRC)* ☐ No symptoms	☐ Symptoms: dysphagia, anorexia, nausea, vomiting, abdominal pain or diarrhea with weight loss (<5%)	☐ Symptoms associated with mild to moderate weight loss (5-15%)	☐ Symptoms with significant weight loss >15%, requires nutritional supplements OR esophageal dilation
Eye Score	*(PCGEYE)* ☐ No symptoms	☐ Mild dry eye not affecting ADL OR asymptomatic signs of kerato-conjunctivitis sicca	☐ Moderate dry eye partially affecting ADL WITHOUT vision impairment	☐ Severe dry eye symptoms significantly affecting ADL OR unable to work OR loss of vision
Joint and Fascia Score	*(PCGJOINT)* ☐ No symptoms	☐ Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting ADL	☐ Tightness of arms or legs OR joint contractures, erythema due to fasciitis, moderate decrease in ROM	☐ Contracture WITH significant decrease of ROM AND significant limitation of ADL
Genital Tract Score (score even if no GYN exam; score required for men, too)*(PCGNOEXM)* ☐ **No GYN Exam**	*(PCGGNITL)* ☐ No symptoms	☐ Symptomatic, mild distinct signs on exam and no effect on coitus, minimal discomfort w/ GYN exam	☐ Symptomatic, distinct signs on exam and mild dyspareunia or discomfort w/ GYN exam	☐ Symptomatic, advanced signs, severe pain with coitus or inability to insert vaginal spectrum
Lung Score	*(PCGLUNG)* ☐ No symptoms	☐ Mild symptoms (shortness of breath after climbing one flight of steps)	☐ Moderate symptoms (shortness of breath after walking on flat ground)	☐ Severe symptoms (shortness of breath at rest; requiring oxygen)

Please rate the severity of this person's chronic GVHD

on this scale	*(PCGSEV1)* ☐ 1 - None	☐ 2 - Mild	☐ 3 - Moderate	☐ 4 - Severe

and on this scale	*(PCGSEV2)* ☐ 0 - cGVHD symptoms are not at all severe	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 - cGVHD symptoms are most severe possible

Is an erythematous or maculopapular rash present?*(PCGRASH)* ☐ 1 - Yes ☐ 2 - No

Does the patient have nausea, vomiting or diarrhea?*(PCGVOMIT)* ☐ 1 - Yes ☐ 2 - No

Liver score to be completed using most recent LFTs from within +/- 2 weeks of the assessment

	0	1	2	3
Liver Score	*(PCGLIVER)* ☐ Normal LFTs	☐ Elevated bilirubin, alkaline phosphatase, AST or ALT < 2x ULN	☐ Bilirubin > 3 mg/dl or bilirubin, AST or ALT 2-5x ULN	☐ Bilirubin, AST or ALT > 5x ULN

Date LFT sample obtained:*(PCGLFTDT)* *(mm/dd/yyyy)*

PFT values from within one month of the assessment

% FEV1*(PCGFEV1)* *(xxx)* %	Date of FEV1*(PCGFEVDT)* *(mm/dd/yyyy)*	*(PCGFEVND)* ☐ Not Done
% DLCOc*(PCGDLCO)* *(xxx)* %	Date of DLCOc*(PCGDLCDT)* *(mm/dd/yyyy)*	*(PCGDLCND)* ☐ Not Done

Comments:*(PCGCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Progression/Relapse Form - 1203 (PRF)

Web Version: 1.0; 1.00; 10-16-15

Segment *(PROTSEG)*: A

1. Progression/Relapse date:*(PRFPRDT)* _____ *(mm/dd/yyyy)*
2. Disease type:*(PRFDISES)*

01 - Acute Lymphoblastic Leukemia (ALL)
02 - Acute Myelogenous Leukemia (AML)
03 - Chronic Myelogenous Leukemia (CML)
04 - Chronic Lymphocytic Leukemia (CLL)
05 - Myelodysplastic Syndrome (MDS)
*Additional Options Listed Below

Institution of any therapy to treat persistent, progressive or relapsed disease, including the withdrawal of immunosuppressive therapy or donor lymphocyte infusion, will be considered evidence of relapse/progression regardless of whether the criteria below were met.

Leukemia/MDS

3. Have leukemic blast cells reappeared in the peripheral blood?*(PRFLBPB)* ☐ 1 - Yes ☐ 2 - No
4. Date leukemic blasts reappeared:*(PRFLBPDT)* _____ *(mm/dd/yyyy)*
5. Have new dysplastic changes appeared or have previous dysplastic changes reappeared within the bone marrow?*(PRFDYSBM)* ☐ 1 - Yes ☐ 2 - No
6. Date dysplastic changes appeared or reappeared:*(PRFDYSDT)* _____ *(mm/dd/yyyy)*
7. Were leukemic blasts documented in the bone marrow after transplantation? *(PRFLB1BM)* ☐ 1 - Yes ☐ 2 - No
8. Date leukemic blasts documented:*(PRFLB1DT)* _____ *(mm/dd/yyyy)*
9. % leukemic blasts documented:*(PRFLB1PC)* _____ *(xxx.x)*
10. Were the leukemic blasts attributed to another cause (e.g. bone marrow regeneration)?*(PRFLBATT)* ☐ 1 - Yes ☐ 2 - No
11. Specify the other cause:*(PRFLBASP)* _____
12. Were leukemic blasts documented in the bone marrow after transplantation by a second biopsy?*(PRFLB2BM)* ☐ 1 - Yes ☐ 2 - No
13. Date leukemic blasts documented in second biopsy:*(PRFLB2DT)* _____ *(mm/dd/yyyy)*
14. % leukemic blasts documented in second biopsy:*(PRFLB2PC)* _____ *(xxx.x)*
15. Was leukemia detected at an extramedullary site?*(PRFLBEXT)* ☐ 1 - Yes ☐ 2 - No
16. Date leukemia was first detected at an extramedullary site:*(PRFLBEDT)* _____ *(mm/dd/yyyy)*
17. Were leukemic cells detected in the cerebrospinal fluid?*(PRFLBCSF)* ☐ 1 - Yes ☐ 2 - No
18. Date leukemic cells were first detected in CSF:*(PRFCSFDT)* _____ *(mm/dd/yyyy)*
19. Was cytogenetic testing done?*(PRFCYT)* ☐ 1 - Yes ☐ 2 - No
20. Date of cytogenetic testing:*(PRFCYTDT)* _____ *(mm/dd/yyyy)*
21. Was there a reappearance of cytogenetic abnormalities present prior to transplantation?*(PRFCYTAB)* ☐ 1 - Yes ☐ 2 - No

Lymphoproliferative Diseases

Select which clinical or laboratory findings indicated progression or relapse:

22. CT:	*(PRFCT)* ☐ 1 - Yes ☐ 2 - No
23. MRI:	*(PRFMRI)* ☐ 1 - Yes ☐ 2 - No
24. PET Scan:	*(PRFPET)* ☐ 1 - Yes ☐ 2 - No
25. Ultrasound:	*(PRFULTSD)* ☐ 1 - Yes ☐ 2 - No

26. Physical Exam:	*(PRFPHYS)* ☐ 1 - Yes ☐ 2 - No
27. Biopsy:	*(PRFBIOPS)* ☐ 1 - Yes ☐ 2 - No
If biopsy indicated progression or relapse, record the site(s) of the biopsy:	
Bone Marrow:	*(PRFBSBM)* ☐ 1 - Yes ☐ 2 - No
Lymph Node:	*(PRFBSLN)* ☐ 1 - Yes ☐ 2 - No
Extranodal Site:	*(PRFBSEN)* ☐ 1 - Yes ☐ 2 - No

28. Were there any new lesions or sites of disease?*(PRFLESN)* ☐ 1 - Yes ☐ 2 - No

29. Date of appearance of new lesions or sites of disease:*(PRFLESDT)* _____ *(mm/dd/yyyy)*

30. Was there a ≥50% increase from nadir in the sum of the product diameters (SPD) of any previously identified abnormal node?*(PRFSPDIN)* ☐ 1 - Yes ☐ 2 - No

31. Date of the occurrence:*(PRFSPDDT)* _____ *(mm/dd/yyyy)*

32. For patients with CLL, have circulating malignant cells phenotypically characteristic of CLL reappeared?*(PRFCLLRL)* ☐ 1 - Yes ☐ 2 - No

33. Date circulating malignant cells reappeared:*(PRFCLLDT)* _____ *(mm/dd/yyyy)*

Comments:*(PRFCOMM)*

Additional Selection Options for PRF

Disease type:
06 - Small Lymphocytic Lymphoma (SLL)
07 - Follicular Lymphoma
08 - Marginal Zone Lymphoma
09 - Diffuse Large B-Cell Lymphoma (DLBL)
10 - Mantle Cell Lymphoma
11 - Hodgkin's Lymphoma

Blood and Marrow Transplant Clinical Trials Network

Specimen Acquisition Form - 1203 (S12)

Web Version: 1.0; 1.00; 10-16-15

Segment *(PROTSEG)*: A

Visit Number *(VISNO)*:

Optional Patient Samples for Future Testing

1. Was a serum sample drawn for future Proteomic testing?*(S12SERUM)* ☐ 1 - Yes ☐ 2 - No
2. Date serum sample was collected:*(S12SERDT)* _____ *(mm/dd/yyyy)*
3. Was a Whole Blood sample collected for future Genomic DNA Isolation research?*(S12WHOBL)* ☐ 1 - Yes ☐ 2 - No
4. Date Whole Blood sample was collected:*(S12WBLDT)* _____ *(mm/dd/yyyy)*
5. Was a PBMC sample collected for future Cell-Functional and Gene Expression research?*(S12PBMC)* ☐ 1 - Yes ☐ 2 - No
6. Date PBMC sample was collected:*(S12PBMDT)* _____ *(mm/dd/yyyy)*

IMPORTANT: Remember to enter the sample into the GlobalTrace Specimen Tracking System the same day it is collected.

Comments:*(S12COMM)*

Blood and Marrow Transplant Clinical Trials Network

Secondary Graft Failure (SGR)

Web Version: 1.0; 4.01; 01-04-17

Segment *(PROTSEG)*: A

Secondary Graft Fail Date *(SGFDATE)*:

1. Was there a decline in neutrophil counts to <500/mm^3 for three consecutive measurements on different days after initial neutrophil engraftment?*(DECLANC)* ☐ 1 - Yes ☐ 2 - No

2. Record the first three consecutive neutrophil counts and specimen collection dates:

Day 1:	*(DAY1ANC)*	*(xxx)* /mm^3	*(SG1ANCDT)*	*(mm/dd/yyyy)*
Day 2:	*(DAY2ANC)*	*(xxx)* /mm^3	*(SG2ANCDT)*	*(mm/dd/yyyy)*
Day 3:	*(DAY3ANC)*	*(xxx)* /mm^3	*(SG3ANCDT)*	*(mm/dd/yyyy)*

3. Was growth factor administered following the decline in neutrophil counts? *(GIVEGF)* ☐ 1 - Yes ☐ 2 - No

4. Has the percent of donor chimerism decreased to <5% donor?*(DONDEC)* ☐ 1 - Yes ☐ 2 - No

5. Record percent donor cell:*(PERDONOR)* *(x)* %

6. Record date of collection of the sample indicating secondary graft failure: *(TCCHIMDT)* *(mm/dd/yyyy)*

Comments:*(SGRCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 1203 (T23)

Web Version: 1.0; 2.02; 06-16-16

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

1. Record date of evaluation:*(TXYEVLDT)* _____ *(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 4.02.

Note that toxicities may be related to transplant or study drug.

General Disorders

2. Fever:*(TXFEVER)*
   - 0 - Grades 0-2
   - 3 - >40.0 degrees C (>104.0 degrees F) for < = 24 hours
   - 4 - >40 degrees C (>104.0 degrees F) for >24 hours
   - 5 - Death

3. Fatigue:*(T23FATIG)*
   - 0 - Grades 0-2
   - 3 - Fatigue not relieved by rest, limiting self care ADL

Immune System Disorders

4. Allergic reaction:*(ALRGCRXN)*
   - 0 - Grades 0-2
   - 3 - Prolonged; recurrence of symptoms following initial improvement; hospitalization indicated
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

5. Anaphylaxis:*(ANAPHYLX)*
   - 0 - No event
   - 3 - Symptomatic bronchospasm; parenteral intervention indicated; allergy-related edema/angioedema
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

GI Disorders

6. Oral mucositis:*(ORLMUCOS)*
   - 0 - Grades 0-2
   - 3 - Severe pain; interfering with oral intake
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

7. Nausea:*(TXNAUSEA)*
   - 0 - Grades 0-2
   - 3 - Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated

8. Vomiting:*(VOMIT)*
   - 0 - Grades 0-2
   - 3 - >=6 episodes [separated by 5 minutes] in 24 hrs; tube feeding, TPN or hospitalization indicated
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

9. Diarrhea:*(DIARRHEA)*
   - 0 - Grades 0-2
   - 3 - Increase of >=7 stools per day; incontinence; severe increase in ostomy; limiting self care ADL
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

10. Abdominal pain:*(T23ABDPN)*
    - 0 - Grades 0-2
    - 3 - Severe pain; limiting self care ADL

11. Anorexia:*(T23ANORX)*

0 - Grades 0-2
3 - Associated with significant weight loss or malnutrition; tube feeding or TPN indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

12. Constipation:*(T23CNSTP)*

0 - Grades 0-2
3 - Obstipation with manual evacuation indicated; limiting self care ADL
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

13. Dysgeusia (taste alteration):*(T23DYSGS)* ☐ 1 - Yes ☐ 2 - No

14. Dyspepsia (heartburn):*(T23DSPEP)*

0 - Grades 0-2
3 - Severe symptoms; surgical intervention indicated

15. Gastroenteritis:*(T23GASTR)*

0 - Grades 0-2
3 - Severely altered eating or gastric function; TPN or hospitalization indicated
4 - Life-threatening consequences; urgent operative intervention indicated
5 - Death

16. Intestinal obstruction:*(T23INTOB)* ☐ 1 - Yes ☐ 2 - No

Renal Disorders

17. Cystitis noninfective:*(CYSTNINF)*

0 - Grades 0-2
3 - Gross hematuria; transfusion, IV meds or hosp indicated;
4 - Life-threatening consequences; urgent radiologic or operative intervention indicated
5 - Death

18. Acute kidney injury:*(ACKIDINJ)*

0 - Grades 0-2
3 - Creatinine >3x baseline; >4.0 mg/dL; hospitalization indicated
4 - Life-threatening consequences; dialysis indicated
5 - Death

19. Chronic kidney disease:*(CHKIDDIS)*

0 - Grades 0-2
3 - eGFR or CrCl 29-15 ml/min/1.73 m^2
4 - eGFR <15 ml/min/1.73 m^2; dialysis or renal transplant indicated
5 - Death

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

21. If yes, were laboratory values corrected? *(LBVALCOR)* ☐ 1 - Yes ☐ 2 - No

22. Serum creatinine:*(T23CREAT)*

0 - Grades 0-2
3 - >3.0 baseline; >3.0 - 6.0 x ULN
4 - >6.0 x ULN

Hemorrhagic Disorders

23. Hemorrhage:*(HEMORRHG)*

0 - Grades 0-2
3 - Transfusion, radiologic, endoscopic, or elective operative intervention indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

24. Which organ system was the hemorrhage associated with?*(ORGSYHEM)*

1 - CNS
2 - Gastrointestinal
3 - Genitourinary
4 - Pulmonary, Upper Respiratory
5 - Other

Specify other organ system: *(ORGSYHSP)*

Cardiac Disorders

25. Hypotension:*(HYPOTEN)*

0 - Grades 0-2
3 - Medical intervention or hospitalization indicated
4 - Life-threatening and urgent intervention indicated
5 - Death

26. Hypertension:*(HYPERTSN)*

0 - Grades 0-2
3 - Stage 2 [SBP 160+ mmHg or DBP 100+ mmHg]; medical intervention indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

27. Cardiac arrhythmia:*(CRDARRHY)*

0 - Grades 0-2
3 - Severe, medically significant; medical intervention indicated
4 - Life-threatening consequences; hemodynamic compromise; urgent intervention indicated
5 - Death

28. Specify arrhythmia:*(CRDARRSP)*

29. Myocardial infarction:*(MYOCDINF)*

0 - Grades 0-2
3 - Severe symptoms; hemodynamically stable; ECG changes consistent with infarction
4 - Life-threatening consequences; hemodynamically unstable
5 - Death

30. Left ventricular systolic dysfunction: *(LFVTSYDF)*

0 - Grades 0-2
3 - Symptomatic due to drop in ejection fraction responsive to intervention
4 - Refractory or poorly controlled HF; ventricular device, iv vaso, or heart transplant indicated
5 - Death

31. Pericardial effusion:*(PERCRDEF)*

0 - Grades 0-2
3 - Effusion with physiologic consequences
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

32. Restrictive cardiomyopathy:*(RSTCDMYP)*

0 - No event
3 - Symptomatic heart failure or other cardiac symptoms, responsive to intervention
4 - Refractory heart failure or other poorly controlled cardiac symptoms
5 - Death

33. New or worsening heart failure:*(T23HFAIL)*

0 - Grades 0-2
3 - Severe with symptoms at rest or with minimal activity or exertion; intervention indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

34. Pericarditis:*(T23PERCD)*

0 - Grades 0-2
3 - Pericarditis with physiologic consequences (e.g., pericardial constriction)
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

35. Peripheral edema:*(T23PERED)*

0 - Grades 0-2
3 - >30% inter-limb discrepancy in volume;gross deviation from normal contour;limiting self care ADL

Nervous System Disorders

36. Somnolence:*(SOMNOLN)*

0 - Grades 0-2
3 - Obtundation or Stupor
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

37. Seizure:*(TXSEIZR)*

0 - Grades 0-2
3 - Multiple seizures despite medical intervention
4 - Life-threatening; prolonged repetitive seizures
5 - Death

38. Neuropathy:*(NEURPTHY)*

0 - Grades 0-2
3 - Severe symptoms; limiting self care ADL
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

39. Specify neuropathy type:*(NEURTYSP)*

1 - Motor
2 - Sensory
3 - Both motor and sensory

40. Anxiety:*(T23ANXTY)*

0 - Grades 0-2
3 - Severe symptoms; limiting self-care ADL; hospitalization not indicated
4 - Life-threatening; hospitalization indicated
5 - Death

41. Confusion:*(T23CNFUS)*

0 - Grades 0-2
3 - Severe disorientation; limiting self care ADL
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

42. Depression:*(T23DEPRS)*

0 - Grades 0-2
3 - Severe depressive symptoms; limiting self care ADL; hospitalization not indicated
4 - Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5 - Death

43. Dizziness:*(T23DIZZY)*

0 - Grades 0-2
3 - Severe unsteadiness or sensation of movement; limiting self care ADL

44. Encephalopathy:*(T23ENCEP)*

☐ 1 - Yes ☐ 2 - No

45. Headache:*(T23HDACH)*

0 - Grades 0-2
3 - Severe pain; limiting self care ADL

46. Insomnia:*(T23INSOM)*

0 - Grade 0-2
3 - Severe difficulty in falling asleep, staying asleep or waking up early

47. Reversible posterior leukoencephalopathy syndrome (PRES):*(T23PRES)*

0 - Grades 0-2
3 - Severe symptoms; very abnormal imaging studies; limiting self care ADL
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

48. Severe muscle weakness/paralysis: *(T23PARAL)*

☐ 1 - Yes ☐ 2 - No

49. Syncope (fainting):*(T23SYNCP)*

0 - No event
3 - Fainting; orthostatic collapse

Blood and Lymphatic Disorders

50. Thrombotic thrombocytopenic purpura: *(THRMBPUR)*

0 - Grades 0-2
3 - Laboratory findings with clinical consequences [e.g., renal insufficiency, petechiae]
4 - Life-threatening consequences [e.g., CNS hemorrhage or thrombosis/embolism or renal failure]
5 - Death

51. Anemia:*(T23ANEM)*

0 - Grades 0-2
3 - Hgb <8.0-6.5g/dL; <4.9-4.0mmol/L; <80-65g/L; transfusion indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

52. Neutropenia (neutrophil count decreased): *(T23NEUTR)*

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

53. Thrombocytopenia (platelet count decreased): *(T23THROM)*

0 - Grades 0 - 2
3 - <50,000 - 25,000/mm^3 or <50.0 - 25.0 x 10^9/L
4 - <25,000/mm^3 or <25.0 x 10^9/L
5 - Death

Vascular Disorders

54. Capillary leak syndrome:*(CAPLKSYN)*

0 - Grades 0-2
3 - Severe symptoms; intervention indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

55. Thromboembolic event:*(THROMBEV)*

0 - Grades 0-2
3 - Thrombosis; medical intervention indicated
4 - Life-threatening; urgent intervention indicated
5 - Death

Musculoskeletal and Connective Tissue Disorders

56. Arthralgia (joint pain):*(T23ARTHR)*

0 - Grades 0-2
3 - Severe pain; limiting self care ADL

57. Myalgia (muscle pain):*(T23MYALG)*

0 - Grades 0-2
3 - Severe pain; limiting self care ADL

58. Muscle weakness, generalized or specific area (not due to neuropathy):*(T23MUSCL)*

0 - Grades 0-2
3 - Weakness limiting self care ADL; disabling

Respiratory, Thoracic and Mediastinal Disorders

59. Hypoxia:*(TXHYPXIA)*

0 - Grades 0-2
3 - Decreased oxygen saturation at rest (e.g. pulse oximeter <88% or PaO2 <= 55 mm Hg)
4 - Life-threatening airway compromise; urgent intervention indicated
5 - Death

60. Dyspnea:*(TXDYSPNA)*

0 - Grades 0-2
3 - Shortness of breath at rest; limiting self care ADL
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

61. Cough:*(T23COUGH)*

0 - Grades 0-2
3 - Severe symptoms; limiting self care ADL

62. Pleural effusion:*(T23PLEFU)*

0 - Grades 0-2
3 - Symptomatic w resp distress & hypoxia;surgical intervention incl chest tube or pleurodesis indic
4 - Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indic
5 - Death

63. Sinusitis:*(T23SINUS)*

0 - Grades 0-2
3 - IV antibiotic, antifungal, antiviral int indic; radiologic, endoscopic, operarative int indic
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

64. Sore throat:*(T23SRTHT)*

0 - Grades 0-2
3 - Severe pain; limiting self care ADL; limiting ability to swallow

Metabolism and Nutrition Disorders

65. Hypercalcemia:*(T23HYPRC)*

0 - Grades 0-2
3 - Ca >12.5 - 13.5 mg/dL;>3.1 - 3.4 mmol/L; Ca(ion)>1.6 - 1.8 mmol/L; hospitalization indicated
4 - Ca >13.5 mg/dL; >3.4 mmol/L; Ca(ion) >1.8 mmol/L; life-threatening consequences
5 - Death

66. Hyperglycemia:*(HYPRGLYC)*

0 - Grades 0-2
3 - >250-500 mg/dL; >13.9-27.8 mmol/L; hospitalization indicated
4 - >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5 - Death

67. Hypoglycemia:*(T23HYPOG)*

0 - Grades 0-2
3 - <40 - 30 mg/dL; <2.2 - 1.7 mmol/L
4 - <30 mg/dL; <1.7 mmol/L; life-threatening consequences; seizures
5 - Death

68. Hypokalemia:*(T23HYPOK)*

0 - Grades 0-2
3 - <3.0 - 2.5 mmol/L; hospitalization indicated
4 - <2.5 mmol/L; life-threatening consequences
5 - Death

69. Hyponatremia:*(T23HYPON)*

0 - Grades 0-2
3 - <130 - 120 mmol/L
4 - <120 mmol/L; life-threatening consequences
5 - Death

70. Tumor lysis syndrome:*(T23TMLYS)* ☐ 1 - Yes ☐ 2 - No

Auditory Disorders

71. Hearing loss:*(T23HEAR)*

0 - Grades 0-2
3 - Hearing loss with hearing aid or intervention indicated; limiting self care ADL.
4 - Profound bilateral hearing loss (threshold >80dB HL at kHz and above); non-serviceable hearing

Skin and Subcutaneous Tissue Disorders

72. Pruritus/itching:*(T23PRURI)*

0 - Grades 0-2
3 - Intense, widespread; limiting self care ADL/sleep; oral steroid or immunosuppressant indicated

73. Rash:*(T23RASH)*

0 - Grades 0-2
3 - Macules/papules covering >30% BSA +/- associated symptoms; limiting self care ADL
4 - Papules/pustules covering any % BSA, +/- pruritus; IV antibiotics indicated; life-threatening

74. Hyperhidrosis:*(T23HYPHD)*

0 - Grades 0-2
3 - Generalized at sites other than palms/soles/axillae; assoc w/ electrolyte/hemodynamic imbalance

Ocular/Visual Disorders

75. Blurred vision:*(T23BLRVS)*

0 - Grades 0-2
3 - Limiting self care ADL

76. Conjunctivitis:*(T23CNJCT)*

0 - Grades 0-2
3 - Limiting self care ADL

77. Sudden vision loss:*(T23VISLS)* ☐ 1 - Yes ☐ 2 - No

Hepatobiliary/Pancreas Disorders

78. Hepatitis:*(T23HEPAT)* ☐ 1 - Yes ☐ 2 - No

79. Liver failure:*(T23LVRFL)* ☐ 1 - Yes ☐ 2 - No

80. Pancreatitis:*(T23PANCR)*

0 - Grades 0-2
3 - Severe pain; vomiting; medical intervention indicated (e.g., analgesia, nutritional support)
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

81. ALT:*(TXALT)*

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

82. AST:*(TXAST)*

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

83. Alkaline phosphatase:*(TXALKPH)*

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

84. Bilirubin:*(TXBILIRB)*

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

Indicate all clinical signs/symptoms of abnormal liver functioning during this assessment period:

85. Jaundice:*(TXJAUND)* ☐ 1 - Yes ☐ 2 - No

86. Hepatomegaly:*(HEPTMGLY)* ☐ 1 - Yes ☐ 2 - No

87. Right upper quadrant pain:*(RTQUADPN)* ☐ 1 - Yes ☐ 2 - No

88. Weight gain (>5%) from baseline: *(TXWGHTGN)* ☐ 1 - Yes ☐ 2 - No

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
89. VOD:	(VODETIOL) 1 - Yes 2 - No	(VODBIOP) 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	(VODDOPP) 1 - Confirmed 2 - Not Confirmed 3 - Not Done
90. GVHD:	(GVHETIOL) 1 - Yes 2 - No	(GVHBIOP) 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	(GVHDOPP) 1 - Confirmed 2 - Not Confirmed 3 - Not Done
91. Infection:	(INFETIOL) 1 - Yes 2 - No	(INFBIOP) 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	(INFDOPP) 1 - Confirmed 2 - Not Confirmed 3 - Not Done
92. Other:	(OTHETIOL) 1 - Yes 2 - No	(OTHBIOP) 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	(OTHDOPP) 1 - Confirmed 2 - Not Confirmed 3 - Not Done
93. Unknown:	(UNKETIOL) 1 - Yes 2 - No	N/A	N/A

Specify other etiology:*(OTHETSP)*

Stem Cell Infusional Toxicities (Within 24 Hours of Infusion)

94. Allergic reaction/hypersensitivity:*(T23IALRG)*
0 - Grades 0-2
3 - Prolonged (not responsive); recurrence after initial improvement; hospitalization indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

95. Cardiac arrhythmia:*(T23ICRDA)*
0 - Grades 0-2
3 - Severe, medically significant; medical intervention indicated
4 - Life-threatening consequences; hemodynamic compromise; urgent intervention indicated
5 - Death

96. Fever:*(T23IFEVR)*
0 - Grades 0-2
3 - >40.0 degrees C (>104.0 degrees F) for < = 24 hours
4 - >40 degrees C (>104.0 degrees F) for >24 hours
5 - Death

97. Hypotension:*(T23IHYPO)*
0 - Grades 0-2
3 - Medical intervention or hospitalization indicated
4 - Life-threatening and urgent intervention indicated
5 - Death

98. Hypertension:*(T23IHYPR)*
0 - Grades 0-2
3 - Stage 2 [SBP 160+ mmHg or DBP 100+ mmHg]; medical intervention indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

99. Hypoxia:*(T23IHYPX)*
0 - Grades 0-2
3 - Decreased oxygen saturation at rest (e.g. pulse oximeter <88% or PaO2 <= 55 mm Hg)
4 - Life-threatening airway compromise; urgent intervention indicated
5 - Death

100. Rigors or chills:*(T23IRIGR)*
0 - Grades 0-2
3 - Severe or prolonged, not responsive to narcotics

101. Vomiting:*(T23IVOMT)*

0 - Grades 0-2
3 - >=6 episodes [separated by 5 minutes] in 24 hrs; tube feeding, TPN or hospitalization indicated
4 - Life-threatening consequences; urgent intervention indicated
5 - Death

Serious Adverse Event Reporting

102. Were there any toxicities that met the definition of a serious adverse event?*(T23SAEDF)*

☐ 1 - Yes ☐ 2 - No ?

103. Specify which toxicities met the definition of a serious adverse event:*(T23SAESP)*

Comments:*(T23COMM)*

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

Web Version: 1.0; 16.01; 10-03-16

Segment *(PROTSEG)*: A
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 patient weight on day of transplant:*(PTWGTTB)* _____ *(xxx.x)* kg
4. Record the $CD34^+$ cell count of the infused product:*(CDCNTINF)* _____ *(xxxx.xx)* x 10^6
5. Record the patient's pre-transplant CMV antibody (IgG) status:*(CMVSTAT)* ☐ 1 - Positive ☐ 2 - Negative
6. Record the stem cell source:*(TXPSTMSR)*
   - 1 - Peripheral Blood
   - 2 - Bone Marrow

Comments:*(COMMTXP1)*