Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

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

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

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

3. Record PRIMARY discharge diagnosis: *(PHSPREAS)*

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

*Specify organ: *(ADM4SPEC)*
**Specify other: *(ADM1SPEC)*

4. Record secondary discharge diagnoses:

a. GVHD: *(REASGVHD)*	☐ 1 - Contributory	☐ 2 - Noncontributory
b. Relapse/progression: *(REASRLPS)*	☐ 1 - Contributory	☐ 2 - Noncontributory
c. Graft failure: *(REASGF)*	☐ 1 - Contributory	☐ 2 - Noncontributory
d. Fungal infection: *(REASFINF)*	☐ 1 - Contributory	☐ 2 - Noncontributory
e. Non-fungal infection: *(REASNFIN)*	☐ 1 - Contributory	☐ 2 - Noncontributory
f. Fever: *(REASFVR)*	☐ 1 - Contributory	☐ 2 - Noncontributory
g. Seizure: *(REASSZR)*	☐ 1 - Contributory	☐ 2 - Noncontributory
h. Bleeding/hemorrhage: *(REASGIBL)*	☐ 1 - Contributory	☐ 2 - Noncontributory
i. Diarrhea: *(REASDRH)*	☐ 1 - Contributory	☐ 2 - Noncontributory
j. Nausea/vomiting: *(REASNV)*	☐ 1 - Contributory	☐ 2 - Noncontributory
k. Organ failure: *(REASORGF)*	☐ 1 - Contributory	☐ 2 - Noncontributory
Specify organ: *(ADM3SPEC)*		
l. Trauma: *(REASTRAM)*	☐ 1 - Contributory	☐ 2 - Noncontributory
m. Psychiatric: *(REASPSYC)*	☐ 1 - Contributory	☐ 2 - Noncontributory
n. Secondary malignancy: *(REASMALG)*	☐ 1 - Contributory	☐ 2 - Noncontributory
o. Scheduled procedure/treatment: *(REASPROC)*	☐ 1 - Contributory	☐ 2 - Noncontributory
p. Thrombosis/thrombus/embolism: *(REASTRMB)*	☐ 1 - Contributory	☐ 2 - Noncontributory
q. Other: *(REASOTHR)*	☐ 1 - Contributory	☐ 2 - Noncontributory
Specify other: *(ADM2SPEC)*		

5. Record re-admission institution: *(ADMCENTR)*

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

Comments: *(ADMCOMM1)*

Additional Selection Options for ADM

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

Blood and Marrow Transplant Clinical Trials Network

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

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

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

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

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

Comments: *(AE1COMM)*

Additional Selection Options for AE1

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

Blood and Marrow Transplant Clinical Trials Network

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

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

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

1. Report activation status: *(AVSTAT_A)*

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

Relevant Past Medical History

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

☐ 1 - Yes ☐ 2 - No

(SEMEDHX)

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

(SESUMM)

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4. Initial submitter: *(SEISUBBY)*

Name: Date: *(SEISUBDT)* *(mm/dd/yyyy)*

5. Authorized submitter: *(SEASUBBY)*

Name: Date: *(SEASUBDT)* *(mm/dd/yyyy)* ?

Blood and Marrow Transplant Clinical Trials Network

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

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

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

1. Report activation status: *(AVSTAT_B)*

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

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

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

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

Comments: *(AE3COMM)*

Blood and Marrow Transplant Clinical Trials Network

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

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

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

1. Report activation status: *(AVSTAT_C)*

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

Laboratory Test Results

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

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

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

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

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

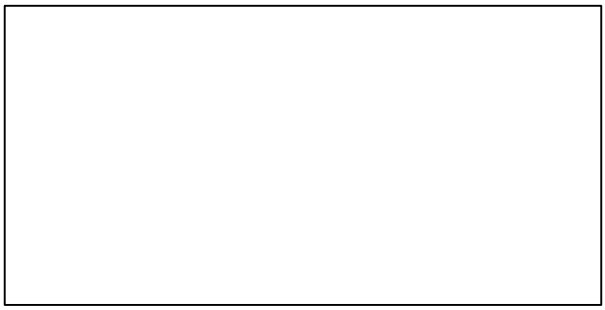
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

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

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

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

Comments: *(AE4COMM)*



Blood and Marrow Transplant Clinical Trials Network

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

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

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

1. Report activation status: *(AVSTAT_D)*

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

2. Reviewed: *(AEREVIEW)*

☐ 1 - Yes ☐ 2 - No

3. Reviewed by: *(ARFREVBY)*

4. Review date: *(ARFREVDT)*

(mm/dd/yyyy)

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

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

Blood and Marrow Transplant Clinical Trials Network

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

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

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

1. Adverse event status: *(AVSTAT_E)*

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

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

6. If **No**, what additional information is required: *(AMREVINF)*

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

Comments: *(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Follow Up GVHD Form (CGV)

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

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

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

Answer questions 3-9 relating to acute GVHD.

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

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

Answer questions 10-20 relating to chronic GVHD.

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

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

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

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

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

Skin/Hair

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

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

?

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

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

Ocular

22. Xerophthalmia: *(DRYEYES)*

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

Oral

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

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

Pulmonary

24. Dyspnea: *(CGVDYSPN)*

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

25. Pulmonary fibrosis: *(PULMFIBR)*

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

26. Bronchiolitis obliterans: *(BRNCOBLT)*

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

27. FEV1: *(CGVFEV1)*

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

28. Oxygen saturation: *(O2SAT)*

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

Gastrointestinal

29. Esophagus: *(ESOPHAGS)*

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

30. Nausea and vomiting: *(NAUSVOMT)*

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

31. Diarrhea: *(CGVDIARH)*

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

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

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

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

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

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

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

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

35. Malabsorption: *(MALABSRP)*

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

Hepatic

36. Bilirubin level: *(LIVERBIL)*

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

Genitourinary

37. Vaginitis: *(VAGNITIS)*

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

Musculoskeletal

38. Contractures: *(CONTRCTR)*

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

39. Myositis: *(MYOSITIS)*

☐ 1 - Yes ☐ 2 - No

Hematologic

40. Eosinophilia: *(EOSINPHL)*

☐ 1 - Yes ☐ 2 - No

Other

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

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

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

Specify other organ: *(ORGSPEC)* _____

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

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

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

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

Answer questions 51-54 relating to GVHD therapy.

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

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

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

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

b. Azathioprine: *(THRPYAZA)*

c. Cyclosporine: *(THRPYCYC)*

d. Systemic Corticosteroids: *(THRPYSCO)*

e. Topical Corticosteroids: *(THRPYTCO)*

f. Thalidomide: *(THRPYTHA)*

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

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

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

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

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

l. Etretinate: *(THRPYETR)*

m. Lamprene: *(THRPYLAM)*

n. Etanercept: *(THRPYETA)*

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

p. Chloroquine Phosphate: *(THRPYCPH)*

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

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

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

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

r. In Vivo Immunotoxin: *(THRPYIMM)*

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

Specify in vivo immunotoxin used: *(IMMAGNT)*

s. Other: *(THRPYOTH)*

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

Specify other agent used: *(OTHAGNT)*

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

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

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

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

?

Answer questions 55-58 relating to current patient status.

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

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

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

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

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

Comments: *(CGVCOMM)*

Additional Selection Options for CGV

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

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

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

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

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

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

7. Race: *(RACE)*

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

Specify race: *(RACESP)*

8. Secondary Race: *(RACE2)*

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

Specify secondary race: *(RACE2SP)*

Comments: *(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Specimen Acquisitions Form - Event-Driven Samples (EDS)

Web Version: 1.0; 4.01; 03-09-10

Segment *(PROTSEG)*:
Sample Events *(SAMPEVEN)*:
Date Event Occurred *(DATOCCRD)*:

Pharmacokinetics

1. Record date study drug infused or orally administered: *(DATEINFA)* *(mm/dd/yyyy)*
2. Record time study drug infused or orally administered: *(TIMEINFA)* *(hh:mm)*
3. Record date sample collected: *(PHARDATE)* *(mm/dd/yyyy)*
4. Record time sample collected: *(PHARTIME)* *(hh:mm)*
5. Window of time after start of infusion or administration of oral dose sample was drawn: *(WINSACOL)*

1-1 - Window 1 (1-5 Hours after Infusion/Administration)
2-2 - Window 2 (5-8 Hours after Infusion/Administration)
3-3 - Window 3 (8-12 Hours after Infusion/Administration)
4-4 - Other

Note: Samples must be collected twice weekly during empirical therapy with Ampho B or Caspofungin for up to 14 days.
Note: Samples must be collected twice weekly for 4 weeks and then once every 2 weeks for 8 weeks (for a total of 12 samples) during antifungal therapy.

Investigational Fungal Diagnostic Assays
Note: 2 samples must be collected; 1 for blood and 1 for serum.

6. Record date samples collected: *(FDDATE)* *(mm/dd/yyyy)*
7.

Sample (1 blood and 1 serum)	Was a sample collected?	Date Collected
Week 1, 1st Collection	*(E4F1W1CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT411)* *(mm/dd/yyyy)*
Week 1, 2nd Collection	*(E4F1W2CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT412)* *(mm/dd/yyyy)*
Week 2, 1st Collection	*(E4F2W1CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT421)* *(mm/dd/yyyy)*
Week 2, 2nd Collection	*(E4F2W2CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT422)* *(mm/dd/yyyy)*

8.

Sample (1 Blood and 1 Serum)	Was a sample collected?	Date Collected
Week 1, 1st Collection	*(E5F1W1CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT511)* *(mm/dd/yyyy)*
Week 1, 2nd Collection	*(E5F1W2CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT512)* *(mm/dd/yyyy)*
Week 2, 1st Collection	*(E5F2W1CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT521)* *(mm/dd/yyyy)*
Week 2, 2nd Collection	*(E5F2W2CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT522)* *(mm/dd/yyyy)*
Week 3, 1st Collection	*(E5F3W1CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT531)* *(mm/dd/yyyy)*
Week 3, 2nd Collection	*(E5F3W2CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT532)* *(mm/dd/yyyy)*
Week 4, 1st Collection	*(E5F4W1CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT541)* *(mm/dd/yyyy)*
Week 4, 2nd Collection	*(E5F4W2CL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT542)* *(mm/dd/yyyy)*
Week 6 Collection	*(E5F6WCL)* ☐ 1 - Yes ☐ 2 - No	*(FDDATE56)* *(mm/dd/yyyy)*
Week 8 Collection	*(E5F8WCL)* ☐ 1 - Yes ☐ 2 - No	*(FDDATE58)* *(mm/dd/yyyy)*
Week 10 Collection	*(E5F10WCL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT510)* *(mm/dd/yyyy)*
Week 12 Collection	*(E5F12WCL)* ☐ 1 - Yes ☐ 2 - No	*(FDDAT125)* *(mm/dd/yyyy)*

Antifungal Susceptibility Testing

9. Was a sample for Antifungal Susceptibility Testing collected? *(AFUNOBT)* ☐ 1 - Yes ☐ 2 - No
10. Record date sample collected: *(AFUNDAT)* *(mm/dd/yyyy)*

Infected Tissue

11. Was a paraffin block of infected tissue obtained? *(INFTOBT)* ☐ 1 - Yes ☐ 2 - No
12. Record date sample collected: *(INFTDAT)* _____ *(mm/dd/yyyy)*

Investigational Galactomannan Assay

13. Was a BAL sample obtained? *(BALOBT)* ☐ 1 - Yes ☐ 2 - No
14. Record date sample collected: *(BALDAT)* _____ *(mm/dd/yyyy)*

Diagnostic Galactomannan Assay

15. Record date the sample was collected: *(DGADAT2)* _____ *(mm/dd/yyyy)*
16.

Blood Sample	Was a sample collected?	Date Collected
Week 1, 1st Collection	*(E4G1W1CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT411)* _____ *(mm/dd/yyyy)*
Week 1, 2nd Collection	*(E4G1W2CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT412)* _____ *(mm/dd/yyyy)*
Week 2, 1st Collection	*(E4G2W1CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT421)* _____ *(mm/dd/yyyy)*
Week 2, 2nd Collection	*(E4G2W2CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT422)* _____ *(mm/dd/yyyy)*

Investigational Monitoring of Treatment Galactomannan Assays

17. Record date sample collected: *(MGADATE)* _____ *(mm/dd/yyyy)*
18.

Blood Sample	Was a sample collected?	Date Collected
Week 1, 1st Collection	*(E5G1W1CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT511)* _____ *(mm/dd/yyyy)*
Week 1, 2nd Collection	*(E5G1W2CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT512)* _____ *(mm/dd/yyyy)*
Week 2, 1st Collection	*(E5G2W1CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT521)* _____ *(mm/dd/yyyy)*
Week 2, 2nd Collection	*(E5G2W2CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT522)* _____ *(mm/dd/yyyy)*
Week 3, 1st Collection	*(E5G3W1CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT531)* _____ *(mm/dd/yyyy)*
Week 3, 2nd Collection	*(E5G3W2CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT532)* _____ *(mm/dd/yyyy)*
Week 4, 1st Collection	*(E5G4W1CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT541)* _____ *(mm/dd/yyyy)*
Week 4, 2nd Collection	*(E5G4W2CL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT542)* _____ *(mm/dd/yyyy)*
Week 6 Collection	*(E5G6WCL)* ☐ 1 - Yes ☐ 2 - No	*(DGDATE56)* _____ *(mm/dd/yyyy)*
Week 8 Collection	*(E5G8WCL)* ☐ 1 - Yes ☐ 2 - No	*(DGDATE58)* _____ *(mm/dd/yyyy)*
Week 10 Collection	*(E5G10WCL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT510)* _____ *(mm/dd/yyyy)*
Week 12 Collection	*(E5G12WCL)* ☐ 1 - Yes ☐ 2 - No	*(DGDAT125)* _____ *(mm/dd/yyyy)*

Comments: *(EDSCOMM)*

Additional Selection Options for EDS

Sample Events *(SAMPEVEN)* (key field):
1-1 - Onset of Serious, Suspected Drug Toxicity
2-2 - Onset of Possible Fungal Infection
3-3 - Onset of Presumptive, Probable or Proven Fungal Infection
4-4 - Treatment of Possible Fungal Infection with Empirical Amphotericin B or Caspofungin
5-5 - Treatment of Presumptive, Probable or Proven Fungal Infection with Antifungal Therapy
6-6 - Infection Relapse After Discontinuation of Antifungal Therapy
7-7 - Bronchoscopy Performed

Blood and Marrow Transplant Clinical Trials Network

0101B (ENR)

Web Version: 1.0; 3.00; 08-10-09

1. Record date of initiation of conditioning: *(CONDINDT)* _____ *(mm/dd/yyyy)*
2. Record proposed date of transplant: *(PROPTXDT)* _____ *(mm/dd/yyyy)*

3. Record the following information within 72 hours of Day 0 (date of transplant):

	Most Recent Value	ULN for your Institution	Date Sample Obtained
ALT:	*(ALT72HRS)* _____ *(xxx)* Units/L	*(ALTULN72)* _____ *(xx)* Units/L	*(ALTDTOBT)* _____ *(mm/dd/yyyy)*

4. Was a baseline GM blood sample drawn? *(GMADRAW)* ☐ 1 - Yes ☐ 2 - No
5. Record date baseline GM sample was drawn: *(GMADRWDT)* _____ *(mm/dd/yyyy)*
6. Have results of the baseline GM sample been obtained? *(GMRESLTS)* ☐ 1 - Yes ☐ 2 - No
7. Was a CT scan of the chest obtained within the last 6 weeks? *(CTSCAN)* ☐ 1 - Yes ☐ 2 - No
8. Record date CT scan was obtained: *(CTSCANDT)* _____ *(mm/dd/yyyy)*

Comments: *(COMM1ENR)*

Blood and Marrow Transplant Clinical Trials Network

Fungal Infection Form (FIN)

Web Version: 1.0; 5.00; 04-20-09

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

1. What is the patient's fungal infection grade? *(FINGRADE)*

1-1 - Proven Fungal Infection
2-2 - Probable Fungal Infection
3-3 - Possible Fungal Infection
4-4 - Presumptive Fungal Infection
5-5 - Possible Due to GM Only

Complete Specimen Acquisitions Form - Event Driven Samples to record sample(s) obtained for diagnosis of proven, probable, presumptive or possible fungal infection.

2. Does the patient have a deep tissue infection? *(DPTISINF)* ☐ 1 - Yes ☐ 2 - No

3. Record the type of deep tissue infection: *(TYPDPTIS)*

1-1 - Mold
2-2 - Yeast
3-3 - Other

4. Record organism: *(DTIORG)*

01-01 - Aspergillus Flavus
02-02 - Aspergillus Fumigatus
03-03 - Aspergillus Niger
04-04 - Aspergillus Terreus
05-05 - Aspergillus (NOS)
*Additional Options Listed Below

Specify other: *(DTORGSPC)*

5. Record biopsy/needle aspirate results: *(DTBIOPSY)*

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

6. Record biopsy/needle aspirate site: *(DTBIOPST)*

02-02 - Disseminated - Generalized, Isolated at 2 or More Distinct Sites
00--- Central Nervous System ---
03-03 - Brain
04-04 - Spinal Cord
05-05 - Meninges and CSF
*Additional Options Listed Below

If disseminated, record the 2 or more positive sites: *(DTDISEMB)*

7. Record specimen type: *(DTBIOPSP)*

1-1 - Tissue
2-2 - Fluid
3-3 - Mucous Membranes
4-4 - CSF
5-5 - Urine

8. Were other biopsy/needle aspirate results obtained? *(DTOTHRBP)* ☐ 1 - Yes ☐ 2 - No

Specify other biopsy/needle aspirate sites and their results (positive or negative): *(DTOTHBSP)*

9. Record culture results: *(DTCULTRS)*

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

10. Record culture site: *(DTCULTST)*

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
*Additional Options Listed Below

If disseminated, record the 2 or more positive sites: *(DTDISCLT)*

11. Record specimen type: *(DTSPECTY)*

1-1 - Urine
2-2 - Mucous Membranes
3-3 - CSF
4-4 - Blood (Whole, Plasma, or Serum)
5-5 - Sputum
*Additional Options Listed Below

12. Were other culture results obtained? *(DTOTHCLT)* ☐ 1 - Yes ☐ 2 - No

Specify other culture sites and their results (positive or negative): *(DTOTHCST)*

13. Record microscopic examination results: *(DTMICRO)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

14. Record specimen type: *(DTMCROST)*

1-1 - Urine
2-2 - Mucous Membranes
3-3 - CSF
4-4 - Blood (Whole, Plasma, or Serum)
5-5 - Sputum
*Additional Options Listed Below

15. Record CSF antigen testing results: *(DTANTIGN)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

16. Record histopathologic examination results: *(DTHISTO)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

17. Record cytopathologic examination results: *(DTCYTOEX)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

18. Were hyphae present? *(DTHYPHAE)* ☐ 1 - Yes ☐ 2 - No

19. Was there evidence of associated tissue damage (either microscopically or unequivocally by imaging)? *(DTTISDMG)* ☐ 1 - Yes ☐ 2 - No

20. Were yeast cells present? *(DTYEASTC)* ☐ 1 - Yes ☐ 2 - No

21. Does the patient have fungemia? *(FUNGEMIA)* ☐ 1 - Yes ☐ 2 - No

22. Record type of fungemia: *(FUNGTYPE)*

1-1 - Mold
2-2 - Yeast
3-3 - Other

23. Record organism: *(FUNGORG)*

01-01 - Aspergillus Flavus
02-02 - Aspergillus Fumigatus
03-03 - Aspergillus Niger
04-04 - Aspergillus Terreus
05-05 - Aspergillus (NOS)
*Additional Options Listed Below

Specify other: *(FNGORGSP)*

24. Record culture results: *(FUNGCULT)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

25. Did the culture yield *aspergillus* species? *(FGCAPERG)* ☐ 1 - Yes ☐ 2 - No

26. Did the culture yield *penicillium* species? *(FGCPENIC)* ☐ 1 - Yes ☐ 2 - No

27. Was the species *penicillium marneffei*? *(FGCPMARN)* ☐ 1 - Yes ☐ 2 - No

28. Does the patient have an endemic fungal infection? *(ENDEMIC)* ☐ 1 - Yes ☐ 2 - No

29. Record culture results: *(ENDCULT)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

30. Record culture site: *(ENDCLTRS)*

1-1 - Blood/Buffy Coat
2-2 - Disseminated - Generalized, Isolated at 2 or More Distinct Sites
3-3 - Meninges and CSF
4-4 - Lower Respiratory Tract (Lung)
5-5 - Kidneys, Renal Pelvis, Ureters and Bladder
*Additional Options Listed Below

If disseminated, record the 2 or more positive sites: *(ENDDISCL)*

31. Record specimen type: *(ENDCLTSP)*

1-1 - Blood (Whole, Plasma or Serum)
2-2 - Urine
3-3 - Bronchoalveolar Lavage Fluid
4-4 - Tissue

32. Record organism(s) present: *(ENDORGAN)*

1-1 - Histoplasmosis
2-2 - Blastomycosis
3-3 - Coccidioidomycosis
4-4 - Paracoccidioidomycosis
5-5 - Multiple Organisms

Specify multiple endemic organisms: *(ENDORGSP)*

33. Record RIA results: *(ENDRIA)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

34. Record RIA specimen type: *(ENDRIAST)* ☐ 1 - Urine ☐ 2 - Blood (Whole, Plasma or Serum)

35. Record histopathologic examination results: *(ENDHISTO)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

36. Were the appropriate morphological forms present? *(ENDMRPH1)* ☐ 1 - Yes ☐ 2 - No

37. Record microscopic examination results: *(ENDMICRO)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

38. Were the appropriate morphological forms present? *(ENDMRPH2)* ☐ 1 - Yes ☐ 2 - No

39. Is the infection systemic? *(ENDSYSTE)* ☐ 1 - Yes ☐ 2 - No

40. Is the infection confined to the lungs? *(ENDLUNGS)* ☐ 1 - Yes ☐ 2 - No

Host Factors

Indicate if the patient meets any of the host factors below relative to the infection start date:

41. Neutropenia (< 500 neutrophils/mm^3 for > 10 days)? *(NEUTROP)* ☐ 1 - Yes ☐ 2 - No Ten days prior to infection start date: *(NEUTRDT)* *(mm/dd/yyyy)*

42. Persistent fever for > 96 hours? *(PERSFEVR)* ☐ 1 - Yes ☐ 2 - No 96 hours prior to infection start date: *(PERFEVDT)* *(mm/dd/yyyy)*

43. Was the fever refractory to broad-spectrum antibacterial treatment? *(RFRCRX)* ☐ 1 - Yes ☐ 2 - No

44. Was the body temperature either >38^0 or <36^{0}C? *(BODYTEMP)* ☐ 1 - Yes ☐ 2 - No

45. Prolonged neutropenia (>10 days) in previous 60 days? *(PRONEUT)* ☐ 1 - Yes ☐ 2 - No 60 days prior to infection start date: *(PRNEUTDT)* *(mm/dd/yyyy)*

46. Use of significant immunosuppressive agents in previous 30 days *(IMUNAGNT)* ☐ 1 - Yes ☐ 2 - No 30 days prior to infection start date: *(IMUNAGDT)* *(mm/dd/yyyy)*

47. Prior proven, probable or presumptive fungal infection during a previous episode of neutropenia? *(PREVNEUT)* ☐ 1 - Yes ☐ 2 - No

48. Acute graft-versus-host disease (Grade ≥2 or extensive chronic disease)? *(GVHDSGNS)* ☐ 1 - Yes ☐ 2 - No

49. Use of systemic corticosteroids for 3 weeks or more in the previous 60 days? *(CRTSTRDS)* ☐ 1 - Yes ☐ 2 - No 60 days prior to infection start date: *(CORTICDT)* *(mm/dd/yyyy)*

50. Record average daily dose of systemic corticosteroids 3 weeks before the infection start date: *(AVGDOSE)*

1-1 - 0 mg/kd/day
2-2 - <1 mg/kg/day
3-3 - 1-2 mg/kg/day
4-4 - >2 mg/kg/day

3 weeks prior to infection start date: *(AVGDSDT)* *(mm/dd/yyyy)*

Microbiological Factors

Indicate if the patient meets any of the microbiological factors below:

51. Culture for mold (including *Aspergillus, Fusaruim, Scedosporium* species or *Zygomycetes*): *(CULTMOLD)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

52. Record culture method: *(CLTMTHD1)*
    ☐ 1 - Sputum Sample ☐ 2 - Bronchoalveolar Lavage Fluid Sample

53. Culture for *Cryptococcus neoformans*: *(CNEOFORM)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

54. Record culture method: *(CLTMTHD2)*
    ☐ 1 - Sputum Sample ☐ 2 - Bronchoalveolar Lavage Fluid Sample

55. Culture for an endemic fungal pathogen (i.e. histoplasmosis, blastomycosis, coccidioidomycosis and paracoccidioidomycosis): *(CENDPATH)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

56. Record culture method: *(CLTMTHD3)*
    ☐ 1 - Sputum Sample ☐ 2 - Bronchoalveolar Lavage Fluid Sample

57. Culture or findings of cytologic/direct microscopic evaluation for mold from sinus aspirate specimen? *(CSINUS)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

58. Cytologic/direct microscopic evaluation for mold? *(CYTMOLD)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

59. Record evaluation method: *(CLTMTHD4)*
    ☐ 1 - Sputum Sample ☐ 2 - Bronchoalveolar Lavage Fluid Sample

60. Cytologic/direct microscopic evaluation for *Cryptococcus* species? *(CYTCRYPT)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

61. Record evaluation method: *(CLTMTHD5)*
    ☐ 1 - Sputum Sample ☐ 2 - Bronchoalveolar Lavage Fluid Sample

62. Result for Galactomannan Assay in a blood sample? *(GMBLOOD)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

63. Was the patient on Zosyn at time of blood draw? *(ZOSYN1)*
    ☐ 1 - Yes ☐ 2 - No

    Patient must be off Zosyn for 5 days prior to allowance of a positive GM result as a microbiological criterion to support documentation of an invasive (proven, probable, presumptive or possible) fungal infection.

64. Result for Galactomannan Assay in sample other than blood? *(GMOTHER)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

65. Record specimen type: *(GMOTHSPC)*
    ☐ 1 - Bronchoalveolar Lavage Fluid ☐ 2 - CSF

66. Was the patient on Zosyn at time of sample draw? *(ZOSYN2)*
    ☐ 1 - Yes ☐ 2 - No

    Patient must be off Zosyn for 5 days prior to allowance of a positive GM result as a microbiological criterion to support documentation of an invasive (proven, probable, presumptive or possible) fungal infection.

67. Result for cryptococcal antigen in blood sample? *(CRYPTBLD)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

68. Cytologic or direct microscopic examination for fungal elements in sterile body fluid sample? *(FNGELEMN)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

69. Result for *Histoplasma capsulatum* antigen? *(HISTOCAP)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

70. Record specimen type: *(HISTOSPM)*
    1-1 - Blood
    2-2 - Urine
    3-3 - CSF

71. Culture or urine samples for yeast in absence of urinary catheter? *(CULTYEAS)*
    1-1 - Positive
    2-2 - Negative
    3-3 - NotDone

72. Were two positive samples obtained? *(TWOPOSY)*
    ☐ 1 - Yes ☐ 2 - No

73. *Candida* casts in urine in absence of urinary catheter? *(CANDIDAU)*

1-1 - Positive
2-2 - Negative
3-3 - NotDone

Clinical Factors

Indicate if the patient meets any of the clinical factors below:

Lower Respiratory Tract Infection:

74. New infiltrates detected by CT imaging? *(NEWINFLT)*

1-1 - Yes
2-2 - No
3-3 - NotApplicable

75. Record the new infiltrate: *(INFLTRTS)*

1-1 - Halo-Sign
2-2 - Air-CrescentSign
3-3 - Cavity within Area of Consolidation
4-4 - Wedge Shaped Infiltrate
5-5 - New Nonspecific Focal Infiltrate
*Additional Options Listed Below

Specify other infiltrate: *(FIN1SPEC)*

If the new infiltrate is Halo-Sign, was there a well defined nodule of at least 1 cm in diameter? *(INFLHALO)* ☐ 1 - Yes ☐ 2 - No

76. Lower respiratory symptoms? *(LOWRRESP)* ☐ 1 - Yes ☐ 2 - No

Record symptoms of lower respiratory tract infection.

77. Cough: *(RSPCOUGH)* ☐ 1 - Yes ☐ 2 - No
78. Chest pain: *(RSPCHSTP)* ☐ 1 - Yes ☐ 2 - No
79. Hemoptysis: *(RSPHEMOP)* ☐ 1 - Yes ☐ 2 - No
80. Dyspnea: *(RSPDYSPN)* ☐ 1 - Yes ☐ 2 - No
81. Other: *(RSPOTHER)* ☐ 1 - Yes ☐ 2 - No

Specify other lower respiratory tract symptoms: *(FIN2SPEC)*

82. Physical findings of pleural rub? *(PLEURRUB)* ☐ 1 - Yes ☐ 2 - No
83. Pleural effusion? *(PLEUREFF)* ☐ 1 - Yes ☐ 2 - No
84. Pleural pain? *(PLEUPAIN)* ☐ 1 - Yes ☐ 2 - No
85. Broncoscopic evidence suggesting other etiology? *(BRONCEDI)* ☐ 1 - Yes ☐ 2 - No

If yes, specify other etiology: *(OTHRETIO)*

Sinonasal Infection:

86. Radiological evidence of invasive infection in sinuses? *(INVSINUS)*

1-1 - Yes
2-2 - No
3-3 - NotApplicable

87. Record radiological evidence: *(INFEVID)*

1-1 - Erosion of Sinus Walls or Extension of Infection to Neighboring Structures
2-2 - Extensive Skull Base Destruction
3-3 - Other

Specify other radiologic evidence: *(FIN3SPEC)*

88. Upper respiratory symptoms? *(UPPRRESP)* ☐ 1 - Yes ☐ 2 - No

Record symptoms of upper respiratory infection.

89. Nasal discharge: *(UPPRNSLD)* ☐ 1 - Yes ☐ 2 - No
90. Stuffiness: *(UPPRSTUF)* ☐ 1 - Yes ☐ 2 - No
91. Other: *(UPPROTHR)* ☐ 1 - Yes ☐ 2 - No

Specify other symptoms: *(FIN4SPEC)*

92. Nose ulceration? *(ULCRATN)* ☐ 1 - Yes ☐ 2 - No
93. Eschar of nasal mucosa? *(NSLMUCSA)* ☐ 1 - Yes ☐ 2 - No
94. Epistaxis? *(EPISTAXS)* ☐ 1 - Yes ☐ 2 - No
95. Periorbital swelling? *(ORBTLSWL)* ☐ 1 - Yes ☐ 2 - No
96. Maxillary tenderness? *(MAXTNDRN)* ☐ 1 - Yes ☐ 2 - No
97. Black necrotic lesions? *(NCRTCLSN)* ☐ 1 - Yes ☐ 2 - No
98. Perforation of hard palate? *(PERFPLT)* ☐ 1 - Yes ☐ 2 - No

CNS Infection:

99. Radiological evidence suggesting CNS infection? *(CNSRAD)*

1-1 - Yes
2-2 - No
3-3 - Not Applicable

100. Record radiologic evidence: *(RADEVIDN)*

1-1 - Mastoiditis
2-2 - Other Parameningeal Foci
3-3 - Extradural Empyema
4-4 - Intraparenchymal Brain Lesion
5-5 - Spinal Cord Mass Lesion
*Additional Options Listed Below

Specify other radiological evidence: *(FIN5SPEC)*

101. Focal neurological symptoms and signs? *(NEUROINF)* ☐ 1 - Yes ☐ 2 - No

Record focal neurological symptoms and signs.

102. Focal seizures: *(NEURFOCL)* ☐ 1 - Yes ☐ 2 - No

103. Hemiparesis: *(NEURHEMI)* ☐ 1 - Yes ☐ 2 - No

104. Cranial nerve palsies: *(NEURCRNI)* ☐ 1 - Yes ☐ 2 - No

105. Other: *(NEUROTHR)* ☐ 1 - Yes ☐ 2 - No

Specify other focal neurological symptoms and signs: *(FIN6SPEC)*

106. Mental changes (e.g. lethargy, delerium, stupor)? *(MNTLCHNG)* ☐ 1 - Yes ☐ 2 - No

107. Meningeal irritation findings (e.g. photophobia, stiff neck)? *(MENINGEL)* ☐ 1 - Yes ☐ 2 - No

108. Abnormalities in CSF biochemistry and cell count? *(CSFABNRM)*

1-1 - Yes
2-2 - No
3-3 - Not Applicable

109. Is CSF negative for other pathogens by culture or microscopy? *(CSFPTHGN)* ☐ 1 - Yes ☐ 2 - No

110. Is CSF negative for malignant cells? *(CSFNMALC)* ☐ 1 - Yes ☐ 2 - No

Disseminated Fungal Infection:

111. Papular or nodular skin lesions without any other explanation? *(SKNLSNS)* ☐ 1 - Yes ☐ 2 - No

112. Intraocular findings suggestive of hematogenous fungal chorioretinitis or endophthalmitis? *(OCULAR)* ☐ 1 - Yes ☐ 2 - No

Chronic Disseminated Candidiasis:

113. Small, peripheral, target-like abscesses (bull's-eye lesions) in liver and/or spleen: *(BULLSEYE)*

1-1 - Yes
2-2 - No
3-3 - Not Applicable

114. Record method of demonstrating abscesses: *(CANDEVAL)*

1-1 - CT Scan
2-2 - MRI
3-3 - Ultrasound

	Most Recent Value	ULN for your Institution	Date Value Obtained
115. Serum Alkaline Phosphatase:	*(ALKPHOS)* _____ *(xxx)* U/L	*(ALKULN)* _____ *(xxx)* U/L	*(ALKPHSDT)* _____ *(mm/dd/yyyy)*

Comments: *(FIN1COMM)*

Additional Selection Options for FIN

Record organism:
06-06 - Histoplasma Species
07-07 - Fusarium Species
08-08 - Mold (NOS)
09-09 - Candida Albicans
10-10 - Candida Krusei
11-11 - Candida Parapsilosis
12-12 - Candida Tropicalis
13-13 - Candida Glabrata/Torulopsis Glabrata
14-14 - Candida (NOS)
15-15 - Cryptococcus Species
16-16 - Yeast (NOS)
17-17 - Mucormycosis/Zygomycetes
99-99 - Other

Record biopsy/needle aspirate site:
06-06 - Central Nervous System Unspecified
00---- Gastrointestinal Tract ---
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
15-15 - Peritoneum
16-16 - Liver
17-17 - Gastrointestinal Tract Unspecified
00---- Respiratory Tract ---
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
00---- Genito-Urinary Tract ---
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
00---- Skin ---
30-30 - Genital Area
31-31 - Rash, Pustules, or Abscesses Not Typical of Any of the Above
32-32 - Skin Unspecified
00---- Other ---
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

Record culture site:
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

Record specimen type:
6-6 - Bronchoalveolar Lavage Fluid
7-7 - Tissue
8-8 - Fluid
9-9 - Feces/Stool

Record culture site:
9-9 - Other

Record the new infiltrate:
9-9 - Other

Record radiologic evidence:
6-6 - Other

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 been treated for progression/relapse? *(RELAPSTX)* ☐ 1 - Yes ☐ 2 - No

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

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

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

Specify other treatment: *(FUS1SPEC)* _____

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

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

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

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

11.

12. Has the patient experienced any new clinically significant infections? *(NEWINFX)* ☐ 1 - Yes ☐ 2 - No

13. Did the patient experience a possible, probable, presumptive, or proven fungal infection? *(FUSFUNGL)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Fungal Infection Form must be submitted.

14. Date of fungal infection: *(FNGLINDT)* _____ *(mm/dd/yyyy)*

15. Did the patient experience any non-fungal infections? *(FUSNONFN)* ☐ 1 - Yes ☐ 2 - No
If Yes, an Infection Form must be submitted.

16. Date of non-fungal infection: *(NONFNGDT)* _____ *(mm/dd/yyyy)*

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

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

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

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

21. Has the patient been prematurely permanently withdrawn from the study drug prior to Day 100 (or Day 180)? *(WITHDRAW)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Premature Permanent Withdrawal Form must be submitted.

22. Date of premature permanent withdrawal: *(WTHDRWDT)* _____ *(mm/dd/yyyy)*

23. Has the patient been given any systemic fungal prophylaxis medication other than protocol study drug during the assessment period? *(PROPHMED)* ☐ 1 - Yes ☐ 2 - No
If Yes, a Non-Study Drug Prophylaxis Form must be submitted.

24. Will the patient continue on study drug until Day 180 for protocol-specified reasons? *(CONTSTDR)* ☐ 1 - Yes ☐ 2 - No

Comments: *(FUS1COMM)*

Additional Selection Options for FUS

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

Blood and Marrow Transplant Clinical Trials Network

Diagnostic GM Assay Form - Event Driven Samples (GME)

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

Segment *(PROTSEG)*:
Date GM Sample Drawn *(GMEDTSD)*:

Record the result of the event driven diagnostic GM assay blood draw. Event driven diagnostic GM Assay samples should be drawn at the onset of a possible fungal infection and during an empirical trial of Amphotericin B.

1. Record result: *(GMERESLT)* ☐ 1 - Positive ☐ 2 - Negative

2. Record index value(s) if available: *(GMEINXV1)* _____ *(x.xx)* *(GMEINXV2)* _____ *(x.xx)*

Note: If a sample is positive, two index values (one for the initial and one for the repeat test) of the SAME sample are required to be reported if available.

Comments: *(GMECOMM1)*

Blood and Marrow Transplant Clinical Trials Network

Diagnostic GM Assay Form - Scheduled Samples (GMS)

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

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

1. Is the patient a recipient of a T cell depleted transplant and received post-transplant GVHD prophylaxis, OR currently taking steriods, OR has or has had acute GVHD requiring systemic therapy? *(FREQCOND)* ☐ 1 - Yes ☐ 2 - No

Record the result(s) of the scheduled diagnostic GM assay blood draw(s) for the previous week.
Record the result of the baseline diagnostic Galactomannan Assay sample drawn prior to the initiation of conditioning.

1st Weekly Sample:

2. Record date of 1st weekly blood draw: *(BLDRWDT1)* _____ *(mm/dd/yyyy)*
3. Record date of baseline blood draw: *(BSLBDDT1)* _____ *(mm/dd/yyyy)*

4. Record result: *(GMRESLT1)* ☐ 1 - Positive ☐ 2 - Negative
5. Record index value(s) if available: *(GMSINXV1)* _____ *(x.xx)* *(GMSINXV2)* _____ *(x.xx)*

Note: If a sample is positive, two index values (one for the initial and one for the repeat test) of the SAME sample are required to be reported if available.

2nd Weekly Sample:

6. Record date of 2nd weekly blood draw: *(BLDRWDT2)* _____ *(mm/dd/yyyy)*

7. Record result: *(GMRESLT2)* ☐ 1 - Positive ☐ 2 - Negative
8. Record index value(s) if available: *(GMSINXV3)* _____ *(x.xx)* *(GMSINXV4)* _____ *(x.xx)*

Note: If a sample is positive, two index values (one for the initial and one for the repeat test) of the SAME sample are required to be reported if available.

Comments: *(COMMENTS)*

Blood and Marrow Transplant Clinical Trials Network

Acute GVHD Form (GVH)

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

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

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

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

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

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

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

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

5. Skin abnormalities: *(GVHSKINA)*

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

   ?

6. Skin etiologies:

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

Specify other skin etiologies: *(GVHSKNSP)*

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

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

8. Upper GI abnormalities: *(GVHUPGIA)*

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

9. Upper intestinal tract etiologies:

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

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

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

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

11. Lower GI abnormalities: *(GVHINTA)*

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

?

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

12. Lower intestinal tract etiologies:

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

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

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

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

14. Liver abnormalities: *(GVHLIVRA)*

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

15. Liver etiologies:

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

Specify other liver etiologies: *(GVHLIVRS)*

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

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

') }

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

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

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

Specify other agent: *(GVHAGNSP)*

18. Indicate treatment modification: *(GVHTRMOD)*

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

Comments: *(GVHCOMM)*

Additional Selection Options for GVH

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

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

Blood and Marrow Transplant Clinical Trials Network

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)*

3. Was a CD4 count performed? *(CD4DONE)* ☐ 1 - Yes ☐ 2 - No
4. Date specimen collected: *(CD4DATE)* *(mm/dd/yyyy)*
5. Results: *(CD4COUNT)* *(xxxx)* per uL

Record Chimerism Assay Data for Marrow and/or Blood

Marrow

6. Was a chimerism performed on a marrow sample? *(MRWDONE)* ☐ 1 - Yes ☐ 2 - No
7. Date specimen collected: *(MRWDT2)* *(mm/dd/yyyy)*
8. 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)*

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

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

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

Blood

12. Was a chimerism performed on a blood sample? *(BLDDONE)* ☐ 1 - Yes ☐ 2 - No
13. Date specimen collected: *(BLDCHMDT)* *(mm/dd/yyyy)*
14. 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)*

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

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

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

T Cell Chimerism

18. Was a chimerism performed on a T cell sample? *(TCLDONE)*
☐ 1 - Yes ☐ 2 - No

19. Type of sample: *(TCLSMPL)*
☐ 1 - Blood ☐ 2 - Marrow

20. Date specimen collected: *(TCLDATE)*
(mm/dd/yyyy)

21. 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)*

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

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

23. % Donor: *(PCNTDNR3)*
(xx) %

24. Did the patient receive a stem cell re-infusion due to inadequate hematopoietic function? *(REINFUSE)*
☐ 1 - Yes ☐ 2 - No

25. 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 - Protozoal
O - O - Other

2. Organism I: *(ORGN01)*

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

If other specify: *(INFSPEC1)*

3. Severity of infection: *(SVRTY01)*

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

INFECTION II

4. Type of infection: *(INFTYP02)*

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

5. 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)*

6. Severity of infection: *(SVRTY02)*

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

INFECTION III

7. Type of infection: *(INFTYP03)*

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

8. 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)*

9. Severity of infection: *(SVRTY03)*

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

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

Provide agent(s) administered for this infectious period:

11. 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)*

12. 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)*

13. 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)*

14. 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

Medication Form (MED)

Web Version: 1.0; 6.00; 04-20-09

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

1. Record start date of assessment period: *(SRTASSPD)* _____ *(mm/dd/yyyy)*
2. Record end date of assessment period: *(ENDASSPD)* _____ *(mm/dd/yyyy)*
3. Since the last assessment period has the patient been prematurely permanently withdrawn from study drug prior to Day 100 (or 180)? *(PERMWD)* ☐ 1 - Yes ☐ 2 - No

   If Yes, complete Premature Permanent Withdrawal Form

4. Record total number of days during this assessment period the patient received study drug: *(NDRECSD)* _____ *(xx)*
5. Was the study drug withheld at any time during this assessment period? *(SDWTHHLD)* ☐ 1 - Yes ☐ 2 - No
6. Record reason(s) study drug was withheld during this assessment period:

a. **FUNGAL INFECTION -**

Presumptive invasive fungal infection: *(PRESIFI)* ☐ 1 - Yes ☐ 2 - No

Presumptive invasive fungal infection: *(PRESIFI)* ☐ 1 - Yes ☐ 2 - No

If Yes, complete Fungal Infection Form, Premature Permanent Withdrawal Form and Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for diagnosis of presumptive fungal infection.

Probable invasive fungal infection: *(PROBIFI)* ☐ 1 - Yes ☐ 2 - No

If Yes, complete Fungal Infection Form, Premature Permanent Withdrawal Form and Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for diagnosis of probable fungal infection.

Proven invasive fungal infection: *(PROVIFI)* ☐ 1 - Yes ☐ 2 - No

If Yes, complete Fungal Infection Form, Premature Permanent Withdrawal Form and Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for diagnosis of proven fungal infection.

b. **HEPATIC TOXICITY -**

ALT greater than 5 times the upper limit of normal, but less than 10 times the upper limit of normal: *(ALT5UPLM)* ☐ 1 - Yes ☐ 2 - No

ALT greater or equal to 10 times the upper limit of normal: *(ALTUPLMT)* ☐ 1 - Yes ☐ 2 - No

c. **VISUAL TOXICITY -**

Loss of vision (blindness): *(BLIND)* ☐ 1 - Yes ☐ 2 - No

d. **CUTANEOUS TOXICITY -**

Skin necrosis: *(NECROSIS)* ☐ 1 - Yes ☐ 2 - No

Ulcerations: *(ULCER)* ☐ 1 - Yes ☐ 2 - No

Generalized exfoliative dermatitis: *(EXDERM)* ☐ 1 - Yes ☐ 2 - No

e. **NEUROLOGIC TOXICITY -**

Hallucinations after reduction of the dose(s) of concomitant opiates or benzodiazepines: *(HALLUCIN)* ☐ 1 - Yes ☐ 2 - No

f. **CARDIAC TOXICITY -**

Arrhythmia: *(ARRHYTHM)* ☐ 1 - Yes ☐ 2 - No

g. **OTHER TOXICITY -**

Other grade III or IV toxicity: *(OTHRTOX)* ☐ 1 - Yes ☐ 2 - No

Specify other toxicity: *(MEDSPEC1)* _____

If Yes to any toxicity, complete Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for diagnosis of serious, suspected drug toxicity.

h. **MEDICATION -**

Requires Terfenadine: *(TERFENAD)* ☐ 1 - Yes ☐ 2 - No

Requires Astemizole: *(ASTEMIZO)* ☐ 1 - Yes ☐ 2 - No

Requires Cisapride: *(CISAPRID)* ☐ 1 - Yes ☐ 2 - No

Requires Sirolimus: *(SIROLIMU)* ☐ 1 - Yes ☐ 2 - No

Requires maintenance Phenytoin/anitconvulsant therapy: *(PHENYTOI)* ☐ 1 - Yes ☐ 2 - No

If Yes to any medication reasons, complete Premature Permanent Withdrawal Form

i. **OTHER -**

Pregnancy: *(PREGNANT)* ☐ 1 - Yes ☐ 2 - No

Withdrawal of consent: *(CNSNTWD)* ☐ 1 - Yes ☐ 2 - No

Other reason for withdrawal: *(OTHERWDL)* ☐ 1 - Yes ☐ 2 - No

Specify other reason for withdrawal: *(MEDSPEC2)* _____

If Yes to any other reasons, complete Premature Permanent Withdrawal Form

7. Record total number of days during this assessment period study drug was withheld: *(TDYSSDWH)* _____ *(xx)*
8. Has the study drug been withheld for more than 14 consecutive days during this assessment period for any of the toxicities outlined in 6b-g? *(SDWH10DY)* ☐ 1 - Yes ☐ 2 - No

If Yes, complete Premature Permanent Withdrawal Form

9. Has study drug been re-initiated? *(SDREINIT)* ☐ 1 - Yes ☐ 2 - No
10. During this assessment period how many treatment courses of systemic amphotericin B or caspofungin did the patient receive? *(RXAMPBAP)*

0-0 - No Treatment Course
1-1 - One Treatment Course
2-2 - Two Treatment Courses
3-3 - Three Treatment Courses

TREATMENT COURSE I

11. Record date treatment initiated: *(RXINDT1)* _____ *(mm/dd/yyyy)*
12. Treatment Agent: *(RXIN1TRT)*

1-1 - Amphotericin B or Lipid Formulation of Amphotericin B (Ambisome or Abelcet)
2-2 - Caspofungin or Other Echinocandin (Micafungin or Anidulafungin)
9-9 - Other, Specify

13. Specify other treatment: *(RXIN1SPE)* _____
14. Has amphotericin B or caspofungin treatment been discontinued? *(AMPDSCT1)* ☐ 1 - Yes ☐ 2 - No
15. Record date treatment ended: *(RXENDDT1)* _____ *(mm/dd/yyyy)*
16. Days during Treatment Course I patient was treated with amphotericin B or caspofungin: *(TDYAMPB1)* _____ *(xx)*

If greater than 14 days, complete Premature Permanent Withdrawal Form

17. Record usual daily dose: *(USUALDD1)* _____ *(xxx.xx)* *(UNITP1)*

1-1 - mg
2-2 - mg/kg
3-3 - mg/m^2

18. If clinically possible, were all focal lesions suspicious for fungi biopsied? *(FOCALMD1)*

1-1 - Yes
2-2 - No
3-3 - Not Applicable

19. Were cultures of urine and/or blood obtained? *(CLTRSMD1)* ☐ 1 - Yes ☐ 2 - No
20. Were two galactomannan assay blood samples obtained during the seven days before treatment initiation? *(ASSAYMD1)* ☐ 1 - Yes ☐ 2 - No
21. Was at least one blood sample obtained within 48 hours of treatment initiation? *(HRSBFMD1)* ☐ 1 - Yes ☐ 2 - No

Complete Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for Treatment Course I.

Complete Diagnostic GM Assay Form - Event Driven Samples to record result of sample obtained before Treatment Course I.

TREATMENT COURSE II

22. Record date treatment initiated: *(RXINDT2)* _____ *(mm/dd/yyyy)*
23. Treatment agent: *(RXIN2TRT)*

1-1 - Amphotericin B or Lipid Formulation of Amphotericin B (Ambisome or Abelcet)
2-2 - Caspofungin or Other Echinocandin (Micafungin or Anidulafungin)
9-9 - Other, Specify

24. Specify other treatment: *(RXIN2SPE)* _____
25. Has amphotericin B or caspofungin treatment been discontinued? *(AMPDSCT2)* ☐ 1 - Yes ☐ 2 - No
26. Record date treatment ended: *(RXENDDT2)* _____ *(mm/dd/yyyy)*
27. Days during Treatment Course II patient was treated with amphotericin B or caspofungin: *(TDYAMPB2)* _____ *(xx)*

If greater than 14 days, complete Premature Permanent Withdrawal Form

28. Record usual daily dose: *(USUALDD2)*

1-1 - mg
2-2 - mg/kg
3-3 - mg/m^2

(xxx.xx) *(UNITP2)*

29. If clinically possible, were all focal lesions suspicious for fungi biopsied? *(FOCALMD2)*

1-1 - Yes
2-2 - No
3-3 - NotApplicable

30. Were cultures of urine and/or blood obtained? *(CLTRSMD2)* ☐ 1 - Yes ☐ 2 - No

31. Were two galactomannan assay blood samples obtained during the seven days before treatment initiation? *(ASSAYMD2)* ☐ 1 - Yes ☐ 2 - No

32. Was at least one blood sample obtained within 48 hours of treatment initiation? *(HRSBFMD2)* ☐ 1 - Yes ☐ 2 - No

Complete Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for Treatment Course II.

Complete Diagnostic GM Assay Form - Event Driven Samples to record result of sample obtained before Treatment Course II.

TREATMENT COURSE III

33. Record date treatment initiated: *(RXINDT3)* *(mm/dd/yyyy)*

34. Treatment agent: *(RXIN3TRT)*

1-1 - Amphotericin B or Lipid Formulation of Amphotericin B (Ambisome or Abelcet)
2-2 - Caspofungin or Other Echinocandin (Micafungin or Anidulafungin)
9-9 - Other, Specify

35. Specify other treatment: *(RXIN3SPE)*

36. Has amphotericin B or caspofungin treatment been discontinued? *(AMPDSCT3)* ☐ 1 - Yes ☐ 2 - No

37. Record date treatment ended: *(RXENDDT3)* *(mm/dd/yyyy)*

38. Days during Treatment Course III patient was treated with amphotericin B or caspofungin: *(TDYAMPB3)* *(xx)*

If greater than 14 days, complete Premature Permanent Withdrawal Form

39. Record usual daily dose: *(USUALDD3)*

1-1 - mg
2-2 - mg/kg
3-3 - mg/m^2

(xxx.xx) *(UNITP3)*

40. If clinically possible, were all focal lesions suspicious for fungi biopsied? *(FOCALMD3)*

1-1 - Yes
2-2 - No
3-3 - NotApplicable

41. Were cultures of urine and/or blood obtained? *(CLTRSMD3)* ☐ 1 - Yes ☐ 2 - No

42. Were two galactomannan assay blood samples obtained during the seven days before treatment initiation? *(ASSAYMD3)* ☐ 1 - Yes ☐ 2 - No

43. Was at least one blood sample obtained within 48 hours of treatment initiation? *(HRSBFMD3)* ☐ 1 - Yes ☐ 2 - No

Complete Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for Treatment Course III.

Complete Diagnostic GM Assay Form - Event Driven Samples to record result of sample obtained before Treatment Course III.

44. Was the patient treated with a topical anti-fungal agent during this assessment period? *(TOPAFRX)* ☐ 1 - Yes ☐ 2 - No

45. Was the patient treated with any other anti-fungal agent during this assessment period? *(OTHRAGAD)* ☐ 1 - Yes ☐ 2 - No

Specify other agent administered: *(MEDSPEC3)*

Comments: *(MEDCOMM1)*

Blood and Marrow Transplant Clinical Trials Network

Non-Study Drug Prophylaxis Form (NSD)

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

Segment *(PROTSEG)*:

Provide information for up to three courses of systemic fungal prophylaxis medication(s) other than protocol study drug that were given to the patient through Day 180.

Medication	Specify Other	Start Date	Stop Date	Average Daily Dose	Dose Unit
1. *(PRMED1)* 1-1 -Amphotericin B or Lipid Formulation 2-2 -Caspofungin 3-3 -Fluconazole 4-4 -Voriconazole 5-5 -Itraconazole *Additional Options Listed Below	*(PRMEDSP1)*	*(PRSTRTD1)* *(mm/dd/yyyy)*	*(PRSTOPD1)* *(mm/dd/yyyy)*	*(PRADD1)* *(xxx.x)*	*(PRUNIT1)* 1-1 -mg 2-2 -mg/kg 3-3 -mg/m^2
2. *(PRMED2)* 1-1 -Amphotericin B or Lipid Formulation 2-2 -Caspofungin 3-3 -Fluconazole 4-4 -Voriconazole 5-5 -Itraconazole *Additional Options Listed Below	*(PRMEDSP2)*	*(PRSTRTD2)* *(mm/dd/yyyy)*	*(PRSTOPD2)* *(mm/dd/yyyy)*	*(PRADD2)* *(xxx.x)*	*(PRUNIT2)* 1-1 -mg 2-2 -mg/kg 3-3 -mg/m^2
3. *(PRMED3)* 1-1 -Amphotericin B or Lipid Formulation 2-2 -Caspofungin 3-3 -Fluconazole 4-4 -Voriconazole 5-5 -Itraconazole *Additional Options Listed Below	*(PRMEDSP3)*	*(PRSTRTD3)* *(mm/dd/yyyy)*	*(PRSTOPD3)* *(mm/dd/yyyy)*	*(PRADD3)* *(xxx.x)*	*(PRUNIT3)* 1-1 -mg 2-2 -mg/kg 3-3 -mg/m^2

4. Record the patient's weight at time of the first relevant treatment course (i.e., mg/kg dose unit): *(NSDWEIGH)* *(xxx.x)* kg
5. Date weight obtained: *(NSDWGHDT)* *(mm/dd/yyyy)*
6. Record the patient's body surface area at time of the first relevant treatment course (i.e., mg/m^2 dose unit): *(NSDBSA)* *(x.xx)* m^2
7. Date body surface area obtained: *(NSDBSADT)* *(mm/dd/yyyy)*

Comments: *(NSDCOMNT)*

Additional Selection Options for NSD

Prophylaxis Med 1
9-9 - Other (specify)

Blood and Marrow Transplant Clinical Trials Network

Premature Permanent Withdrawal of Study Drug Form (PWD)

Web Version: 1.0; 8.00; 04-20-09

Segment *(PROTSEG)*:

1. Record start date of assessment period: *(PWSASSPD)* _____ *(mm/dd/yyyy)*
   Day after previous Medication Form's assessment period end date
2. Record date of premature permanent withdrawal: *(PWEASSPD)* _____ *(mm/dd/yyyy)*
3. Record total number of days during this assessment period the patient received study drug: *(PWDRECSD)* _____ *(xxx)*

4. Record reason(s) study drug was prematurely permanently withdrawn prior to day 100 (or 180):

a. **FUNGAL INFECTION -**

Presumptive invasive fungal infection: *(PSTIFIPW)* ☐ 1 - Yes ☐ 2 - No

Presumptive invasive fungal infection: *(PSTIFIPW)* ☐ 1 - Yes ☐ 2 - No

If yes, complete Fungal Infection Form and Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for diagnosis of presumptive fungal infection.

Probable invasive fungal infection: *(PRBIFIPW)* ☐ 1 - Yes ☐ 2 - No

If Yes, complete Fungal Infection Form and Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for diagnosis of probable fungal infection.

Proven invasive fungal infection: *(PRVIFIPW)* ☐ 1 - Yes ☐ 2 - No

If Yes, complete Fungal Infection Form and Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for diagnosis of proven fungal infection.

b. **HEPATIC TOXICITY -**

ALT greater than 5 times the upper limit of normal, but less than 10 times the upper limit of normal, for > 14 days: *(ALT5ULPW)* ☐ 1 - Yes ☐ 2 - No

ALT greater or equal to 10 times the upper limit of normal for > 10 days: *(ALTLMTPW)* ☐ 1 - Yes ☐ 2 - No

Recurrent hepatic toxicity: *(RECHEPTX)* ☐ 1 - Yes ☐ 2 - No

c. **VISUAL TOXICITY -**

Loss of vision (blindness): *(BLINDPW)* ☐ 1 - Yes ☐ 2 - No

d. **CUTANEOUS TOXICITY -**

Skin necrosis: *(NCRSISPW)* ☐ 1 - Yes ☐ 2 - No

Ulcerations: *(ULCERPW)* ☐ 1 - Yes ☐ 2 - No

Generalized exfoliative dermatitis: *(EXDERMPW)* ☐ 1 - Yes ☐ 2 - No

e. **NEUROLOGIC TOXICITY -**

Hallucinations after reduction of the dose(s) of concomitant opiates or benzodiazepines for > 10 days: *(HALLUCPW)* ☐ 1 - Yes ☐ 2 - No

f. **CARDIAC TOXICITY -**

Arrhythmia: *(ARRHYTPW)* ☐ 1 - Yes ☐ 2 - No

g. **RENAL TOXICITY -**

Hemodialysis: *(DIALYSPW)* ☐ 1 - Yes ☐ 2 - No

h. **OTHER TOXICITY -**

Other grade III or IV toxicity: *(OTHRTXPW)* ☐ 1 - Yes ☐ 2 - No

Specify other toxicity: *(PWDSPEC1)* _____

If Yes to any toxicity, complete Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for diagnosis of serious, suspected drug toxicity.

i. **MEDICATION -**

Requires Terfenadine: *(TERFENPW)* ☐ 1 - Yes ☐ 2 - No

Requires Astemizole: *(ASTEMZPW)* ☐ 1 - Yes ☐ 2 - No

Requires Cisapride: *(CISAPRPW)* ☐ 1 - Yes ☐ 2 - No

Requires Sirolimus: *(SIROLIPW)* ☐ 1 - Yes ☐ 2 - No

Requires maintenance phenytoin/anitconvulsant therapy: *(PHENYTPW)* ☐ 1 - Yes ☐ 2 - No

j. **OTHER -**

Patient has failed to engraft and requires chemotherapy: *(ENGRFTPW)* ☐ 1 - Yes ☐ 2 - No

Patient has relapsed and requires chemotherapy: *(RELAPSPW)* ☐ 1 - Yes ☐ 2 - No

Amphotericin B or caspofungin administration for more than 14 consecutive days: *(AMPHOPW)* ☐ 1 - Yes ☐ 2 - No

Patient's creatinine clearance declined to less than 25 ml/min and persisted for more than two weeks and patient requires IV study drug: *(CRCLIVD)* ☐ 1 - Yes ☐ 2 - No

Patient is an outpatient **receiving treatment at the transplant center** and requires IV study drug for more than two weeks and cannot tolerate oral study drug: *(OUTPTIVD)* ☐ 1 - Yes ☐ 2 - No

Patient is an outpatient **receiving treatment from home health care** and requires IV study drug: *(NOTXCTIV)* ☐ 1 - Yes ☐ 2 - No

Pregnancy: *(PREGNTPW)* ☐ 1 - Yes ☐ 2 - No

Withdrawal of consent: *(CONSNTPW)* ☐ 1 - Yes ☐ 2 - No

Other reason for withdrawal: *(OTHERPWD)* ☐ 1 - Yes ☐ 2 - No

Specify other reason for withdrawal: *(PWDSPEC2)*

5. Record date physical examination, including vital signs, was performed: *(PHYSEXDT)* *(mm/dd/yyyy)*

6. At time of withdrawal, record the patient's status regarding fungal infection: *(PWSTATUS)*

1-1 - No Evidence of Fungal Infection
2-2 - Colonization
3-3 - Superficial Fungal Infection
4-4 - Possible Invasive Fungal Infection
5-5 - Probable Invasive Fungal Infection
*Additional Options Listed Below

7. During this assessment period how many treatment courses of systemic amphotericin B or caspofungin did the patient receive? *(CRSAMPPW)*

0-0 - No Treatment Course
1-1 - One Treatment Course
2-2 - Two Treatment Courses
3-3 - Three Treatment Courses

TREATMENT COURSE I

8. Record date treatment initiated: *(RXIDTPW1)* *(mm/dd/yyyy)*

9. Treatment Agent: *(RXID1TRT)*

1-1 - Amphotericin B or Lipid Formulation of Amphotericin B (Ambisome or Abelcet)
2-2 - Caspofungin or Other Echinocandin (Micafungin or Anidulafungin)
9-9 - Other, Specify

10. Specify other treatment: *(RXID1SPE)*

11. Has amphotericin B or caspofungin treatment been discontinued? *(AMPDSPW1)* ☐ 1 - Yes ☐ 2 - No

12. Record date treatment ended: *(RXEDTPW1)* *(mm/dd/yyyy)*

13. Days during Treatment Course I patient was treated with amphotericin B or caspofungin: *(TDAMPPW1)* *(xx)*

14. Record usual daily dose: *(USUALPW1)*

(xxx.xx) *(UNITPW1)*

1-1 - mg
2-2 - mg/kg
3-3 - mg/m^2

15. If clinically possible, were all focal lesions suspicious for fungi biopsied? *(FOCALPW1)*

1-1 - Yes
2-2 - No
3-3 - Not Applicable

16. Were cultures of urine and/or blood obtained? *(CLTRSPW1)* ☐ 1 - Yes ☐ 2 - No

17. Were two galactomannan assay blood samples obtained during the seven days before treatment initiation? *(ASSAYPW1)* ☐ 1 - Yes ☐ 2 - No

18. Was at least one galactomannan assay blood sample obtained within 48 hours of treatment initiation? *(HRSBFPW1)* ☐ 1 - Yes ☐ 2 - No

Complete Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for Treatment Course I.

Complete Diagnostic GM Assay Form - Event Driven Samples to record result for sample obtained for Treatment Course I.

TREATMENT COURSE II

19. Record date treatment initiated: *(RXIDTPW2)* *(mm/dd/yyyy)*

20. Treatment Agent: *(RXID2TRT)*

1-1 - Amphotericin B or Lipid Formulation of Amphotericin B (Ambisome or Abelcet)
2-2 - Caspofungin or Other Echinocandin (Micafungin or Anidulafungin)
9-9 - Other, Specify

21. Specify other treatment: *(RXID2SPE)*

22. Has amphotericin B or caspofungin treatment been discontinued? *(AMPDSPW2)* ☐ 1 - Yes ☐ 2 - No

23. Record date treatment ended: *(RXEDTPW2)* *(mm/dd/yyyy)*

24. Days during Treatment Course II patient was treated with amphotericin B or caspofungin: *(TDAMPPW2)* _____ *(xx)*

25. Record usual daily dose: *(USUALPW2)*

_____ *(xxx.xx)* *(UNITPW2)*

1-1 - mg
2-2 - mg/kg
3-3 - mg/m^2

26. If clinically possible, were all focal lesions suspicious for fungi biopsied? *(FOCALPW2)*

1-1 - Yes
2-2 - No
3-3 - Not Applicable

27. Were cultures of urine and/or blood obtained? *(CLTRSPW2)* ☐ 1 - Yes ☐ 2 - No

28. Were two galactomannan assay blood samples obtained during the seven days before treatment initiation? *(ASSAYPW2)* ☐ 1 - Yes ☐ 2 - No

29. Was at least one galactomannan assay blood sample obtained within 48 hours of treatment initiation? *(HRSBFPW2)* ☐ 1 - Yes ☐ 2 - No

Complete Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for Treatment Course II.

Complete Diagnostic GM Assay Form - Event Driven Samples to record result for sample obtained for Treatment Course II.

TREATMENT COURSE III

30. Record date treatment initiated: *(RXIDTPW3)* _____ *(mm/dd/yyyy)*

31. Treatment Agent: *(RXID3TRT)*

1-1 - Amphotericin B or Lipid Formulation of Amphotericin B (Ambisome or Abelcet)
2-2 - Caspofungin or Other Echinocandin (Micafungin or Anidulafungin)
9-9 - Other, Specify

32. Specify other treatment: *(RXID3SPE)* _____

33. Has amphotericin B or caspofungin treatment been discontinued? *(AMPDSPW3)* ☐ 1 - Yes ☐ 2 - No

34. Record date treatment ended: *(RXEDTPW3)* _____ *(mm/dd/yyyy)*

35. Days during Treatment Course III patient was treated with amphotericin B or caspofungin: *(TDAMPPW3)* _____ *(xx)*

36. Record usual daily dose: *(USUALPW3)*

_____ *(xxx.xx)* *(UNITPW3)*

1-1 - mg
2-2 - mg/kg
3-3 - mg/m^2

37. If clinically possible, were all focal lesions suspicious for fungi biopsied? *(FOCALPW3)*

1-1 - Yes
2-2 - No
3-3 - Not Applicable

38. Were cultures of urine and/or blood obtained? *(CLTRSPW3)* ☐ 1 - Yes ☐ 2 - No

39. Were two galactomannan assay blood samples obtained during the seven days before treatment initiation? *(ASSAYPW3)* ☐ 1 - Yes ☐ 2 - No

40. Was at least one galactomannan assay blood sample obtained within 48 hours of treatment initiation? *(HRSBFPW3)* ☐ 1 - Yes ☐ 2 - No

Complete Specimen Acquisitions Form - Event-Driven Samples to record sample(s) obtained for Treatment Course III.

Complete Diagnostic GM Assay Form - Event Driven Samples to record result for sample obtained for Treatment Course III.

41. Was the patient treated with a topical anti-fungal agent during this assessment period? *(TOPRXPW)* ☐ 1 - Yes ☐ 2 - No

42. Was the patient treated with any other anti-fungal agents during this assessment period? *(OTHRADPW)* ☐ 1 - Yes ☐ 2 - No

Specify other agent administered: *(PWDSPEC3)* _____

Comments: *(PWDCOMM1)*

Additional Selection Options for PWD

At time of withdrawal, record the patient's status regarding fungal infection:
6-6 - Proven Invasive Fungal Infection
7-7 - Presumptive Invasive Fungal Infection

Blood and Marrow Transplant Clinical Trials Network

Secondary Graft Failure Form (SGF)

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

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

Specimen Acquisitions Form - Scheduled Samples (SSF)

Web Version: 1.0; 5.01; 03-09-10

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

DONOR SNPs

1. Was informed consent obtained from the donor? *(SNPIFCON)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable
2. If yes, record date consent was given: *(SNPICDAT)* _____ *(mm/dd/yyyy)*
3. Was a donor sample for the SNP assay collected? *(SNPSAMPL)* ☐ 1 - Yes ☐ 2 - No
4. If yes, record date sample collected: *(DATSNPCO)* _____ *(mm/dd/yyyy)*

INVESTIGATIONAL FUTURE TESTING

5. Record date Investigational Future Testing sample collected: *(DATIFTCO)* _____ *(mm/dd/yyyy)*

PHARMACOKINETICS

6. Record date study drug infused or orally administered: *(DATPHAR2)* _____ *(mm/dd/yyyy)*
7. Record time study drug infused or orally administered: *(TIMPHAR2)* _____ *(hh:mm)*
8. Record date sample collected: *(DATPHAR1)* _____ *(mm/dd/yyyy)*
9. Record time sample collected: *(TIMPHAR1)* _____ *(hh:mm)*
10. Indicate window of time after start of infusion or administration of oral dose sample was drawn: *(PHARWIND)*
    - 1-1 - Window 1 (1-5 Hours after Infusion/Administration)
    - 2-2 - Window 2 (5-8 Hours after Infusion/Administration)
    - 3-3 - Window 3 (8-12 Hours after Infusion/Administration)
    - 4-4 - Other
11. Is the patient a recipient of a T-Cell depleted transplant and received post-transplant GVHD prophylaxis, OR on steriods, OR has or has had acute GVHD? *(RECTCELL)* ☐ 1 - Yes ☐ 2 - No

    Is the patient a recipient of a T-Cell depleted transplant and received post-transplant GVHD prophylaxis, OR on steriods, OR has or has had acute GVHD? *(RECTCELL)* ☐ 1 - Yes ☐ 2 - No

INVESTIGATIONAL FUNGAL DIAGNOSTIC ASSAYS

12. Record date first set of Investigational Fungal Diagnostic Assay samples collected: *(DATSET1C)* _____ *(mm/dd/yyyy)*
13. Record date second set of Investigational Fungal Diagnostic Assay samples collected (if required): *(DATSET2C)* _____ *(mm/dd/yyyy)*

This form is for patients who gave consent to have samples of blood taken post-transplant for future research and testing.
Please return to the Data Entry Main Screen.

Comments: *(SASCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0101 (TOX)

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

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

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

Record the highest grade of toxicity diagnosed since the previous evaluation. If this is the first evaluation, record the highest grade of toxicity diagnosed since Day 0. The toxicity grades are based on the NCI CTCAE Version 3.0. The toxicity grades for questions 3, 8, 11 and 13 are based on the Bearman scale.

Ocular/Visual Toxicity

2. Photopsia: *(VISUAL)*

0-0 - Normal
1-1 - Symptomatic not Interfering with Function
2-2 - Symptomatic and Interfering with Function, but not Interfering with ADL
3-3 - Symptomatic and Interfering with ADL
4-4 - Blindness (20/200 or Worse)
*Additional Options Listed Below

Neurologic Toxicity

3. CNS: *(SOMNOLEN)*

0-0 - No CNS Toxicity
1-1 - Somnolence; Patient Easily Arousable and Oriented after Arousal
2-2 - Somnolence with Confusion after Arousal
3-3 - Seizures or Coma Not Explained by Other Medication; CNS Infection or Bleeding
4-4 - Fatal CNS Toxicity

4. Psychosis: *(PSYCHOSI)*

0-0 - Normal
2-2 - Transient Episode
3-3 - Interfering with ADL; Medication, Supervision or Restraints Indicated
4-4 - Harmful to Others or Self; Life-Threatening Consequences
5-5 - Death

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

6. Seizure(s): *(SEIZRTOX)*

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

7. Confusion: *(NEUROCON)*

0-0 - Normal
1-1 - Transient Confusion, Disorientation, or Attention Deficit
2-2 - Confusion, Disorientation, or Attention Deficit Interfering with Function, but not ADL
3-3 - Confusion or Delirium Interfering with ADL
4-4 - Harmful to Others or Self; Hospitalization Indicated
*Additional Options Listed Below

Cardiovascular Toxicity

8. Cardiac: *(SYSTOLIC)*

0-0 - No Cardiac Toxicity
1-1 - Mild EKG Abnormality Not Requiring Medical Intervention
2-2 - Moderate EKG Abnormalities Requiring and Repsonding to Medical Intervention
3-3 - Severe EKG Abnormalities with No or Only Parial Response to Medical Intervention
4-4 - Fatal Cardiac Toxicity

9. Cardiac arrhythmia: *(CARDARRH)*

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

10. Hypotension: *(HYPOTNSN)*

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

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

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

Renal Toxicity

12. Has the patient experienced renal failure severe enough to warrant dialysis? *(RNLFAILR)* ☐ 1 - Yes ☐ 2 - No

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

14. Hemorrhagic cystitis: *(HEMCYSTI)*

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

Hepatic Toxicity

15. Hepatic dysfunction: *(HEPDYSFN)*

0-0 - No Hepatic Toxicity
1-1 - Mild Hepatic Dysfunction with 2.0 mg/dL < Bilirubin < 6.0 mg/dL
2-2 - Moderate Hepatic Dysfunction Bilirubin > 6 mg/dL < 20 mg/dL
3-3 - Severe Hepatic Dysfunction with Bilirubin > 20 mg/dL
4-4 - Fatal Hepatic Toxicity

	Peak Value During Interval	ULN for your Institution	Date Sample Obtained
16. ALT:	*(SGPT_ALT)* *(xxxx)* Units/L	*(ALTULN)* *(xxx)* Units/L	*(ALTOBTDT)* *(mm/dd/yyyy)*
17. AST:	*(SGOT_AST)* *(xxxx)* Units/L	*(ASTULN)* *(xx)* Units/L	*(ASTOBTDT)* *(mm/dd/yyyy)*
18. Bilirubin:	*(BILI)* *(xx.x)* mg/dL		*(BILIOBDT)* *(mm/dd/yyyy)*

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

Indicate if the patient developed any of the following clinical signs/symptoms of abnormal liver function during this assessment period:

20. Jaundice: *(JAUNDICE)* ☐ 1 - Yes ☐ 2 - No
21. Hepatomegaly: *(HEPATMEG)* ☐ 1 - Yes ☐ 2 - No
22. Right upper quadrant pain: *(QUADPAIN)* ☐ 1 - Yes ☐ 2 - No
23. Weight gain (>5%) from baseline: *(WGHTGAIN)* ☐ 1 - Yes ☐ 2 - No
24. Other clinical signs/symptoms: *(OTHLIVTX)* ☐ 1 - Yes ☐ 2 - No

Specify other clinical signs/symptoms: *(OTHSPEC1)*

Indicate the suspected etiology of the abnormal liver function and any applicable biopsy and doppler ultrasound results:

	Etiology	Biopsy Results	Doppler Ultrasound Results
25. VOD:	*(TOXVODET)* 1-1 - Yes; 2-2 - No	*(TOXVODBI)* 1-1 - Positive; 2-2 - Negative; 3-3 - Equivocal; 4-4 - Not Done	*(TOXVODDP)* 1-1 - Confirmed; 2-2 - Not Confirmed; 3-3 - Not Done
26. GVHD:	*(TOXGVHET)* 1-1 - Yes; 2-2 - No	*(TOXGVHBI)* 1-1 - Positive; 2-2 - Negative; 3-3 - Equivocal; 4-4 - Not Done	*(TOXGVHDP)* 1-1 - Confirmed; 2-2 - Not Confirmed; 3-3 - Not Done
27. Infection:	*(TOXINFET)* 1-1 - Yes; 2-2 - No	*(TOXINFBI)* 1-1 - Positive; 2-2 - Negative; 3-3 - Equivocal; 4-4 - Not Done	*(TOXINFDP)* 1-1 - Confirmed; 2-2 - Not Confirmed; 3-3 - Not Done
28. Other:	*(TOXOTHET)* 1-1 - Yes; 2-2 - No	*(TOXOTHBI)* 1-1 - Positive; 2-2 - Negative; 3-3 - Equivocal; 4-4 - Not Done	*(TOXOTHDP)* 1-1 - Confirmed; 2-2 - Not Confirmed; 3-3 - Not Done

29. Unknown:	*(TOXUNKET)* 1-1 - Yes 2-2 - No	*(TOXUNKBI)* 1-1 - Positive 2-2 - Negative 3-3 - Equivocal 4-4 - Not Done	*(TOXUNKDP)* 1-1 - Confirmed 2-2 - Not Confirmed 3-3 - Not Done

Specify other etiology: *(OTHSPEC2)*

Gastrointestinal Toxicity

30. Mucositis/stomatitis (clinical exam): *(MUCOSITS)*

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

Hemorrhagic Toxicity

31. Hemorrhage: *(OTHRHEMR)*

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

Coagulation Toxicity

32. HUS/TTP/thrombotic microangiopathy: *(HUSTTPDC)*

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

Vascular Toxicity

33. Vascular leak syndrome: *(VASCULAR)*

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

Pulmonary Toxicity

34. Hypoxia (for more than 24 hours): *(HYPOXIA)*

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

35. Dyspnea: *(DYSPNEA)*

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

36. During this assessment period, was an FEV1 performed? *(FEV1DONE)* ☐ 1 - Yes ☐ 2 - No

37. Record FEV1 value obtained: *(FEVVALUE)* _____ *(xxx)* % of predicted value

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

39. Record FVC value obtained: *(FVCVALUE)* _____ *(xxx)* % of predicted value

40. Has Amphotericin B been administered since the last report? *(AMPOADMN)* ☐ 1 - Yes ☐ 2 - No

Record the highest grade of the following toxicities diagnosed within 72 hours PRIOR to the first administration of amphotericin B during this assessment period.

41. Allergic reaction/hypersensitivity: *(ALLERGY0)*

0-0 - None
1-1 - Transient Flushing or Rash; Drug Fever < 38.0C (< 100.4F)
2-2 - Rash; Flushing; Urticaria; Dyspnea; Drug Fever >/= 38.0C (>/= 100.4F)
3-3 - Symptomatic Bronchospasm, with or without Urticaria; Parenteral Med(s) Indicated
4-4 - Anaphylaxis
*Additional Options Listed Below

42. Cardiac arrhythmia: *(INFARHT0)*

0-0 - None
1-1 - Mild
2-2 - Moderate
3-3 - Severe
4-4 - Life Threatening; Disabling
*Additional Options Listed Below

43. Hypertension: *(HYPRTNS0)*

0-0 - Normal
1-1 - Asymptomatic, Transient Increase by >20 mm Hg; Intervention not Indicated
2-2 - Recurrent or Persistent or Symptomatic Increase by >20 mm Hg; Monotherapy may be Indicated
3-3 - Requiring More than One Drug or More Intensive Therapy than Previously
4-4 - Life-Threatening Consequences (e.g., Hypertensive Crisis)
*Additional Options Listed Below

44. Hypotension: *(HYPOTNS0)*

0-0 - None
1-1 - Changes, Intervention not Indicated
2-2 - Brief (<24 hrs) Fluid Replacement or Other Therapy; No Physiologic Consequences
3-3 - Sustained (>/=24 hrs) Therapy, Resolves without Persisting Physiologic Consequences
4-4 - Shock (e.g., Acidemia; Impairment of Vital Organ Function)
*Additional Options Listed Below

45. Fever: *(FEVER0)*

0-0 - None
1-1 - 38.0-39.0C (100.4-102.2F)
2-2 - >39.0-40.0C (102.3-104.0F)
3-3 - >40.0C (>104.0F) for < 24 hrs
4-4 - >40.0C (104.0F) for > 24 hrs
*Additional Options Listed Below

46. Rigors, chills: *(RIGORS0)*

0-0 - None
1-1 - Mild
2-2 - Moderate, Narcotics Indicated
3-3 - Severe or Prolonged; not Responsive to Narcotics

47. Nausea: *(NAUSEA0)*

0-0 - None
1-1 - Loss of Appetite without Alteration in Eating Habits
2-2 - Oral Intake Decreased without Significant Weight Loss; Dehydration or Malnutrition
3-3 - Inadequate Oral Caloric or Fluid Intake; IV Fluids, Tube Feedings, or TPN Indicated >/=24 hrs
4-4 - Life-Threatening Consequences
*Additional Options Listed Below

48. Vomiting: *(VOMTING0)*

0-0 - None
1-1 - 1 Episode in 24 hrs
2-2 - 2-5 Episodes in 24 hrs; IV Fluids Indicated <24 hrs
3-3 - >/= 6 Episodes in 24 hrs; IV Fluids, or TPN Indicated >/= 24 hrs
4-4 - Life-Threatening Consequences
*Additional Options Listed Below

49. Dyspnea: *(DYSPNEA0)*

0-0 - Normal
1-1 - Dyspnea on Exertion, but can Walk 1 Flight of Stairs w/o Stopping
2-2 - Dyspnea on Exertion, but Unable to Walk 1 Flight of Stairs/1 City Block w/o Stopping
3-3 - Dyspnea with ADL
4-4 - Dyspnea at Rest; Intubation/Ventilator Indicated
*Additional Options Listed Below

50. Hypoxia: *(HYPOXIA0)*

0-0 - Normal
2-2 - Decreased Oxygen Saturation with Exercise; Intermittent Supplemental Oxygen
3-3 - Decreased Oxygen Saturation at Rest; Continuous Oxygen Indicated
4-4 - Life-Threatening; Intubation or Ventilation Indicated
5-5 - Death

Record the highest grade of the following infusional toxicities diagnosed within 72 hours AFTER the first administration of amphotericin B during this assessment period.

51. Allergic reaction/hypersensitivity: *(ALLERGY1)*

0-0 - None
1-1 - Transient Flushing or Rash; Drug Fever < 38.0C (< 100.4F)
2-2 - Rash; Flushing; Urticaria; Dyspnea; Drug Fever >/= 38.0C (>/= 100.4F)
3-3 - Symptomatic Bronchospasm, with or without Urticaria; Parenteral Med(s) Indicated
4-4 - Anaphylaxis
*Additional Options Listed Below

52. Cardiac arrhythmia: *(INFARHTH)*

0-0 - None
1-1 - Mild
2-2 - Moderate
3-3 - Severe
4-4 - Life Threatening; Disabling
*Additional Options Listed Below

53. Hypertension: *(HYPRTNS2)*

0-0 - Normal
1-1 - Asymptomatic, Transient Increase by >20mm Hg; Intervention not Indicated
2-2 - Recurrent or Persistent or Symptomatic Increase by >20mm Hg; Monotherapy may be Indicated
3-3 - Requiring More than One Drug or More Intensive Therapy than Previously
4-4 - Life-Threatening Consequences (e.g., Hypertensive Crisis)
*Additional Options Listed Below

54. Hypotension: *(HYPOTNS2)*

0-0 - None
1-1 - Changes, Intervention not Indicated
2-2 - Brief (<24 hrs) Fluid Replacement or Other Therapy; No Physiologic Consequences
3-3 - Sustained (>/=24 hrs) Therapy, Resolves without Persisting Physiologic Consequences
4-4 - Shock (e.g., Acidemia; Impairment of Vital Organ Function)
*Additional Options Listed Below

55. Fever: *(FEVER)*

0-0 - None
1-1 - 38.0-39.0C (100.4-102.2F)
2-2 - > 39.0-40.0C (102.3-104.0F)
3-3 - > 40.0C (>104.0F) for < 24 hrs
4-4 - > 40.0C (104.0F) for > 24 hrs
*Additional Options Listed Below

56. Rigors, chills: *(RIGORS)*

0-0 - None
1-1 - Mild
2-2 - Moderate, Narcotics Indicated
3-3 - Severe or Prolonged; not Responsive to Narcotics

57. Nausea: *(NAUSEA)*

0-0 - None
1-1 - Loss of Appetite without Alteration in Eating Habits
2-2 - Oral Intake Decreased without Significant Weight Loss; Dehydration or Malnutrition
3-3 - Inadequate Oral Caloric or Fluid Intake; IV Fluids, Tube Feedings, or TPN Indicated >/=24 hrs
4-4 - Life-Threatening Consequences
*Additional Options Listed Below

58. Vomiting: *(VOMTING)*

0-0 - None
1-1 - 1 Episode in 24 hrs
2-2 - 2-5 Episodes in 24 hrs; IV Fluids Indicated <24 hrs
3-3 - >/= 6 Episodes in 24 hrs; IV Fluids, or TPN Indicated >/= 24 hrs
4-4 - Life-Threatening Consequences
*Additional Options Listed Below

59. Dyspnea: *(DYSPNEA2)*

0-0 - Normal
1-1 - Dyspnea on Exertion, but can Walk 1 Flight of Stairs w/o Stopping
2-2 - Dyspnea on Exertion, but Unable to Walk 1 Flight of Stairs/1 City Block w/o Stopping
3-3 - Dyspnea with ADL
4-4 - Dyspnea at Rest; Intubation/Ventilator Indicated
*Additional Options Listed Below

60. Hypoxia: *(HYPOXIA2)*

0-0 - Normal
2-2 - Decreased Oxygen Saturation with Exercise; Intermittent Supplemental Oxygen
3-3 - Decreased Oxygen Saturation at Rest; Continuous Oxygen Indicated
4-4 - Life-Threatening; Intubation or Ventilation Indicated
5-5 - Death

Comments: *(TOX1COMM)*

Additional Selection Options for TOX

Photopsia:
5-5 - Death

Confusion:
5-5 - Death

Allergic reaction/hypersensitivity:
5-5 - Death

Cardiac arrhythmia:
5-5 - Death

Hypertension:
5-5 - Death

Hypotension:
5-5 - Death

Fever:
5-5 - Death

Nausea:
5-5 - Death

Vomiting:
5-5 - Death

Dyspnea:
5-5 - Death

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

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

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

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

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

Comments: *(COMMTXP1)*