Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Version: 2.02; 06-24-08

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

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

Blood and Marrow Transplant Clinical Trials Network

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

Version: 2.03; 05-23-08

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

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

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

Comments: *(AE1COMM)*

Additional Selection Options for AE1

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

Blood and Marrow Transplant Clinical Trials Network

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

Version: 2.02; 05-23-08

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

1. Report activation status: *(AVSTAT_A)*

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

Relevant Past Medical History

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

(SEMEDHX)

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

(SESUMM)

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

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

Blood and Marrow Transplant Clinical Trials Network

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

Version: 2.02; 05-23-08

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

1. Report activation status: *(AVSTAT_B)*

1 - Keep report active
2 - Deactivate - Report filed in
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
(SPNAME1)	*(SP1DOSE)*	*(SP1ROUTE)*	*(SP1SCHED)*
(SPNAME2)	*(SP2DOSE)*	*(SP2ROUTE)*	*(SP2SCHED)*
(SPNAME3)	*(SP3DOSE)*	*(SP3ROUTE)*	*(SP3SCHED)*
(SPNAME4)	*(SP4DOSE)*	*(SP4ROUTE)*	*(SP4SCHED)*
(SPNAME5)	*(SP5DOSE)*	*(SP5ROUTE)*	*(SP5SCHED)*

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, Sche
(CONMED1)	*(CM1STDT)*	*(CM1SPDT)*	*(CM1DOSE)*
(CONMED2)	*(CM2STDT)*	*(CM2SPDT)*	*(CM2DOSE)*
(CONMED3)	*(CM3STDT)*	*(CM3SPDT)*	*(CM3DOSE)*
(CONMED4)	*(CM4STDT)*	*(CM4SPDT)*	*(CM4DOSE)*
(CONMED5)	*(CM5STDT)*	*(CM5SPDT)*	*(CM5DOSE)*

(CONMED6)	(CM6STDT)	(CM6SPDT)	(CM6DOSE)
(CONMED7)	(CM7STDT)	(CM7SPDT)	(CM7DOSE)
(CONMED8)	(CM8STDT)	(CM8SPDT)	(CM8DOSE)
(CONMED9)	(CM9STDT)	(CM9SPDT)	(CM9DOSE)
(CONMED10)	(CM10STDT)	(CM10SPDT)	(CM10DOSE)
(CONMED11)	(CM11STDT)	(CM11SPDT)	(CM11DOSE)
(CONMED12)	(CM12STDT)	(CM12SPDT)	(CM12DOSE)
(CONMED13)	(CM13STDT)	(CM13SPDT)	(CM13DOSE)
(CONMED14)	(CM14STDT)	(CM14SPDT)	(CM14DOSE)
(CONMED15)	(CM15STDT)	(CM15SPDT)	(CM15DOSE)
(CONMED16)	(CM16STDT)	(CM16SPDT)	(CM16DOSE)
(CONMED17)	(CM17STDT)	(CM17SPDT)	(CM17DOSE)
(CONMED18)	(CM18STDT)	(CM18SPDT)	(CM18DOSE)
(CONMED19)	(CM19STDT)	(CM19SPDT)	(CM19DOSE)
(CONMED20)	(CM20STDT)	(CM20SPDT)	(CM20DOSE)
(CONMED21)	(CM21STDT)	(CM21SPDT)	(CM21DOSE)
(CONMED22)	(CM22STDT)	(CM22SPDT)	(CM22DOSE)
(CONMED23)	(CM23STDT)	(CM23SPDT)	(CM23DOSE)

(CONMED24)	*(CM24STDT)*	*(CM24SPDT)*	*(CM24DOSE)*
(CONMED25)	*(CM25STDT)*	*(CM25SPDT)*	*(CM25DOSE)*

Comments: *(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

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

Version: 2.02; 05-23-08

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

1. Report activation status: *(AVSTAT_C)*

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

Laboratory Test Results

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

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

Test	Collection Date *(mm/dd/yyyy)*	Result (Include units)	Site Normal Range (Include units)
(ADLTST1)	*(ADL1CD)*	*(ADL1RES)*	*(ADL1NORG)*
(ADLTST2)	*(ADL2CD)*	*(ADL2RES)*	*(ADL2NORG)*
(ADLTST3)	*(ADL3CD)*	*(ADL3RES)*	*(ADL3NORG)*
(ADLTST4)	*(ADL4CD)*	*(ADL4RES)*	*(ADL4NORG)*
(ADLTST5)	*(ADL5CD)*	*(ADL5RES)*	*(ADL5NORG)*
(ADLTST6)	*(ADL6CD)*	*(ADL6RES)*	*(ADL6NORG)*
(ADLTST7)	*(ADL7CD)*	*(ADL7RES)*	*(ADL7NORG)*
(ADLTST8)	*(ADL8CD)*	*(ADL8RES)*	*(ADL8NORG)*
(ADLTST9)	*(ADL9CD)*	*(ADL9RES)*	*(ADL9NORG)*
(ADLTST10)	*(ADL10CD)*	*(ADL10RES)*	*(ADL10NRG)*

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)

Version: 2.02; 05-23-08

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

1. Report activation status: *(AVSTAT_D)*

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

2. Reviewed: *(AEREVIEW)* ☐ 1 - Yes ☐ 2 - No
3. Reviewed by: *(ARFREVBY)*
4. Review date: *(ARFREVDT)* *(mm/dd/yyyy)*
5. Comment 1 - For Distribution: *(ARCM1DIS)*
6. Comment 2 - All Other Reviewers/Data Coordinating Center *(ARCM2ALL)*

Blood and Marrow Transplant Clinical Trials Network

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

Version: 3.01; 05-23-08

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

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

Comments: *(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Baseline Form - 0302 (BL1)

Version: 2.01; 08-07-08

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

Pre-transplant Status

Complete the following questions regarding the patient's pre-transplant status.

1. Patient's primary diagnosis pre-transplant: *(PM0302DX)*

1 - Acute Myelogenous Leukemia (AML)
2 - Acute Lymphoblastic Leukemia (ALL)
3 - Chronic Myelogenous Leukemia (CML)
4 - Myelodysplastic Syndrome (MDS)
5 - Lymphoma
*Additional Options Listed Below

2. If Other, specify primary diagnosis pre-transplant: *(OPRIMDX)*

3. If AML, record the disease stage pre-transplant: *(AML302SG)*

1 - First Remission
2 - Second Remission
3 - Third or Subsequent Remission
4 - Primary Induction Failure
5 - First Complete Remission
*Additional Options Listed Below

4. If ALL, record the disease stage pre-transplant: *(ALL302SG)*

1 - First Remission
2 - Second Remission
3 - Third or Subsequent Remission
4 - Primary Induction Failure
5 - First Complete Remission
*Additional Options Listed Below

5. If CML, record the disease stage pre-transplant: *(CML302SG)*

1 - First Chronic Phase
2 - Second or Subsequent Chronic Phase
3 - Accelerated Phase
4 - Blast Phase

6. If MDS, record the disease stage pre-transplant: *(MDS302SG)*

1 - Refractory Anemia
2 - Refractory Anemia with Ringed Sideroblasts
3 - Refractory Cytopenia with Multilineage Dysplasia
4 - Refractory Cytopenia with Multilineage Dysplasia and Ringed Sideroblasts
5 - Refractory Anemia with Excess Blasts 1 (5-10% blasts)
*Additional Options Listed Below

7. If Lymphoma, record the disease stage pre-transplant: *(LYM302SG)*

1 - Complete Remission
2 - Partial Remission
3 - Continued Complete Remission
4 - First Relapse
5 - Second Relapse
*Additional Options Listed Below

8. If Other, record the disease stage pre-transplant: *(ODISESG)*

9. HLA Typing Method: *(HLA302RE)*

1 - High Level DNA
2 - Low Level DNA
3 - Serologic
4 - Loci A, B: Serologic, Locus DRB1: Low Level DNA
5 - Loci A, B: Low Level DNA, Locus DRB1: High Level DNA
*Additional Options Listed Below

10. Record your institutions HLA match score for this patient: *(HLA0302S)*

3/6
4/6
5/6
6/6
3/8
*Additional Options Listed Below

11. Record the type of conditioning regimen: *(CON0302R)* ☐ 1 - Myeloablative ☐ 2 - Non-myeloablative or Reduced Intensity

12. Record the Karnofsky/Lansky performace score used to evaluate the patient: *(KA0302SC)*

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

Transplant

Complete the following questions regarding the patients transplant status.

13. Date of transplant: *(T0302DT)* *(mm/dd/yyyy)*

14. Donor source: *(REL0302U)* ☐ 1 - Related ☐ 2 - Unrelated

15. Stem cell type: *(T0302TY)*

1 - Bone Marrow
2 - Peripheral Blood Stem Cells
3 - Cord Blood

16. Was the stem cell product T-Cell depleted? *(T0302CEL)* ☐ 1 - Yes ☐ 2 - No

17. Patient's weight at transplant: *(BL0302WT)* *(xxx)* kg

18. Total nucleated cell dose infused at transplant: *(CEL302DS)* *(xxx)* 10^7 cells/kg

19. CMV status at transplant: *(CMV0302S)*

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

Comments: *(B0302COM)*

Additional Selection Options for BL1

Patient's primary diagnosis pre-transplant:
6 - Other

If AML, record the disease stage pre-transplant:
6 - Second Complete Remission
7 - Third or Subsequent Remission
8 - First Relapse
9 - Second Relapse

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

If Lymphoma, record the disease stage pre-transplant:
6 - Greater Than Second Relapse

HLA Typing Method:
6 - Loci A, B: Serologic, Locus DRB1: High Level DNA
7 - Loci A, B, C: Low Level DNA, Locus DRB1: High Level DNA
8 - Loci A, B, C, DQ: Low Level DNA, Locus DRB1: High Level DNA

Record your institutions HLA match score for this patient:
4/8
5/8
6/8
7/8
8/8
3/10
4/10
5/10
6/10
7/10
8/10
9/10
10/10

Record the Karnofsky/Lansky performace score used to evaluate the patient:
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)

Blood and Marrow Transplant Clinical Trials Network

Follow Up GVHD Form (CGV)

Version: 5.03; 07-24-08

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 - No Symptoms of Acute GVHD
   - 1 - I
   - 2 - II
   - 3 - III
   - 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 - Histologic Evidence
      - 2 - Clinical Evidence
      - 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 - Yes
   - 2 - No
   - 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 - No Symptoms of Chronic GVHD
    - 1 - Mild
    - 2 - Moderate
    - 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 - Histologic Evidence
        - 2 - Clinical Evidence
        - 3 - Both
    14. Date of diagnosis of chronic GVHD: *(DTDGNCGV)*

(mm/dd/yyyy)

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

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

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 - No Rash
1 - <25% of BSA Involvement
2 - 25-50% of BSA Involvement
3 - >50% of BSA Involvement
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 - No Symptoms
1 - Dry Eyes but Not Requiring Therapy
2 - Dryness of Eyes or Inflammation Requiring Therapy

Oral

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

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

24. Dyspnea: *(CGVDYSPN)*

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

25. Pulmonary fibrosis: *(PULMFIBR)*

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

26. Bronchiolitis obliterans: *(BRNCOBLT)*

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

27. FEV1: *(CGVFEV1)*

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

28. Oxygen saturation: *(O2SAT)*

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

Gastrointestinal

29. Esophagus: *(ESOPHAGS)*

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

30. Nausea and vomiting: *(NAUSVOMT)*

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

31. Diarrhea: *(CGVDIARH)*

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

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

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

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

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

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

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

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
3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-83
4 - Diarrhea >1500 mL/day or >833 mL/m^2
5 - Severe Abdominal Pain with or without Ileus, or Stool with Frank Bl

35. Malabsorption: *(MALABSRP)*

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

Hepatic

36. Bilirubin level: *(LIVERBIL)*

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

Genitourinary

37. Vaginitis: *(VAGNITIS)*

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

Musculoskeletal

38. Contractures: *(CONTRCTR)*

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

39. Myositis: *(MYOSITIS)* ☐ 1 - Yes ☐ 2 - No

Hematologic

40. Eosinophilia: *(EOSINPHL)* ☐ 1 - Yes ☐ 2 - No

Other

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

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

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

Specify other organ: *(ORGSPEC)*

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

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

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

Type of Biopsy:	If Other, Specify:	Date of Biopsy:	
45. *(BIOTYP1)* 1 - Skin Biopsy; 2 - Oral Biopsy; 3 - Upper GI Biopsy; 4 - Lower GI Biopsy; 5 - Liver Biopsy; *Additional Options Listed Below	*(TYP1OSPE)*	*(BIODT1)* *(mm/dd/yyyy)*	*(E*
46. *(BIOTYP2)* 1 - Skin Biopsy; 2 - Oral Biopsy; 3 - Upper GI Biopsy; 4 - Lower GI Biopsy; 5 - Liver Biopsy; *Additional Options Listed Below	*(TYP2OSPE)*	*(BIODT2)* *(mm/dd/yyyy)*	*(E*
47. *(BIOTYP3)* 1 - Skin Biopsy; 2 - Oral Biopsy; 3 - Upper GI Biopsy; 4 - Lower GI Biopsy; 5 - Liver Biopsy; *Additional Options Listed Below	*(TYP3OSPE)*	*(BIODT3)* *(mm/dd/yyyy)*	*(E*
48. *(BIOTYP4)* 1 - Skin Biopsy; 2 - Oral Biopsy; 3 - Upper GI Biopsy; 4 - Lower GI Biopsy; 5 - Liver Biopsy; *Additional Options Listed Below	*(TYP4OSPE)*	*(BIODT4)* *(mm/dd/yyyy)*	*(E*
49. *(BIOTYP5)* 1 - Skin Biopsy; 2 - Oral Biopsy; 3 - Upper GI Biopsy; 4 - Lower GI Biopsy; 5 - Liver Biopsy; *Additional Options Listed Below	*(TYP5OSPE)*	*(BIODT5)* *(mm/dd/yyyy)*	*(E*
	(TYP6OSPE)	*(BIODT6)* *(mm/dd/yyyy)*	

50. *(BIOTYP6)*	1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below			*(E*

Answer questions 51-54 relating to GVHD therapy.

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

1 - Yes, Initiated this Assessment Period
2 - Yes, Continuing from Previous Assessment Period
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)*

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

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

n. Etanercept: *(THRPYETA)*

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

p. Chloroquine Phosphate: *(THRPYCPH)*

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

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

r. In Vivo Immunotoxin: *(THRPYIMM)*

Specify in vivo immunotoxin used: *(IMMAGNT)*

s. Other: *(THRPYOTH)*

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 - Complete Resolution of Symptoms
2 - Partial Resolution of Symptoms
3 - Stable Symptoms
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 - 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

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 - 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)

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

Current Karnofsky/Lansky Score:
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)

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

Version: 3.03; 08-14-08

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)*

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

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

Follow Up Status Form (FUS)

Version: 11.00; 03-27-08

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

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

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

2. Has the patient died? *(DIED)* ☐ 1 - Yes ☐ 2 - No
   If Yes, a Death Form must be submitted.
   3. Date of patient death: *(DEATHDT)* *(mm/dd/yyyy)*
4. Has the patient relapsed or experienced disease progression? *(RELAPSE)* ☐ 1 - Yes ☐ 2 - No
   5. Date of relapse or progression: *(RELAPSDT)* *(mm/dd/yyyy)*
6. Has the patient been treated for progression/relapse? *(RELAPSTX)* ☐ 1 - Yes ☐ 2 - No
   7. Date treatment administered: *(TREATDT)* *(mm/dd/yyyy)*
   8. Indicate type of treatment: *(TREATYPE)*

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

Specify other treatment: *(FUS1SPEC)*

9. Has the patient experienced secondary graft failure? *(SECGRFAL)* ☐ 1 - Yes ☐ 2 - No
10. Has the patient experienced secondary graft failure? *(SECGRFAL)* ☐ 1 - Yes ☐ 2 - No
    If Yes, a Secondary Graft Failure Form must be submitted.
    If Yes, a Secondary Graft Failure Form must be submitted.
    11. Date of secondary graft failure: *(SCGRFLDT)* *(mm/dd/yyyy)*
    12. Date of secondary graft failure: *(SCGRFLDT)* *(mm/dd/yyyy)*
13.
14. Has the patient experienced any new clinically significant infections? *(NEWINFX)* ☐ 1 - Yes ☐ 2 - No
    If Yes, an Infection Form must be submitted.
    15. Date of infection: *(INFDT)* *(mm/dd/yyyy)*
16. Has the patient been hospitalized? *(HOSPITAL)* ☐ 1 - Yes ☐ 2 - No
    If Yes, a Re-Admission Form must be submitted.
    17. Date of hospitalization: *(HOSPTLDT)* *(mm/dd/yyyy)*
18. Has the patient received a non-protocol specified transplant? *(TRANSTWO)* ☐ 1 - Yes ☐ 2 - No
    19. Date of non-protocol specified transplant: *(DATRANSP)* *(mm/dd/yyyy)*

Comments: *(FUS1COMM)*

Additional Selection Options for FUS

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

Blood and Marrow Transplant Clinical Trials Network

Acute GVHD Form (GVH)

Version: 8.01; 07-24-08

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

1. Date of staging: *(STAGEDT)* *(mm/dd/yyyy)*
   Start of GVHD Assessment Period: *(GVASSTDT)* *(mm/dd/yyyy)*
   End of GVHD Assessment Period: *(GVASENDT)* *(mm/dd/yyyy)*
   The assessment for which you are entering data must have taken place within the above dates. If the patient was not seen during the assessment period specified above, please exit the form and request an exception for this form.
2. Immunosuppressant (prophylaxis) received: *(IMMUNORC)*
   0 - Prednisone
   1 - Cyclosporine
   2 - Tacrolimus
   3 - Not Given During Assessment Period
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

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

Blood and Marrow Transplant Clinical Trials Network

Infection Form (INF)

Version: 2.03; 06-24-08

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

INFECTION I

1. Type of infection: *(INFTYP01)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other
2. Organism I: *(ORGN01)*
   - B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
   - B02 - Agrobacterium radiobacter
   - B03 - Alcaligenes xylosoxidans
   - B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
   - B05 - Bacillus (cereus, other species)
   - *Additional Options Listed Below

   If other specify: *(INFSPEC1)*
3. Record the level of certainty of the fungal infection diagnosis: *(CERTNTY1)*
   - 1 - Proven Fungal Infection
   - 2 - Probable Fungal Infection
   - 3 - Possible Fungal Infection
4. Severity of infection: *(SVRTY01)*
   - 1 - Moderate
   - 2 - Severe
   - 3 - Life-Threatening/Fatal

INFECTION II

5. Type of infection: *(INFTYP02)*
   - B - Bacteria
   - V - Viral
   - F - Fungal
   - P - Protozoal
   - O - Other
6. Organism II: *(ORGN02)*
   - B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
   - B02 - Agrobacterium radiobacter
   - B03 - Alcaligenes xylosoxidans
   - B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
   - B05 - Bacillus (cereus, other species)
   - *Additional Options Listed Below

   If other specify: *(INFSPEC2)*
7. Record the level of certainty of the fungal infection diagnosis: *(CERTNTY2)*
   - 1 - Proven Fungal Infection
   - 2 - Probable Fungal Infection
   - 3 - Possible Fungal Infection
8. Severity of infection: *(SVRTY02)*
   - 1 - Moderate
   - 2 - Severe
   - 3 - Life-Threatening/Fatal

INFECTION III

9. Type of infection: *(INFTYP03)*

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

10. Organism III: *(ORGN03)*

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

If other specify: *(INFSPEC3)*

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

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

12. Severity of infection: *(SVRTY03)*

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

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

Provide agent(s) administered for this infectious period:

14. 1st agent: *(AGENT1)*

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

15. 2nd agent: *(AGENT2)*

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

16. 3rd agent: *(AGENT3)*

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

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

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

Comments: *(INFCOM)*

Additional Selection Options for INF

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

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

granulosum, other species)
B44 - Pseudomonas (all species except
cepacia and maltophilia)
B45 - Pseudomonas or Burkholderia cepacia
B46 - Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia
B47 - Rhodococcus
B48 - Rickettsia
B49 - Salmonella (all species)
B50 - Serratia marcescens
B51 - Shigella
B52 - Staphylococcus (coag -)
B53 - Staphylococcus (coag +)
B54 - Staphylococcus (NOS)
B55 - Stomatococcus mucilaginosis
B56 - Streptococcus (all species except Enterococcus)
B57 - Treponema (syphilis)
B58 - Tuberculosis (NOS, AFB, acid fast bacillus, Koch bacillus)
B59 - Typical Tuberculosis (TB, Tuberculosis)
B60 - Vibrio (all species)
B99 - Other Bacteria
V01 - Herpes Simplex (HSV1, HSV2)
V02 - Herpes Zoster (Chicken pox, Varicella)
V03 - Cytomegalovirus (CMV)
V04 - Adenovirus
V05 - Enterovirus (Coxsackie, Echo, Polio)
V06 - Hepatitis A (HAV)
V07 - Hepatitis B (HBV, Australian antigen)
V08 - Hepatitis C (includes non-A and non-B, HCV)
V09 - HIV-1, HITLV-III
V10 - Influenza (Flu)
V11 - Measles (Rubeola)
V12 - Mumps
V13 - Papovavirus
V14 - Respiratory Syncytial virus (RSV)
V15 - Rubella (German Measles)
V16 - Parainfluenza
V17 - HHV-6 (Human Herpes Virus)
V18 - Epstein-Barr Virus (EBV)
V19 - Polyomavirus
V20 - Rotavirus
V21 - Rhinovirus (Common Cold)
V22 - Other Viral
P1 - Pneumoncystis (PCP)
P2 - Toxoplasma
P3 - Giardia
P4 - Cryptosporidium
P5 - Amebiasis
P6 - 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

Immune Reconstitution Form - 0302 (IRC)

Version: 2.00; 08-25-06

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

Immunophenotyping

1. Date immunophenotyping was performed: *(IRCFCDT)* *(mm/dd/yyyy)*
2. White blood cell count: *(IRCWBCT)* *(xxxxx)* x 10^9/L
3. Percent lymphocyte of CD45+ cells: *(IRCLYMPH)* *(xxx)* %
4. CD3: *(IRCCD3)* *(xxxx)* cells/uL
5. CD4: *(IRCCD4)* *(xxxx)* cells/uL
6. CD8: *(IRCCD8)* *(xxxx)* cells/uL
7. CD25: *(IRCCD25)* *(xxxx)* cells/uL
8. CD69: *(IRCCD69)* *(xxxx)* cells/uL
9. CD20: *(IRCCD20)* *(xxxx)* cells/uL
10. CD4+/CD25+: *(IRCCD425)* *(xxxx)* cells/uL

Comments: *(IRCCOMMT)*

Blood and Marrow Transplant Clinical Trials Network

Laboratory Assessment Form - 0302 (LAF)

Version: 4.04; 02-12-08

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

Laboratory Assessments

1. Start of Assessment Period: *(LAFAPST)* _____ *(mm/dd/yyyy)*
2. Target Assessment Date: *(LAFAPEND)* _____ *(mm/dd/yyyy)*
3. End of Assessment Period: *(LAFAPEND)* _____ *(mm/dd/yyyy)*

CBC

	Most Recent Value	Date of Sample
4. RBC	*(LABRBC)* _____ *(x.x)* million/mm^3	*(RBCDT)* _____ *(mm/dd/yyyy)*
5. RBC	*(LABRBC)* _____ *(x.x)* million/mm^3	*(RBCDT)* _____ *(mm/dd/yyyy)*
6. Hematocrit	*(LABHCT)* _____ *(xx.x)* %	*(HCTDT)* _____ *(mm/dd/yyyy)*
7. Hematocrit	*(LABHCT)* _____ *(xx.x)* %	*(HCTDT)* _____ *(mm/dd/yyyy)*
8. Hemoglobin	*(LABHGB)* _____ *(xx.x)* g/dL	*(HGBDT)* _____ *(mm/dd/yyyy)*
9. Hemoglobin	*(LABHGB)* _____ *(xx.x)* g/dL	*(HGBDT)* _____ *(mm/dd/yyyy)*
10. WBC	*(LABWBC)* _____ *(xxxxxx)*	*(WBCDT)* _____ *(mm/dd/yyyy)*
11. WBC	*(LABWBC)* _____ *(xxxxxx)*	*(WBCDT)* _____ *(mm/dd/yyyy)*
12. Platelet Count	*(PLATELET)* _____ *(xxxxxx)* /mcL	*(PLATDT)* _____ *(mm/dd/yyyy)*
13. Platelet Count	*(PLATELET)* _____ *(xxxxxx)* /mcL	*(PLATDT)* _____ *(mm/dd/yyyy)*
14. ANC	*(NEUTAGVH)* _____ *(xxxxx)* /mcL	*(GRANDT)* _____ *(mm/dd/yyyy)*
15. ANC	*(NEUTAGVH)* _____ *(xxxxx)* /mcL	*(GRANDT)* _____ *(mm/dd/yyyy)*
16. Lymphocytes	*(LYMPHCYT)* _____ *(xxxxx)* /mcL	*(LYMPHDT)* _____ *(mm/dd/yyyy)*
17. Lymphocytes	*(LYMPHCYT)* _____ *(xxxxx)* /mcL	*(LYMPHDT)* _____ *(mm/dd/yyyy)*

Chemistry and LFT's

	Most Recent Value	Date of Sample
18. Creatinine	*(LABCREAT)* _____ *(x.x)* mg/dL	*(LBCRTDT)* _____ *(mm/dd/yyyy)*
19. Creatinine	*(LABCREAT)* _____ *(x.x)* mg/dL	*(LBCRTDT)* _____ *(mm/dd/yyyy)*
20. Estimated Creatinine Clearance	*(LABCRCL)* _____ *(xxx)* mL/min	*(LBCRCLDT)* _____ *(mm/dd/yyyy)*

21. Estimated Creatinine Clearance	*(LABCRCL)* *(xxx)* mL/min	*(LBCRCLDT)* *(mm/dd/yyyy)*
22. Bilirubin	*(LABBILI)* *(xx.x)* mg/dL	*(LBBILIDT)* *(mm/dd/yyyy)*
23. Bilirubin	*(LABBILI)* *(xx.x)* mg/dL	*(LBBILIDT)* *(mm/dd/yyyy)*
24. Alkaline Phosphatase	*(LBALKPHO)* *(xxxx)* IU/L	*(ALKPHDT)* *(mm/dd/yyyy)*
25. Alkaline Phosphatase	*(LBALKPHO)* *(xxxx)* IU/L	*(ALKPHDT)* *(mm/dd/yyyy)*
26. AST	*(LABAST)* *(xxxx)* IU/L	*(LBASTDT)* *(mm/dd/yyyy)*
27. AST	*(LABAST)* *(xxxx)* IU/L	*(LBASTDT)* *(mm/dd/yyyy)*
28. ALT	*(LBALT)* *(xxxx)* IU/L	*(LBALTDT)* *(mm/dd/yyyy)*
29. ALT	*(LBALT)* *(xxxx)* IU/L	*(LBALTDT)* *(mm/dd/yyyy)*

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

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

Comments: *(LBCMNTS)*

Additional Selection Options for LAF

What is the patient's Karnofsky / Lansky performance score?
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)

Blood and Marrow Transplant Clinical Trials Network

Medication Form - 0302 (MD2)

Version: 3.00; 04-04-06

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

1. Record the start of the assessment period: *(MDSTAP)* _____ *(mm/dd/yyyy)*
2. Record the end of the assessment period: *(MDENDAP)* _____ *(mm/dd/yyyy)*
3. Record the study drug assignment: *(MDDRGASN)*
   - 1 - Etanercept
   - 2 - Mycophenolate Mofetil (MMF)
   - 3 - ONTAK
   - 4 - Pentostatin

Steroid Dose

4. Did the prednisone dose ever drop below 1.4 mg/kg/day OR did the methylprednisolone dose ever drop below 1.0 mg/kg/day during this assessment period? *(STERDROP)* ☐ 1 - Yes ☐ 2 - No
   5. If yes, record the date the steroid dose dropped below 1.4 mg/kg/day for prednisone or 1.0 mg/kg/day for methylprednisolone: *(DTSTRDRP)* _____ *(mm/dd/yyyy)*
   6. Record the dose of steroid given on this date: *(STRLWDOS)* _____ *(x.x)* mg/kg/day
   7. Record the steroid given: *(LOWSTER)*
      - 1 - Prednisone
      - 2 - Methylprednisolone

It is a protocol violation if the prednisone dose drops below 1.4 mg/kg/day or the methylprednisolone dose drops below 1.0 mg/kg/day before Day 28. If this has happened, please contact the protocol coordinator as soon as possible.

Patients Randomized to Receive Etanercept, ONTAK, or Pentostatin

8. Record the total number of doses given during this assessment period: *(NUMBDOS)* _____ *(x)*

Patients Randomized to Receive MMF

9. Was the patient inpatient or outpatient during this assessment period? *(INOUTPT)*
   - 1 - Inpatient
   - 2 - Outpatient
   - 3 - Both
10. Record the total number of inpatient doses of MMF given during this assessment period: *(INPTDOSE)* _____ *(xx)*
11. For outpatients, record the number of MMF doses (expected to be taken twice daily) dispensed during this assessment period: *(MMFDISP)* _____ *(xx)*
12. For outpatients, record the number of MMF doses returned by the patient: *(MMFRET)* _____ *(xx)*
13. For outpatients, does the patient appear to be compliant with taking MMF during this assessment period? (If the patient is taking 90-110% of the prescribed doses, then indicate "Yes." If not, then indicate "No.") *(PTCOMPLI)* ☐ 1 - Yes ☐ 2 - No

All Patients

14. Was study drug withheld at any time during this assessment period? *(MDSDRHLD)* ☐ 1 - Yes ☐ 2 - No
    15. If yes, record the reason study drug was withheld: *(MDDRREA)*
        - 01 - Grade 3-4 toxicity probably related to study drug
        - 02 - ANC < 500 / microliter
        - 03 - Creatinine clearance < 30mL / minute
        - 04 - Progression of GVHD by Day 7
        - 05 - No response in GVHD by Day 14
        - *Additional Options Listed Below

    Specify other reason study drug was withheld: *(MDORSPEC)* _____

16. Did the patient receive anything for GVHD treatment other than the assigned study drug, steroids, and CSA or FK506? *(TRTOTHYN)*

☐ 1 - Yes ☐ 2 - No

17. If yes, indicate the agent name: *(GVHTREAT)*

1 - Etantercept
2 - MMF
3 - ONTAK
4 - Pentostatin
5 - Topical Steroids
*Additional Options Listed Below

Specify other agent: *(MD2SPEC)*

Comments: *(MD2COMM)*

Additional Selection Options for MD2

If yes, record the reason study drug was withheld:
06 - Sustained bacteremia
07 - Persistent culture negative fever
08 - Hemodynamic instability
09 - Patient refused
10 - Patient withdrew consent
11- Other, specify

If yes, indicate the agent name:
6 - ATG
7 - Daclizumab
8 - Other

Blood and Marrow Transplant Clinical Trials Network

Secondary Graft Failure Form (SGF)

Version: 2.00; 07-24-08

Segment *(PROTSEG)*:

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

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

Day 1:	*(ANC1SGF)* _____ *(xxx)* /mm^3	*(ANC1SGDT)* _____ *(mm/dd/yyyy)*
Day 2:	*(ANC2SGF)* _____ *(xxx)* /mm^3	*(ANC2SGDT)* _____ *(mm/dd/yyyy)*
Day 3:	*(ANC3SGF)* _____ *(xxx)* /mm^3	*(ANC3SGDT)* _____ *(mm/dd/yyyy)*

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

4. Did the neutrophil count respond to growth factor therapy? *(RSPNDGF)* ☐ 1 - Yes ☐ 2 - No

Comments: *(SGFCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0302 (TX4)

Version: 4.00; 07-21-08

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

1. Record date of evaluation: *(TX4EVLDT)* _____ *(mm/dd/yyyy)*

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

Blood/Bone Marrow Toxicity

2. Neutrophils: *(TX4ANC)*
   - 0 - Grades 0-2
   - 3 - < 1000 - 500/mm^3
   - 4 - < 500/mm^3
   - 5 - Death
3. Platelets: *(TX4PLAT)*
   - 0 - Grades 0-2
   - 3 - < 50,000 - 25,000/mm^3
   - 4 - < 25,000/mm^3
   - 5 - Death
4. Leukocytes: *(TX4LEUKO)*
   - 0 - Grades 0-2
   - 3 - < 2000 - 1000/mm^3
   - 4 - < 1000/mm^3
   - 5 - Death
5. Anemia: *(TX4ANEMI)*
   - 0 - Grades 0-2
   - 3 - < 8.0 - 6.5 g/dL
   - 4 - < 6.5 g/dL
   - 5 - Death

GI Toxicity

6. Mucositis/stomatitis (clinical exam): *(TX4MCSTS)*
   - 0 - Grades 0-2
   - 3 - Confluent Ulcerations or Pseudomembranes; Bleeding with Minor Trauma
   - 4 - Tissue Necrosis; Significant Spontaneous Bleeding; LT Consequences
   - 5 - Death

   Mouth pain or esophageal pain requiring IV hydration/narcotics.

Renal Toxicity

7. Did the patient experience renal failure severe enough to warrant dialysis? *(TX4RENAL)* ☐ 1 - Yes ☐ 2 - No
   8. Did the patient receive dialysis? *(TX4DIALS)* ☐ 1 - Yes ☐ 2 - No
9. Hemorrhagic cystitis: *(TX4CYSTI)*
   - 0 - Grades 0-2
   - 3 - Transfusion; IV Pain Medications; Bladder Irrigation Indicated
   - 4 - Catastrophic Bleeding; Major Non-Elective Intervention Indicated
   - 5 - Death

Hemorrhagic Toxicity

10. Hemorrhage: *(TX4HEMRG)*

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

Cardiovascular Toxicity

11. Hypotension: *(TX4HYPOT)*

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

12. Cardiac arrhythmia: *(TX4CRDAR)*

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

13. Left ventricular systolic dysfunction: *(TX4LVENT)*

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

Neurologic Toxicity

14. Somnolence: *(TX4SMNLN)*

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

15. Did the patient experience any seizures during this assessment period? *(TX4SEIZR)* ☐ 1 - Yes ☐ 2 - No

16. Record seizure toxicity grade: *(TX4SZGRD)*

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

Coagulation Toxicity

17. HUS/TTP/thrombotic microangiopathy: *(TX4DIC)*

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

Vascular Toxicity

18. Vascular leak syndrome: *(TX4VASLK)*

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

Pulmonary Toxicity

19. Hypoxia (for more than 24 hours): *(TX4HYPXI)*

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

20. Dyspnea: *(TX4DYSPN)*

0 - Grades 0-2
3 - Dyspnea with ADL
4 - Dyspnea at Rest; Intubation or Ventilator Indicated
5 - Death

21. During this assessment period, was an FEV1 performed? *(TX4FEVDN)* ☐ 1 - Yes ☐ 2 - No

22. Record FEV1 value obtained: *(TX4FEVVL)* _____ *(xxx)* % of predicted value

23. During this assessment period, was an FVC performed? *(TX4FVCDN)* ☐ 1 - Yes ☐ 2 - No

24. Record FVC value obtained: *(TX4FVCVL)* _____ *(xxx)* % of predicted value

Hepatic Toxicity

25. Did the patient develop abnormal liver function during this assessment period? *(TX4ABNLF)* ☐ 1 - Yes ☐ 2 - No

26. ALT: *(TX4ALT)*
0 - Grades 0-2
3 - > 5.0 - 20.0 x ULN
4 - > 20.0 x ULN

27. AST: *(TX4AST)*
0 - Grade 0-2
3 - > 5.0 - 20.0 x ULN
4 - > 20.0 x ULN

28. Bilirubin: *(TX4BILI)*
0 - Grades 0-2
3 - >3.0-10.0 x ULN
4 - >10.0 x ULN

29. Creatinine: *(TX4CREAT)*
0 - Grades 0-2
3 - > 3.0 - 6.0 x ULN
4 - > 6.0 x ULN
5 - Death

30. Hypoalbuminemia: *(TX4ALBUM)*
0 - Grades 0-2
3 - < 2 g/dL
5 - Death

31. Hypoglycemia: *(TX4GLYCE)*
0 - Grades 0-2
3 - < 40 - 30 mg/dL
4 - < 30 mg/dL
5 - Death

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

32. Jaundice: *(TX4JANDC)* ☐ 1 - Yes ☐ 2 - No

33. Hepatomegaly: *(TX4HPTMG)* ☐ 1 - Yes ☐ 2 - No

34. Right upper quadrant pain: *(TX4QUADP)* ☐ 1 - Yes ☐ 2 - No

35. Weight gain (>5%) from baseline: *(TX4WGHTG)* ☐ 1 - Yes ☐ 2 - No

36. Other clinical signs/symptoms: *(TX4OTHAB)* ☐ 1 - Yes ☐ 2 - No

Specify other clinical signs/symptoms: *(TX4SPEC1)* _____

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
37. VOD:	*(TX4VODET)* 1 - Yes / 2 - No	*(TX4VODBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(TX4VODDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done
38. GVHD:	*(TX4GVHET)* 1 - Yes / 2 - No	*(TX4GVHBI)* 1 - Positive / 2 - Negative / 3 - Equivocal / 4 - Not Done	*(TX4GVHDP)* 1 - Confirmed / 2 - Not Confirmed / 3 - Not Done

39. Infection:	*(TX4INFET)* 1 - Yes 2 - No	*(TX4INFBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX4INFDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
40. Other:	*(TX4OTHET)* 1 - Yes 2 - No	*(TX4OTHBI)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(TX4OTHDP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
41. Unknown:	*(TX4UNKET)* 1 - Yes 2 - No		

Specify other etiology: *(TX4SPEC2)*

Comments: *(TX4COMM)*

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

Version: 4.00; 03-31-08

1. Name Code: *(NAMECODE)*
2. IUBMID # (if available): *(IUBMID)*
3. CRID # (CIBMTR Recipient ID): *(CRIDNUM)* *(xxxxxxxxxx)*

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

4. Gender: *(GENDER)* ☐ 1 - Male ☐ 2 - Female
5. Date of Birth: *(DOB)* *(mm/dd/yyyy)*
6. Ethnicity: *(ETHNIC)*

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

7. Race: *(RACE)*

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

Specify race: *(RACESP)*

8. Secondary Race: *(RACE2)*

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

Specify secondary race: *(RACE2SP)*

Comments: *(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

0302A (ENR)

Version: 6.01; 12-12-07

Acute GVHD Enrollment Form

1. Record the date informed consent form was signed: *(CNSNT6)* *(mm/dd/yyyy)*
2. Patient's birthdate: *(GVBRTHDT)* *(mm/dd/yyyy)*
3. Record patient's weight: *(PTENTRWT)* *(xxx.x)* kg
4. Date patient's weight assessed: *(PTWTDATE)* *(mm/dd/yyyy)*

Inclusion Criteria

5. Has the patient had an allogeneic hematopoietic stem cell transplant? *(STEMCELL)* ☐ 1 - Yes ☐ 2 - No
   6. Date of transplant: *(TRNSDT)* *(mm/dd/yyyy)*
   7. Transplant type: *(TRNPLTYP)*
      1 - Bone Marrow
      2 - Peripheral Blood Stem Cells
      3 - Cord Blood
   8. Type of conditioning regimen: *(MYELOABL)* ☐ 1 - Myeloablative ☐ 2 - Non-myeloablative or Reduced Intensity
9. Does the patient have de novo Grade B-D acute GVHD requiring systemic therapy and is within 48 hours of diagnosis? *(GVHDDIAG)* ☐ 1 - Yes ☐ 2 - No
   10. Record date and time of diagnosis of GVHD: *(GVHDDATE)* *(mm/dd/yyyy)* *(GVHDTIME)* *(hh:mm)* 24 hour clock

Note: The date and time of diagnosis of GVHD is defined as when it is deemed necessary to initiate therapy for GVHD.

11. Skin abnormalities: *(SKIN_ABN)*
    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
12. Upper GI abnormalities: *(UPPER_GI)*
    0 - No Protracted Nausea and Vomiting
    1 - Persistent Nausea, Vomiting or Anorexia
13. Lower GI abnormalities: *(LOWER_GI)*
    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
14. Liver abnormalities: *(LIVER_AB)*
    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. Did the patient receive immunosuppressive therapy for treatment of acute GVHD (other than a maximum 48 hours of prior corticosteroid therapy = 1mg/kg/day methylprednisolone)? *(IMMUNTHR)* ☐ 1 - Yes ☐ 2 - No
16. Is the patient currently receiving corticosteroid therapy? *(CURSTER)* ☐ 1 - Yes ☐ 2 - No
    17. Corticosteroid given: *(STERTYPE)*
        1 - Prednisone
        2 - Methylprednisolone

18. Record patient's current dose of prednisone: *(PREDDOSE)* *(x.x)* mg/kg/day
19. Record patient's current dose of methylprednisolone: *(METHDOSE)* *(x.x)* mg/kg/day
20. Has the patient undergone a scheduled donor lymphocyte infusion (DLI) as part of their original transplant therapy plan? *(DLI0302P)* ☐ 1 - Yes ☐ 2 - No
21. Does the patient's current clinical status allow for at least 0.6 mg/kg/day methylprednisolone (0.75 mg/kg/day prednisone) for the first 28 days of the study? *(STEROIDS)* ☐ 1 - Yes ☐ 2 - No
22. Has the patient received Mycophenolate Mofetil (MMF) for GVHD prophylaxis within 7 days of enrollment? *(MMFUSED)* ☐ 1 - Yes ☐ 2 - No

	Most Recent Value	ULN for Your Institution	Date Sample Obtained
23. Absolute Neutrophil Count (ANC):	*(REC_ANC)* *(xxxxx)* / µL		*(ANCDATE)* *(mm/dd/yyyy)*
24. Creatinine:	*(SCRGVH)* *(x.x)* (mg/dL)	*(CRULNGVH)* *(x.x)* (mg/dL)	*(CRDTGVH)* *(mm/dd/yyyy)*
25. Creatinine Clearance (mL/min) (calculated or estimated):	*(CRCLGVH)* *(xxx)* (mL/min)		*(CRCLDTGV)* *(mm/dd/yyyy)*

Exclusion Criteria

26. Has the patient received Etanercept, Denileukin Diftitox (Ontak), or Pentostatin within 7 days of enrollment? *(STDYAGNT)* ☐ 1 - Yes ☐ 2 - No
27. Does the patient have an uncontrolled viral or bacterial infection? *(BACVIRAL)* ☐ 1 - Yes ☐ 2 - No
28. Was a GVHD diagnosis made following an unscheduled DLI or a DLI that was not part of their original transplant therapy plan? *(GVHD_DLI)* ☐ 1 - Yes ☐ 2 - No
29. Does the patient have any clinical syndrome resembling de novo chronic GVHD after allotransplantation? *(ALLTRNSP)* ☐ 1 - Yes ☐ 2 - No
30. Has the patient received other investigational drugs for GVHD, including GVHD prophylaxis, within 30 days of enrollment? *(OTH_AGEN)* ☐ 1 - Yes ☐ 2 - No
31. Is the patient willing to use contraceptive techniques for the duration of the study? *(CNTRCPTV)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
32. Is the patient pregnant (positive ß-HCG) or breastfeeding? *(PREGANT)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
33. Does the patient have a history of allergies or intolerance to any of the study drugs? *(ALLERGVH)* ☐ 1 - Yes ☐ 2 - No

Consent for Biological Samples

34. Did the patient give consent to have blood drawn for research purposes? *(O3O2BLD)* ☐ 1 - Yes ☐ 2 - No
35. Did the patient give consent to have skin biopsies taken for research purposes? *(O3O2SKIN)* ☐ 1 - Yes ☐ 2 - No

Comments: *(COMMENTS)*

Additional Selection Options for ENR

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