Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

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

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

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

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

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

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

Comments:*(ADMCOMM1)*

Additional Selection Options for ADM

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

Blood and Marrow Transplant Clinical Trials Network

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

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

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

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

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

Comments:*(AE1COMM)*

Additional Selection Options for AE1

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

Blood and Marrow Transplant Clinical Trials Network

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

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

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

1. Report activation status:*(AVSTAT_A)*

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

Relevant Past Medical History

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

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

(SEMEDHX)

3. **Event Summary**

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

(SESUMM)

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

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

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 4.00; 06-14-12

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

1. Report activation status:*(AVSTAT_B)*

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

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

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

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

Comments:*(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 3.06; 06-14-12

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

1. Report activation status:*(AVSTAT_C)*

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

Laboratory Test Results

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

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

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

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

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

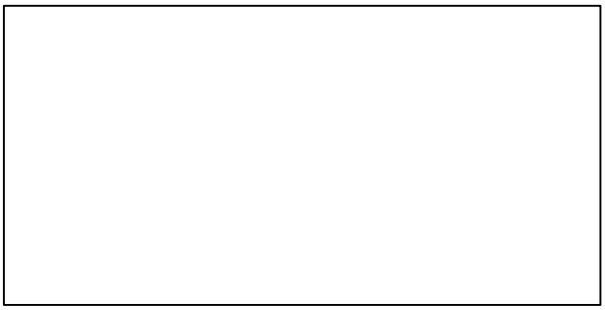
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

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

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

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

Comments:*(AE4COMM)*



Blood and Marrow Transplant Clinical Trials Network

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

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

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

1. Report activation status:*(AVSTAT_D)*

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

2. Reviewed:*(AEREVIEW)* ☐ 1 - Yes ☐ 2 - No

3. Reviewed by:*(ARFREVBY)*

4. Review date:*(ARFREVDT)* *(mm/dd/yyyy)*

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

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

Blood and Marrow Transplant Clinical Trials Network

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

Web Version: 1.0; 5.01; 06-14-12

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

1. Adverse event status:*(AVSTAT_E)*

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

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

Comments:*(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Follow Up GVHD Form (CGV)

Web Version: 1.0; 7.03; 05-15-12

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

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

Answer questions 3-9 relating to acute GVHD.

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

Answer questions 10-20 relating to chronic GVHD.

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

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

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

16. Minimum platelet count at time of diagnosis:*(PLTLTCNT)* *(xxx.x)* x 10^9/L

17. Alkaline phosphatase at time of diagnosis:*(ALKPHOSP)* *(xxxx)* U/L

18. Weight at time of diagnosis:*(CGVWEIGH)* *(xxx.x)* kg

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

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

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

Skin/Hair

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

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

?

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

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

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

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

Ocular

22. Xerophthalmia:*(DRYEYES)*

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

Oral

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

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

Pulmonary

24. Dyspnea:*(CGVDYSPN)*

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

25. Pulmonary fibrosis:*(PULMFIBR)*

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

26. Bronchiolitis obliterans:*(BRNCOBLT)*

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

27. FEV1:*(CGVFEV1)*

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

28. Oxygen saturation:*(O2SAT)*

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

Gastrointestinal

29. Esophagus:*(ESOPHAGS)*

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

30. Nausea and vomiting:*(NAUSVOMT)*

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

31. Diarrhea:*(CGVDIARH)*

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

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

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

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

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

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

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

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

35. Malabsorption:*(MALABSRP)*

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

Hepatic

36. Bilirubin level:*(LIVERBIL)*

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

Genitourinary

37. Vaginitis:*(VAGNITIS)*

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

Musculoskeletal

38. Contractures:*(CONTRCTR)*

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

39. Myositis:*(MYOSITIS)*

☐ 1 - Yes ☐ 2 - No

Hematologic

40. Eosinophilia:*(EOSINPHL)*

☐ 1 - Yes ☐ 2 - No

Other

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

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

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

Specify other organ:*(ORGSPEC)* _____

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

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

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

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

Answer questions 51-54 relating to GVHD therapy.

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

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

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

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

b. Azathioprine:*(THRPYAZA)*

c. Cyclosporine:*(THRPYCYC)*

d. Systemic Corticosteroids:*(THRPYSCO)*

e. Topical Corticosteroids:*(THRPYTCO)*

f. Thalidomide:*(THRPYTHA)*

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

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

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

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

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

l. Etretinate:*(THRPYETR)*

m. Lamprene:*(THRPYLAM)*

n. Etanercept:*(THRPYETA)*

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

p. Chloroquine Phosphate:*(THRPYCPH)*

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

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

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

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

r. In Vivo Immunotoxin: *(THRPYIMM)*

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

Specify in vivo immunotoxin used: *(IMMAGNT)*

s. Other: *(THRPYOTH)*

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

Specify other agent used: *(OTHAGNT)*

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

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

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

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

?

Answer questions 55-58 relating to current patient status.

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

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

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

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

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

Comments: *(CGVCOMM)*

Additional Selection Options for CGV

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

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

1. Name Code:*(NAMECODE)*
2. IUBMID # (if available):*(IUBMID)*
3. Gender:*(GENDER)* ☐ 1 - Male ☐ 2 - Female
4. Date of Birth:*(DOB)* *(mm/dd/yyyy)*
5. Ethnicity:*(ETHNIC)*

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

6. Race:*(RACE)*

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

Specify race:*(RACESP)*

7. Secondary Race:*(RACE2)*

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

Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

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

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

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

If yes, submit autopsy report to DCC

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

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

Specify other:*(DTHSPEC1)*

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

Specify other:*(DTHSPEC2)*

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

Specify other:*(DTHSPEC3)*

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

Specify other:*(DTHSPEC4)*

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

Specify other:*(DTHSPEC5)*

Comments:*(DTCMMNTS)*

Additional Selection Options for DTH

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

Blood and Marrow Transplant Clinical Trials Network

0402A (ENR)

Web Version: 1.0; 6.02; 06-14-12

GVHD Prophylaxis - Segment A

1. Record the date patient's informed consent form was signed: *(CN0402DT)* — *(mm/dd/yyyy)*
2. Patient's birthdate:*(PTDBTDT)* — 07/02/1972 *(mm/dd/yyyy)*
3. Record the proposed start date of conditioning:*(CONDDT)* — *(mm/dd/yyyy)*
4. Conditioning regimen:*(CONDREG)*
   - 1-1 - Cyclophosphamide and Total Body Irradiation (CY-TBI)
   - 2-2 - Etoposide and Total Body Irradiation (VP16-TBI)

Inclusion Criteria

5. Record the participant's primary diagnosis:*(PRIMDX)*
   - 1-1 - Acute Myelogenous Leukemia (AML)
   - 2-2 - Acute Lymphoblastic Leukemia (ALL)
   - 3-3 - Chronic Myelogenous Leukemia (CML)
   - 4-4 - Myelodysplastic Syndrome (MDS)
   - 5-5 - Acute Biphenotypic Leukemia

6. If AML, record the disease stage:*(AML402SG)*
   - 1-1 - First Remission
   - 2-2 - Second Remission
   - 3-3 - Subsequent Remission

7. If ALL, record the disease stage:*(ALL402SG)*
   - 1-1 - First Remission
   - 2-2 - Second Remission
   - 3-3 - Subsequent Remission

8. If CML, record the disease stage:*(CML402SG)*
   - 1-1 - Chronic Phase
   - 2-2 - Accelerated Phase

9. If MDS, record the disease stage:*(MDS402SG)*
   - 1-1 - Refractory Anemia
   - 2-2 - Refractory Anemia with Ringed Sideroblasts
   - 3-3 - Refractory Cytopenia with Multilineage Dysplasia
   - 4-4 - Refractory Cytopenia with Multilineage Dysplasia and Ringed Sideroblasts
   - 5-5 - Refractory Anemia with Excess Blasts - 1 (5-10% blasts)
   - *Additional Options Listed Below

10. If Acute Biphenotypic Leukemia, record the disease stage: *(ABL402SG)*
    - 1-1 - First Remission
    - 2-2 - Second Remission
    - 3-3 - Subsequent Remission

11. If Acute Biphenoytpic Leukemia, per which histology was the patient being treated?*(ABL402HT)*
    - 1-1 - Acute Myelogenous Leukemia (AML)
    - 2-2 - Acute Lymphoblastic Leukemia (ALL)

12. Performance status scale used to evaluate patient (Lansky for patients <16 years old; Karnofsky for patients ≥16 years old):*(PTKARLAN)* — ☐ 1 - Karnofsky ☐ 2 - Lansky
13. Record the patient's performance status:*(PTKLSCR)*
    - 01-01 - 100 (Normal; No Complaints/Fully Active)
    - 02-02 - 90 (Normal Activity/Minor Restriction in Strenuous Play)
    - 03-03 - 80 (Normal Activity with Effort/Restricted in Strenuous Play)
    - 04-04 - 70 (Unable to Carry On Normal Activity/Less Time Spent in Play)
    - 05-05 - 60 (Requires Occasional Assistance/Minimal Active Play)
    - *Additional Options Listed Below
14. If the patient is <18 years old, indicate if he/she is willing and able to take oral medications:*(ORALMED)* — ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

	Most Recent Value	LLN for your Institution	ULN for your Institution	Date Sample Obtained

15. Serum Creatinine:	*(SCRESCR)* *(x.x)* mg/dL	*(SCRELLN)* *(x.x)* mg/dL	*(SCREULN)* *(x.x)* mg/dL	*(SCREDT)* *(mm/dd/yyyy)*
16. Calculated Creatinine Clearance:	*(CRECLSCR)* *(xxx)* mL/min	N/A	N/A	*(CRECLDT)* *(mm/dd/yyyy)*
17. Direct Bilirubin:	*(BILISCR)* *(x.x)* mg/dL	N/A	*(BI402ULN)* *(x.x)* mg/dL	*(BILIDT)* *(mm/dd/yyyy)*
18. ALT:	*(ALTSCR)* *(xxx)* Units/L	N/A	*(AL402ULN)* *(xx)* Units/L	*(ALTDAT)* *(mm/dd/yyyy)*
19. AST:	*(ASTSCR)* *(xxx)* Units/L	N/A	*(AS402ULN)* *(xxx)* Units/L	*(ASTDAT)* *(mm/dd/yyyy)*
20. Cholesterol:	*(CHOLSCR)* *(xxx)* mg/dL	N/A	N/A	*(CHOLDT)* *(mm/dd/yyyy)*
21. Triglycerides:	*(TRIGSCR)* *(xxx)* mg/dL	N/A	N/A	*(TRIGDT)* *(mm/dd/yyyy)*

22. Were pulmonary function tests performed? *(PULFTST)* ☐ 1 - Yes ☐ 2 - No

If PFT's were not performed, then an O_2 saturation must be obtained.

	Most Recent Value Corrected for Hemoglobin	Date Sample Obtained
23. FVC:	*(FVCSCR)* *(xxx)* % of predicted value	*(FVCDAT)* *(mm/dd/yyyy)*
24. FEV1:	*(FEV1SCR)* *(xxx)* % of predicted value	*(FEV1DAT)* *(mm/dd/yyyy)*

25. O_2 saturation on room air: *(O2SATTST)* *(xxx)* % Date O_2 saturation was obtained: *(O2SATDT)* *(mm/dd/yyyy)*

26. Record the type of fraction test performed: *(FR0402TY)*

1 - 1 - Left Ventricular Ejection Fraction (LVEF)
2 - 2 - Shortening Fraction

27. Record the left ventricular ejection fraction: *(EJTFRSCR)* *(xxx)* % Date ejection fraction performed: *(EJTFRDT)* *(mm/dd/yyyy)*

28. Record the shortening fraction at rest: *(SHTFRSCR)* *(xxx)* % Date shortening fraction performed: *(SHTFRDT)* *(mm/dd/yyyy)*

Exclusion Criteria

29. Has the participant had a prior allogeneic or autologous transplant? *(PRIORTXP)* ☐ 1 - Yes ☐ 2 - No

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

31. Is the patient diagnosed with an uncontrolled viral, bacterial, or fungal infection? *(VIBAFUIF)* ☐ 1 - Yes ☐ 2 - No

32. Is the patient pregnant (positive serum or urine β-HCG) or breast feeding? *(PREGSCR)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

33. Does the patient have a documented allergy to Sirolimus? *(SIROALG)* ☐ 1 - Yes ☐ 2 - No

34. Is the patient currently receiving Voriconazole? *(VORIRX)* ☐ 1 - Yes ☐ 2 - No

35. Is the patient receiving an investigational drug? *(INVSDG)*

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

36. Date approved by study chair/medical monitor: *(DGAPPDT)* *(mm/dd/yyyy)*

37. Does the patient have a history of prior malignancies other than resected basal cell carcinoma, treated carcinoma in situ or cancer treated with curative intent >5 years previously? *(MALIGSCR)* ☐ 1 - Yes ☐ 2 - No

38. Does the patient have a cancer treated with curative intent ≤ 5 years previously? *(MALIG5YR)*

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

39. Date approved by study chair/medical monitor: *(MAAPPDT)* *(mm/dd/yyyy)*

HLA Typing

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

DNA_HIGH - High Level DNA
DNA_LOW - Low Level DNA
SEROLOGY - Serologic
AB_SEROLOGY_DRB1_DNA_LOW - Loci A,B: Serologic, Locus DRB1: Low Level DNA
AB_DNA_LOW_DRB1_DNA_HIGH - Loci A,B: Low Level DNA, Locus DRB1: High Level DNA
*Additional Options Listed Below

40. **Recipient HLA Typing**

HLA-A

Typing method:*(RHLAAMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided:*(RHLAANUM)*

1-1 -One
2-2 -Two

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

HLA-B

Typing method:*(RHLABMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided:*(RHLABNUM)*

1-1 -One
2-2 -Two

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

HLA-DRB1

Typing method:*(RHLADMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided:*(RHLADNUM)*

1-1 -One
2-2 -Two

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

41. Donor HLA Typing

HLA-A

Typing method:*(DHLAAMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided:*(DHLAANUM)*

1-1 -One
2-2 -Two

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

HLA-B

Typing method:*(DHLABMET)*

1-1 -DNA Technology
2-2 -Serology

Antigens/alleles provided:*(DHLABNUM)*

1-1 -One
2-2 -Two

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

(DHLAB25X) | *(DHLAB26X)* / | *(DHLAB27X)* / | *(DHLAB28X)* /

HLA-DRB1

Typing method:*(DHLADMET)*

1 - 1 - DNA Technology
2 - 2 - Serology

Antigens/alleles provided:*(DHLADNUM)*

1 - 1 - One
2 - 2 - Two

1st: *(DHLAD11X)* | *(DHLAD12X)* / | *(DHLAD13X)* / | *(DHLAD14X)* /

(DHLAD15X) | *(DHLAD16X)* / | *(DHLAD17X)* / | *(DHLAD18X)* /

2nd: *(DHLAD21X)* | *(DHLAD22X)* / | *(DHLAD23X)* / | *(DHLAD24X)* /

(DHLAD25X) | *(DHLAD26X)* / | *(DHLAD27X)* / | *(DHLAD28X)* /

HLA Match Score required by this protocol:*(HLASCREQ)*

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

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

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

Total calculated HLA Match Score*(HLASCORE)*

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

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

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

Comments*(COMMENTS)*

Additional Selection Options for ENR

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Follow Up Status Form (FUS)

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

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

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

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

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

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

4. Has the patient relapsed or experienced disease progression?*(RELAPSE)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Relapse Form must be submitted.

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

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

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

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

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

10.

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

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

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

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

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

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

Comments:*(FUS1COMM)*

Blood and Marrow Transplant Clinical Trials Network

Acute GVHD Form (GVH)

Web Version: 1.0; 10.05; 06-21-12

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

1. Date of staging:*(STAGEDT)* *(mm/dd/yyyy)*
   Start of GVHD Assessment Period:*(GVASSTDT)* *(mm/dd/yyyy)*
   End of GVHD Assessment Period:*(GVASENDT)* *(mm/dd/yyyy)*
2. Record the study drug assignment:*(GVHTRAS)* ☐ 1 - Sirolimus/Tacrolimus ☐ 2 - Tacrolimus/Methotrexate

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.

3. Immunosuppressant (prophylaxis) received:*(IMMUNORC)*
   0-0 - Prednisone
   1-1 - Cyclosporine
   2-2 - Tacrolimus
   3-3 - Not taken during assessment
4. Record most recent blood level of immunosuppressant (prophylaxis): *(TROUGHLV)* *(xxxx.x)* ng/mL
5. Record date blood sample obtained:*(TROUGHDT)* *(mm/dd/yyyy)* ?
6. Record most recent blood level of sirolimus:*(GVHSIRLV)* *(xxxx.x)* ng/mL
7. Record date blood sample obtained:*(GVHSIRDT)* *(mm/dd/yyyy)*

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

8. Skin abnormalities:*(GVHSKINA)*
   0-0 - No Rash
   1-1 - Maculopapular Rash, <25% of Body Surface
   2-2 - Maculopapular Rash, 25-50% of Body Surface
   3-3 - Generalized Erythroderma
   4-4 - Generalized Erythroderma with Bullus Formation and Desquamation
   ?
9. 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)*

10. Skin biopsy for GVHD:*(GVHSKINB)*
    1-1 - Positive
    2-2 - Negative
    3-3 - Equivocal
    4-4 - Not Done
11. Upper GI abnormalities:*(GVHUPGIA)*
    0-0 - No Protracted Nausea and Vomiting
    1-1 - Persistent Nausea, Vomiting or Anorexia
12. 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)*

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

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

14. Lower GI abnormalities:*(GVHINTA)*

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

?

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

15. 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)*

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

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

17. Liver abnormalities:*(GVHLIVRA)*

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

18. 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)*

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

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

') }

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

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

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

Specify other agent:*(GVHAGNSP)*

21. Indicate treatment modification:*(GVHTRMOD)*

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

Comments:*(GVHCOMM)*

Additional Selection Options for GVH

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

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

Blood and Marrow Transplant Clinical Trials Network

Myeloablative Hematopoiesis Form (HEM)

Web Version: 1.0; 7.01; 03-09-10

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

1. Did the patient achieve ANC recovery ≥500/mm^3 on three consecutive days? *(ENGRFT1)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Previously Reported

2. Record neutrophil count and specimen collection dates:

Day 1:	*(ANCDAY1)*	*(xxxxx)* /mm^3	*(ANC1DT)*		*(mm/dd/yyyy)*
Day 2:	*(ANCDAY2)*	*(xxxxx)* /mm^3	*(ANC2DT)*		*(mm/dd/yyyy)*
Day 3:	*(ANCDAY3)*	*(xxxxx)* /mm^3	*(ANC3DT)*		*(mm/dd/yyyy)*

Record Chimerism Assay Data for Marrow and/or Blood

Marrow

3. Was a chimerism performed on a marrow sample? *(MRWDONE)* ☐ 1 - Yes ☐ 2 - No
4. Date specimen collected: *(MRWDT2)* *(mm/dd/yyyy)*
5. Method of evaluation: *(MTHOD1)*

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

Specify other: *(MRWSPEC)*

6. Cell type: *(MRWCLTYP)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes
7. Marrow assay results: *(MRWASSAY)*

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

8. % Donor: *(PCNTDNR1)* *(xx)* %

Blood

9. Was a chimerism performed on a blood sample? *(BLDDONE)* ☐ 1 - Yes ☐ 2 - No
10. Date specimen collected: *(BLDCHMDT)* *(mm/dd/yyyy)*
11. Method of evaluation: *(MTHOD2)*

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

Specify other: *(BLDSPEC)*

12. Cell type: *(BLDCLTYP)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes
13. Blood assay results: *(BLDASSAY)*

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

14. % Donor: *(PCNTDNR2)* *(xx)* %

T Cell Chimerism

15. Was a chimerism performed on a T cell sample? *(TCLDONE)* ☐ 1 - Yes ☐ 2 - No
16. Type of sample: *(TCLSMPL)* ☐ 1 - Blood ☐ 2 - Marrow
17. Date specimen collected: *(TCLDATE)* *(mm/dd/yyyy)*

18. Method of evaluation:*(MTHOD3)*

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

Specify other:*(TCLSPEC)*

19. T cell assay results:*(TCLASSAY)*

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

20. % Donor:*(PCNTDNR3)*

(xx) %

21. Did the patient receive a stem cell re-infusion due to inadequate hematopoietic function?*(REINFUSE)*

☐ 1 - Yes ☐ 2 - No

22. Record date of infusion:*(INFUSEDT)*

(mm/dd/yyyy)

Comments:*(HEMCOMM1)*

Additional Selection Options for HEM

Method of evaluation:
9-9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Infection Form (INF)

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

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

INFECTION I

1. Type of infection:*(INFTYP01)*

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

2. Organism I:*(ORGN01)*

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

?

If other specify:*(INFSPEC1)*

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

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

4. Severity of infection:*(SVRTY01)*

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

INFECTION II

5. Type of infection:*(INFTYP02)*

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

6. Organism II:*(ORGN02)*

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

If other specify:*(INFSPEC2)*

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

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

8. Severity of infection:*(SVRTY02)*

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

INFECTION III

9. Type of infection:*(INFTYP03)*

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

10. Organism III:*(ORGN03)*

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

If other specify:*(INFSPEC3)*

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

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

12. Severity of infection:*(SVRTY03)*

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

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

☐ 1 - Yes ☐ 2 - No

Provide agent(s) administered for this infectious period:

14. 1st agent:*(AGENT1)*

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

If other specify:*(AGTSPEC1)*

15. 2nd agent:*(AGENT2)*

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

If other specify:*(AGTSPEC2)*

16. 3rd agent:*(AGENT3)*

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

If other specify:*(AGTSPEC3)*

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

☐ 1 - Yes ☐ 2 - No

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

Comments:*(INFCOM)*

Additional Selection Options for INF

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

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Laboratory Assessment Form - 0402 (LA3)

Web Version: 1.0; 4.03; 09-15-10

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

Laboratory Assessments

1. Start of Assessment Period:*(LA3APST)* *(mm/dd/yyyy)*
2. End of Assessment Period:*(LA3APEND)* *(mm/dd/yyyy)*

CBC

	Most Recent Value	Date of Sample
3. Hematocrit	*(LA3HCT)* *(xx.x)* %	*(LA3HCTDT)* *(mm/dd/yyyy)*
4. Hemoglobin	*(LA3HGB)* *(xx.x)* g/dL	*(LA3HGBDT)* *(mm/dd/yyyy)*
5. WBC	*(LA3WBC)* *(xxxxxx)* /mcL	*(LA3WBCDT)* *(mm/dd/yyyy)*
6. Platelet Count	*(LA3PLAT)* *(xxxxxx)* /mcL	*(LA3PLADT)* *(mm/dd/yyyy)*
7. Neutrophils	*(LA3NEUT)* *(xxxxx)* /mcL	*(LA3NEUDT)* *(mm/dd/yyyy)*
8. Lymphocytes	*(LA3LYMP)* *(xxxxx)* /mcl	*(LA3LYMDT)* *(mm/dd/yyyy)*

Chemistry and LFT's

	Most Recent Value	Date of Sample
9. Creatinine	*(LA3CREAT)* *(x.x)* mg/dL	*(LA3CREDT)* *(mm/dd/yyyy)*
10. Bilirubin	*(LA3BILI)* *(xx.x)* mg/dL	*(LA3BILDT)* *(mm/dd/yyyy)*
11. Alkaline Phosphatase	*(LA3ALKPH)* *(xxxx)* IU/L	*(LA3APDT)* *(mm/dd/yyyy)*
12. AST	*(LA3AST)* *(xxxx)* IU/L	*(LA3ASTDT)* *(mm/dd/yyyy)*
13. ALT	*(LA3ALT)* *(xxxx)* IU/L	*(LA3ALTDT)* *(mm/dd/yyyy)*
14. Cholesterol	*(LA3CHOL)* *(xxx)* mg/dL	*(LA3CHODT)* *(mm/dd/yyyy)*
15. Triglycerides	*(LA3TRIG)* *(xxx)* mg/dL	*(LA3TRIDT)* *(mm/dd/yyyy)*
16. Sirolimus	*(LA3SIRO)* *(xxxx.x)* ng/mL	*(LA3SIRDT)* *(mm/dd/yyyy)*

17. What is the patient's Karnofsky / Lansky performance score?*(LA3KALAN)*

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

Comments:*(LA3CMNTS)*

Additional Selection Options for LA3

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

Blood and Marrow Transplant Clinical Trials Network

Mucositis Assessment Form (MUC)

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

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

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

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

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

First Mucositis Assessment

4. Indicate the date of the first mucositis assessment in the assessment period: *(MUC402DT)* _____ *(mm/dd/yyyy)*

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

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

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

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

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

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

17. WHO toxicity grade:*(TOX1SCR)*

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

Second Mucositis Assessment

18. Indicate the date of the second mucositis assessment in the assessment period: *(MUC402D2)* *(mm/dd/yyyy)*

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

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

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

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

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

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

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

31. WHO toxicity grade:*(TOX2SCR)*

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

Third Mucositis Assessment

32. Indicate the date of the third mucositis assessment in the assessment period: *(MUC402D3)* *(mm/dd/yyyy)*

33. Indicate what the patient was able to consume:*(MUC3DIET)*

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

34. If the patient is consuming liquids only or nothing per oral, is it due to oral mucositis?*(MUC3ORAL)* 1 - Yes 2 - No

35. If no, what does the patient believe he/she could eat based on how his/her mouth feels:*(MUC3EATS)*

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

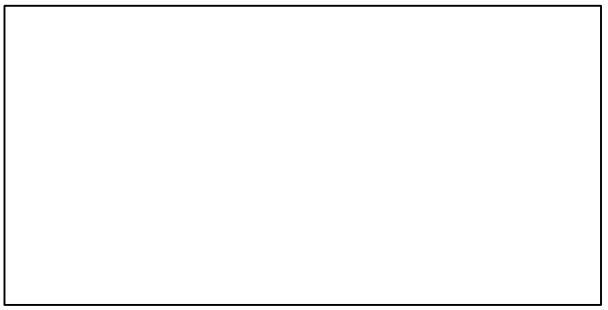
36. Indicate if patient is experiencing any mouth soreness or pain:*(MUC3PAIN)* 1 - Yes 2 - No

Anatomical Site	Presence of Ulceration	Degree of Erythema
37. Maxillary labial mucosa:	*(MAX3ULCR)* 1-1 - Yes 2-2 - No	*(MAX3ERYT)* 0-0 - None 1-1 - Mild to Moderate 2-2 - Severe
38. Mandibular labial mucosa:	*(MAN3ULCR)* 1-1 - Yes 2-2 - No	*(MAN3ERYT)* 0-0 - None 1-1 - Mild to Moderate 2-2 - Severe
39. Right buccal mucosa:	*(RBU3ULCR)* 1-1 - Yes 2-2 - No	*(RBU3ERYT)* 0-0 - None 1-1 - Mild to Moderate 2-2 - Severe
40. Left buccal mucosa:	*(LBU3ULCR)* 1-1 - Yes 2-2 - No	*(LBU3ERYT)* 0-0 - None 1-1 - Mild to Moderate 2-2 - Severe
41. Right lateral and ventral tongue:	*(RTN3ULCR)* 1-1 - Yes 2-2 - No	*(RTN3ERYT)* 0-0 - None 1-1 - Mild to Moderate 2-2 - Severe
42. Left lateral and ventral tongue:	*(LTN3ULCR)* 1-1 - Yes 2-2 - No	*(LTN3ERYT)* 0-0 - None 1-1 - Mild to Moderate 2-2 - Severe
43. Floor of mouth and lingual frenum:	*(MTH3ULCR)* 1-1 - Yes 2-2 - No	*(MTH3ERYT)* 0-0 - None 1-1 - Mild to Moderate 2-2 - Severe
44. Soft palate and fauces:	*(PAL3ULCR)* 1-1 - Yes 2-2 - No	*(PAL3ERYT)* 0-0 - None 1-1 - Mild to Moderate 2-2 - Severe

45. WHO toxicity grade:*(TOX3SCR)*

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

Comments:*(MUCCOMM)*



Blood and Marrow Transplant Clinical Trials Network

Endpoint Review Query Form- 0402 (Q04)

Web Version: 1.0; 1.01; 01-10-12

Case ID *(CASEID)*:

Site:*(QXXSITE)*

Patient ID:*(QXXPATID)*

Number of Queries Indicated:*(QRYNUM)*

Queries

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

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

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

Query Status	Date Query Sent	Query	Date Response Received	Query Response

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT04) 1-1- Resolved 2-2- Not Yet Sent To Site 3-3- Pending Site Response 4-4- Never Resolved	*(QSNTDT04)* *(mm/dd/yyyy)*	*(QDESC04)*	*(QRSPDT04)* *(mm/dd/yyyy)*	*(QRSPNS04)*
(QSTAT05) 1-1- Resolved 2-2- Not Yet Sent To Site 3-3- Pending Site Response 4-4- Never Resolved	*(QSNTDT05)* *(mm/dd/yyyy)*	*(QDESC05)*	*(QRSPDT05)* *(mm/dd/yyyy)*	*(QRSPNS05)*
(QSTAT06) 1-1- Resolved 2-2- Not Yet Sent To Site 3-3- Pending Site Response 4-4- Never Resolved	*(QSNTDT06)* *(mm/dd/yyyy)*	*(QDESC06)*	*(QRSPDT06)* *(mm/dd/yyyy)*	*(QRSPNS06)*
(QSTAT07) 1-1- Resolved 2-2- Not Yet Sent To Site 3-3- Pending Site Response 4-4- Never Resolved	*(QSNTDT07)* *(mm/dd/yyyy)*	*(QDESC07)*	*(QRSPDT07)* *(mm/dd/yyyy)*	*(QRSPNS07)*
(QSTAT08) 1-1- Resolved 2-2- Not Yet Sent To Site 3-3- Pending Site Response 4-4- Never Resolved	*(QSNTDT08)* *(mm/dd/yyyy)*	*(QDESC08)*	*(QRSPDT08)* *(mm/dd/yyyy)*	*(QRSPNS08)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT09) 1-1- Resolved 2-2- Not Yet Sent To Site 3-3- Pending Site Response 4-4- Never Resolved	*(QSNTDT09)* *(mm/dd/yyyy)*	*(QDESC09)*	*(QRSPDT09)* *(mm/dd/yyyy)*	*(QRSPNS09)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT10) 1-1- Resolved 2-2- Not Yet Sent To Site 3-3- Pending Site Response 4-4- Never Resolved	*(QSNTDT10)* *(mm/dd/yyyy)*	*(QDESC10)*	*(QRSPDT10)* *(mm/dd/yyyy)*	*(QRSPNS10)*

Blood and Marrow Transplant Clinical Trials Network

Relapse Form - 0402 (REL)

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

Disease Dx *(RELDX)*:

Acute Leukemia

1. Were leukemic blasts documented in the blood or bone marrow after transplantation?*(REALL1BL)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate the following:<\i>

2. Type of sample:*(RE1TYPE)* ☐ 1 - Blood ☐ 2 - Bone Marrow
3. Date blasts documented:*(REALL1DT)* _____ *(mm/dd/yyyy)*
4. % Leukemic blasts documented:*(REALL1PR)* _____ *(xxx)* %
5. Were these blasts supported by reappearance of cytogenetic abnormality? *(REALLCYT)* ☐ 1 - Yes ☐ 2 - No
6. Date of cytogenetic analysis:*(REALCYDT)* _____ *(mm/dd/yyyy)*
7. Were leukemic blasts documented in the blood or bone marrow after transplantation on a second occasion?*(REALL2BL)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate the following:<\i>

8. Type of sample:*(RE2TYPE)* ☐ 1 - Blood ☐ 2 - Bone Marrow
9. Date blasts documented on second occasion:*(REALL2DT)* _____ *(mm/dd/yyyy)*
10. % Leukemic blasts documented on second occasion:*(REALL2PR)* _____ *(xxx)* %

11. Was leukemia detected at an extramedullary site?*(REALEXTR)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate date disease first detected:*(REALEXDT)* _____ *(mm/dd/yyyy)*

Chronic Myelogenous Leukemia (CML)

Hematologic Relapse

12. Have immature hematopoietic cells been documented in the peripheral blood? *(RECM1IMM)* ☐ 1 - Yes ☐ 2 - No
13. If yes, indicate date cells first documented:*(RECMIMDT)* _____ *(mm/dd/yyyy)*
14. Has myeloid hyperplasia been documented in the bone marrow in the presence of cytogenetics relapse?*(RECMMYHY)* ☐ 1 - Yes ☐ 2 - No
15. If yes, indicate date myeloid hyperplasia first documented:*(RECMMYDT)* _____ *(mm/dd/yyyy)*

Cytogenetic Relapse

16. Have metaphases exhibiting 9;22 translocation been detected?*(RECM1CYT)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate the following:<\i>

17. Date of analysis:*(RECMC1DT)* _____ *(mm/dd/yyyy)*
18. Number of metaphases analyzed:*(RECM1AN)* _____ *(xxx)*
19. Number of metaphases exhibiting 9;22 translocation detected:*(RECMN1TR)* _____ *(xxx)*
20. Have metaphases exhibiting 9;22 translocation been detected on a second analysis?*(RECM2CYT)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate the following:<\i>

21. Date of second analysis:*(RECM2CDT)* _____ *(mm/dd/yyyy)*
22. Number of metaphases analyzed on second analysis:*(RECM2AN)* _____ *(xxx)*
23. Number of metaphases exhibiting 9;22 translocation detected on second analysis:*(RECMN2TR)* _____ *(xxx)*

Myelodysplastic Syndrome (MDS)

24. Have pre-transplant morphologic abnormalities reappeared in a bone marrow specimen?*(REMDMRA)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate the following:<\i>

25. Date specimen obtained:*(REMDM1DT)* _____ *(mm/dd/yyyy)*
26. Have the abnormalities reappeared on a second bone marrow specimen? *(REMD2MRA)* ☐ 1 - Yes ☐ 2 - No
27. If yes, indicate date second specimen obtained:*(REMDM2DT)* _____ *(mm/dd/yyyy)*

28. Have pre-transplant cytogenetic abnormalities reappeared?*(REMD1CY)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate the following:<\i>

29. Date of cytogenetic analysis:*(REMD1CDT)* *(mm/dd/yyyy)*
30. Number of metaphases analyzed:*(REMD1CYA)* *(xxx)*
31. Number of metaphases exhibiting pre-transplant cytogenetic abnormalities: *(REMD1CYN)* *(xxx)*
32. Have pre-transplant cytogenetic abnormalities reappeared on a second analysis?*(REMD2CY)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate the following:<\i>

33. Date of second cytogenetic analysis:*(REMD2CDT)* *(mm/dd/yyyy)*
34. Number of metaphases analyzed on second analysis:*(REMD2CYA)* *(xxx)*
35. Number of metaphases exhibiting pre-transplant cytogenetic abnormalities on second analysis:*(REMD2CYN)* *(xxx)*

Comments:*(RECOMM)*

Additional Selection Options for REL

Disease Dx *(RELDX)* (key field):
1-1 - Acute Myelogenous Leukemia (AML)
2-2 - Acute Lymphoblastic Leukemia (ALL)
3-3 - Chronic Myelogenous Leukemia (CML)
4-4 - Myelodysplastic Syndrome (MDS)

Blood and Marrow Transplant Clinical Trials Network

Research Sample Form - 0402 (RSF)

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

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

1. Did the patient (or if the patient is a minor, the parent/legal guardian) give consent to have blood drawn for research purposes?*(PTSCST)* ☐ 1 - Yes ☐ 2 - No
   Date patient consent signed:*(PTCNSDT)* _____ *(mm/dd/yyyy)*

2. Did the donor (or if the donor is a minor, the parent/legal guardian) give consent to have blood drawn for research purposes?*(DNRCST)* ☐ 1 - Yes ☐ 2 - No
   Date donor consent signed:*(DNRCNSDT)* _____ *(mm/dd/yyyy)*

Comments:*(RSFCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0402 (TX7)

Web Version: 1.0; 4.00; 09-15-10

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

1. Record date of evaluation:*(TX7EVLDT)* _____ *(mm/dd/yyyy)*
2. Randomization treatment assignment:*(TRTASIGN)* ☐ 1 - Sirolimus/Tacrolimus ☐ 2 - Tacrolimus/Methotrexate
3. Record the patient's body surface area (BSA):*(TX7BSA)* _____ *(x.xx)* m^2

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

GI Toxicity

4. Mucositis/stomatitis (clinical exam):*(TX7MCSTS)*

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

Mouth pain or esophageal pain requiring IV hydration/narcotics.

Renal Toxicity

5. Did the patient experience renal failure severe enough to warrant dialysis?*(TX7RENAL)* ☐ 1 - Yes ☐ 2 - No
6. Did the patient receive dialysis?*(TX7DIALS)* ☐ 1 - Yes ☐ 2 - No

7. Hemorrhagic cystitis:*(TX7CYSTI)*

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

Hemorrhagic Toxicity

8. Hemorrhage:*(TX7HEMRG)*

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

Cardiovascular Toxicity

9. Hypotension:*(TX7HYPOT)*

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

10. Cardiac arrhythmia:*(TX7CRDAR)*

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

11. Left ventricular systolic dysfunction:*(TX7LVENT)*

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

Neurologic Toxicity

12. Somnolence:*(TX7SMNLN)*

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

13. Did the patient experience any seizures during this assessment period?*(TX7SEIZR)* ☐ 1 - Yes ☐ 2 - No

14. Record seizure toxicity grade:*(TX7SZGRD)*

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

Coagulation Toxicity

15. HUS/TTP/thrombotic microangiopathy:*(TX7DIC)*

0-0 -None
1-1 -Evidence of RBC destruction (schistocytosis) without clinical consequences
3-3 -Laboratory findings present with clinical consequences (e.g. renal insufficiency, petechiae)
4-4 -Lab findings and LT or disabling consequences (e.g. CNS hemorrhage or thrombosis or renal failure)
5-5 -Death

Vascular Toxicity

16. Vascular leak syndrome:*(TX7VASLK)*

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

Pulmonary Toxicity

17. Hypoxia (for more than 24 hours):*(TX7HYPXI)*

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

18. Dyspnea:*(TX7DYSPN)*

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

19. During this assessment period, was an FEV1 performed? *(TX7FEVDN)*

☐ 1 - Yes ☐ 2 - No

20. Record FEV1 value obtained:*(TX7FEVVL)*

_____ *(xxx)* % of predicted value

21. During this assessment period, was an FVC performed? *(TX7FVCDN)*

☐ 1 - Yes ☐ 2 - No

22. Record FVC value obtained:*(TX7FVCVL)*

_____ *(xxx)* % of predicted value

Chemistry

23. Cholesterol:*(TX7CHOLE)*

0-0 -Grade 0-2
3-3 -400-500 mg/dL or >10.34-12.92 mmol/L
4-4 -500 mg/dL or >12.92 mmol/L
5-5 -Death

24. Triglycerides:*(TX7TRIGL)*

0-0 -Grade 0-2
3-3 ->5.0 -10.0 x ULN
4-4 -> 10.0 x ULN
5-5 -Death

Hepatic Toxicity

25. ALT:*(TX7ALT)*

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

26. AST:*(TX7AST)*

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

27. Bilirubin:*(TX7BILIR)*

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

28. Creatinine:*(TX7CREAT)*

0-0 -Grades 0-2
3-3 -> 3.0 - 6.0 x ULN
4-4 -> 6.0 x ULN
5-5 -Death

29. Alkaline Phosphatase:*(TX7ALKPH)*

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

30. Did the patient develop abnormal liver function during this assessment period?*(TX7ABNLF)* ☐ 1 - Yes ☐ 2 - No

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

31. Jaundice:*(TX7JANDC)* ☐ 1 - Yes ☐ 2 - No
32. Hepatomegaly:*(TX7HPTMG)* ☐ 1 - Yes ☐ 2 - No
33. Right upper quadrant pain:*(TX7QUADP)* ☐ 1 - Yes ☐ 2 - No
34. Weight gain (>5%) from baseline:*(TX7WGHTG)* ☐ 1 - Yes ☐ 2 - No
35. Other clinical signs/symptoms:*(TX7OTHAB)* ☐ 1 - Yes ☐ 2 - No

Specify other clinical signs/symptoms:*(TX7SPEC1)*

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
36. VOD:	*(TX7VODET)* 1-1 - Yes 2-2 - No	*(TX7VODBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - NotDone	*(TX7VODDP)* 1-1 - Confirmed 2-2 - NotConfirmed 3-3 - NotDone
37. GVHD:	*(TX7GVHET)* 1-1 - Yes 2-2 - No	*(TX7GVHBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - NotDone	*(TX7GVHDP)* 1-1 - Confirmed 2-2 - NotConfirmed 3-3 - NotDone
38. Infection:	*(TX7INFET)* 1-1 - Yes 2-2 - No	*(TX7INFBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - NotDone	*(TX7INFDP)* 1-1 - Confirmed 2-2 - NotConfirmed 3-3 - NotDone
39. Other:	*(TX7OTHET)* 1-1 - Yes 2-2 - No	*(TX7OTHBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - NotDone	*(TX7OTHDP)* 1-1 - Confirmed 2-2 - NotConfirmed 3-3 - NotDone
40. Unknown:	*(TX7UNKET)* 1-1 - Yes 2-2 - No	*(TX7UNKBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - NotDone	*(TX7UNKDP)* 1-1 - Confirmed 2-2 - NotConfirmed 3-3 - NotDone

Specify other etiology:*(TX7SPEC2)*

Record the methotrexate dosing for GVHD prophylaxis.

	Day 1	Day 3	Day 6	Day 11
41. Date:	*(MET1DT)* *(mm/dd/yyyy)*	*(MET2DT)* *(mm/dd/yyyy)*	*(MET3DT)* *(mm/dd/yyyy)*	*(MET4DT)* *(mm/dd/yyyy)*
42. Was the full dose given?	*(MET1FULL)* ☐ 1 - Yes ☐ 2 - No	*(MET2FULL)* ☐ 1 - Yes ☐ 2 - No	*(MET3FULL)* ☐ 1 - Yes ☐ 2 - No	*(MET4FULL)* ☐ 1 - Yes ☐ 2 - No
43. Total dose given:	*(MET1DOSE)* *(xx.x)* mg	*(MET2DOSE)* *(xx.x)* mg	*(MET3DOSE)* *(xx.x)* mg	*(MET4DOSE)* *(xx.x)* mg

Comments:*(TX7COMM)*

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

Web Version: 1.0; 12.00; 06-21-12

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

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

Comments:*(COMMTXP1)*