Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Web Version: 1.0; 4.07; 05-24-16

Segment *(PROTSEG)*:

Date of Admission *(ADMITDT)*:

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

2. Patient discharge status:*(DISCPTST)* ☐ 1 - Alive ☐ 2 - Dead

If Dead, a Death Form must be submitted.

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

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

?

Specify organ:(ADM4SPEC)*

**Specify other:*(ADM1SPEC)*

4. Record secondary discharge diagnoses:

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

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

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

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

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

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

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

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

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

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

Specify organ:*(ADM3SPEC)*

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

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

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

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

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

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

Specify other:*(ADM2SPEC)*

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

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

Comments:*(ADMCOMM1)*

Additional Selection Options for ADM

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

Blood and Marrow Transplant Clinical Trials Network

Adverse Event Form (AE1)

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

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

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

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

Comments:*(AE1COMM)*

Additional Selection Options for AE1

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

Blood and Marrow Transplant Clinical Trials Network

AE Summary Form (AE2)

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

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

1. Report activation status:*(AVSTAT_A)*

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

Relevant Past Medical History

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

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

(SEMEDHX)

3. **Event Summary**

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

(SESUMM)

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

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

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AE Therapy Form (AE3)

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

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

1. Report activation status:*(AVSTAT_B)*

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

Study Product/Suspect Medication Data

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

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

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

Concomitant Medications

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

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

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

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

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

Comments:*(AE3COMM)*

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AE Laboratory/Diagnostics Form (AE4)

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

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

1. Report activation status:*(AVSTAT_C)*

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

Laboratory Test Results

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

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

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

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

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

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

Test	Date Performed *(mm/dd/yyyy)*	Results/Comments
(ADDTS1)	*(AD1DTDAT)*	*(AD1DTRES)*

(ADDTS2)	*(AD2DTDAT)*	*(AD2DTRES)*
(ADDTS3)	*(AD3DTDAT)*	*(AD3DTRES)*
(ADDTS4)	*(AD4DTDAT)*	*(AD4DTRES)*
(ADDTS5)	*(AD5DTDAT)*	*(AD5DTRES)*
(ADDTS6)	*(AD6DTDAT)*	*(AD6DTRES)*
(ADDTS7)	*(AD7DTDAT)*	*(AD7DTRES)*
(ADDTS8)	*(AD8DTDAT)*	*(AD8DTRES)*
(ADDTS9)	*(AD9DTDAT)*	*(AD9DTRES)*
(ADDTS10)	*(AD10DTDT)*	*(AD10DTRS)*

Comments:*(AE4COMM)*

Blood and Marrow Transplant Clinical Trials Network

AE Review Form (AE5)

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

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

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

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AE Medical Monitor Reviewer Form (AE6)

Web Version: 1.0; 8.00; 01-28-16

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

1. Adverse event status:*(AVSTAT_E)*
   - 1 - Keep report active
   - 2 - Deactivate - Report filed in error
   - 3 - Deactivate - Key field error
   - 9 - Deactivate - Other reason
2. Has this event been determined to be an unexpected, grade 3-5 adverse event? *(AMDETER)* ☐ 1 - Yes ☐ 2 - No
3. Does this require expedited reporting to the 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)*
8. Medical Monitor CTCAE grade of event:*(CTCAEGRD)*
   - 1 - Grade 1
   - 2 - Grade 2
   - 3 - Grade 3
   - 4 - Grade 4
   - 5 - Grade 5

Comments:*(AE6COMM)*

Blood and Marrow Transplant Clinical Trials Network

Follow Up GVHD Form (CGV)

Web Version: 1.0; 7.04; 10-16-15

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

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

Answer questions 3-9 relating to acute GVHD.

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

Answer questions 10-20 relating to chronic GVHD.

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

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

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

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

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

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

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

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

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

Skin/Hair

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

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

?

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

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

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

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

Ocular

22. Xerophthalmia: *(DRYEYES)*

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

Oral

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

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

Pulmonary

24. Dyspnea: *(CGVDYSPN)*

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

25. Pulmonary fibrosis: *(PULMFIBR)*

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

26. Bronchiolitis obliterans: *(BRNCOBLT)*

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

27. FEV1:*(CGVFEV1)*

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

28. Oxygen saturation:*(O2SAT)*

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

Gastrointestinal

29. Esophagus:*(ESOPHAGS)*

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

30. Nausea and vomiting:*(NAUSVOMT)*

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

31. Diarrhea:*(CGVDIARH)*

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

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

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

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

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

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

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

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

35. Malabsorption:*(MALABSRP)*

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

Hepatic

36. Bilirubin level:*(LIVERBIL)*

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

Genitourinary

37. Vaginitis:*(VAGNITIS)*

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

Musculoskeletal

38. Contractures:*(CONTRCTR)*
0 - No Symptoms
2 - Mild Joint Contractures (Does not Affect ADL)
3 - Severe Joint Contractures (Interferes with ADL)

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

Hematologic

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

Other

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

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

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

Specify other organ:*(ORGSPEC)*

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

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

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

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

50. *(BIOTYP6)*	*(TYP6OSPE)*	*(BIODT6)* (mm/dd/yyyy)	*(BIORSLT6)*
1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below			1 - Positive 2 - Negative 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 - Yes, Initiated this Assessment Period
2 - Yes, Continuing from Previous Assessment Period
3 - No

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

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

b. Azathioprine:*(THRPYAZA)*

c. Cyclosporine:*(THRPYCYC)*

d. Systemic Corticosteroids:*(THRPYSCO)*

e. Topical Corticosteroids:*(THRPYTCO)*

f. Thalidomide:*(THRPYTHA)*

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

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

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

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

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

l. Etretinate:*(THRPYETR)*

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

m. Lamprene:*(THRPYLAM)*

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

n. Etanercept:*(THRPYETA)*

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

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

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

p. Chloroquine Phosphate:*(THRPYCPH)*

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

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

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

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

r. In Vivo Immunotoxin:*(THRPYIMM)*

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

Specify in vivo immunotoxin used:*(IMMAGNT)*

s. Other:*(THRPYOTH)*

1 - Yes, Still Taking Drug
2 - Yes, No Longer Taking Drug
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 - Complete Resolution of Symptoms
2 - Partial Resolution of Symptoms
3 - Stable Symptoms
4 - Progression of Symptoms

?

Answer questions 55-58 relating to current patient status.

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

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

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

57. Current platelet count:*(CURPLTCT)* *(xxx.x)* $x10^9/L$

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

Comments:*(CGVCOMM)*

Additional Selection Options for CGV

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

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

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

Blood and Marrow Transplant Clinical Trials Network

CIBMTR Recipient ID (CID)

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

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

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

Comments:*(CIDCOMM)* _____

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

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

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

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

   Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

Web Version: 1.0; 4.16; 05-20-16

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

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

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

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

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

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

Specify other:*(DTHSPEC1)*

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

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

Specify other:*(DTHSPEC2)*

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

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

Specify other:*(DTHSPEC3)*

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

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

Specify other:*(DTHSPEC4)*

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

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

Specify other:*(DTHSPEC5)*

Comments:*(DTCMMNTS)*

Additional Selection Options for DTH

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

Blood and Marrow Transplant Clinical Trials Network

EQ-5D Survey (EQ5)

Web Version: 1.0; 1.03; 12-08-15

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

Date of Assessment:*(EQ5ASTDT)* _____ *(mm/dd/yyyy)*

Please indicate which statements best describe your own health state today.

1. Mobility*(EQ5MBTLY)*
   - 01 - I have no problems in walking about
   - 02 - I have some problems in walking about
   - 03 - I am confined to bed
   - 88 - Not answered

2. Self-Care*(EQ5SLFCR)*
   - 01 - I have no problems with self-care
   - 02 - I have some problems washing or dressing myself
   - 03 - I am unable to wash or dress myself
   - 88 - Not answered

3. Usual Activities (e.g. work, study, housework, family, or leisure activities) *(EQ5ACTIV)*
   - 01 - I have no problems with performing my usual activities
   - 02 - I have some problems with performing my usual activities
   - 03 - I am unable to perform my usual activities
   - 88 - Not answered

4. Pain/Discomfort*(EQ5PAIND)*
   - 01 - I have no pain or discomfort
   - 02 - I have moderate pain or discomfort
   - 03 - I have extreme pain or discomfort
   - 88 - Not answered

5. Anxiety/Depression*(EQ5ANXDE)*
   - 01 - I am not anxious or depressed
   - 02 - I am moderately anxious or depressed
   - 03 - I am extremely anxious or depressed
   - 88 - Not answered

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0. We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

6. Indicate the number that corresponds to the point on the scale where the line is drawn:*(EQ5HTHST)* _____ *(xxx)*

Comments:*(EQ5COMM)*

Blood and Marrow Transplant Clinical Trials Network

0901A (ENR)

Web Version: 1.0; 8.01; 10-16-15

RIC vs MAC in MDS/AML Enrollment Form - Segment A

1. Record the proposed start date of the conditioning regimen:*(MRCRSTDT)* _____ *(mm/dd/yyyy)*
2. Declared Reduced Intensity Conditioning (RIC) regimen:*(MRCRRIC)*
   - 1 - Fludarabine/Busulfan (Flu/Bu)
   - 2 - Fludarabine/Melphalan (Flu/Mel)
3. Declared RIC GVHD prophylaxis regimen:*(MRGVHRIC)*
   - 1 - Tacrolimus/Methotrexate
   - 2 - Sirolimus/Tacrolimus
   - 3 - Tacrolimus/MMF
   - 4 - Cyclosporine/MMF
   - 5 - Cyclosporine/Methotrexate
   - *Additional Options Listed Below

   If other, specify:*(MRGVOTHR)* _____
4. Declared Myeloablative Conditioning (MAC) regimen:*(MRCRMAC)*
   - 1 - Busulfan/Fludarabine (Bu/Flu)
   - 2 - Busulfan/Cyclophosphamide (Bu/Cy)
   - 3 - Cyclophosphamide/Total Body Irradiation (Cy/TBI)
5. Declared MAC GVHD prophylaxis regimen:*(MRGVHMAC)*
   - 1 - Tacrolimus/Methotrexate
   - 2 - Sirolimus/Tacrolimus
   - 3 - Tacrolimus/MMF
   - 4 - Cyclosporine/MMF
   - 5 - Cyclosporine/Methotrexate
   - *Additional Options Listed Below

   If other, specify:*(MRGVOTHM)* _____
6. Will antithymocyte globulin (Thymoglobulin or ATGAM) be used as part of the conditioning regimen?*(MRATGCR)* ☐ 1 - Yes ☐ 2 - No

Inclusion Criteria

7. Record the patient's primary diagnosis:*(MRPRIMDX)*
   - 1 - Myelodysplastic Syndrome
   - 2 - Acute Myelogenous Leukemia

   8. If MDS, record WHO classification at diagnosis:*(MRMDSWHO)*
      - 1 - Refractory Anemia
      - 2 - Refractory Anemia with Ringed Sideroblasts
      - 3 - Refractory Cytopenia with Multilineage Dysplasia
      - 4 - Refractory Cytopenia with Multilineage Dysplasia and Ringed Sideroblasts
      - 5 - Refractory Anemia with Excess Blasts - 1 (5-10% blasts)
      - *Additional Options Listed Below

   9. If AML, record WHO classification at diagnosis:*(MRAMLWHO)*
      - 1 - Acute myeloid leukemia with recurrent cytogenetic abnormalities
      - 2 - Acute myeloid leukemia with multilineage dysplasia
      - 3 - Acute myeloid leukemia and myelodysplastic syndromes, therapy related
      - 4 - Acute myeloid leukemia, not otherwise categorized
10. Date bone marrow assessment was performed:*(MRBMEVDT)* _____ *(mm/dd/yyyy)*
11. Does the patient have <5% myeloblasts in the bone marrow?*(MRBMMYEL)* ☐ 1 - Yes ☐ 2 - No

    If the last bone marrow assessment was done more than 30 days (AML or high grade MDS) or 50 days (low grade MDS) prior to conditioning, this assessment must be repeated before starting conditioning.

12. Date peripheral blood assessment was performed:*(MRPBPDT)* _____ *(mm/dd/yyyy)*
13. Were there myeloblasts in the peripheral blood?*(MRPBMOR)* ☐ 1 - Yes ☐ 2 - No

14. Has the patient received treatment of their MDS or AML prior to transplantation? *(MRPRIOTX)* ☐ 1 - Yes ☐ 2 - No

15. Has the patient received conventional cytotoxic chemotherapy? *(MRCYCHEM)* ☐ 1 - Yes ☐ 2 - No

16. If yes, record the start date of the most recently administered conventional cytotoxic chemotherapy regimen: *(MRCYTODT)* _____ *(mm/dd/yyyy)*

17. Has the patient received treatment with a hypomethylating agent or other noncytotoxic chemotherapy? *(MRNCYCHE)* ☐ 1 - Yes ☐ 2 - No

18. If yes, record the completion date of treatment with a hypomethylating agent or other noncytotoxic chemotherapy: *(MRNOCYDT)* _____ *(mm/dd/yyyy)*

19. Does the patient have an HCT-Specific Comorbidity Index Score (HCT-CI) ≤ 4? *(MRHCTCI)* ☐ 1 - Yes ☐ 2 - No

20. Record left ventricular ejection fraction at rest: *(MRRSTLVE)* _____ *(xxx)* % Date ejection fraction performed: *(MRLVEFDT)* _____ *(mm/dd/yyyy)*

	Most Recent Value	ULN at Your Institution	Date Sample Obtained
21. Bilirubin (mg/dL):	*(MRBILIRV)* _____ *(xx.x)*	*(MRBILULN)* _____ *(xx.x)*	*(MRBILIDT)* _____ *(mm/dd/yyyy)*
22. ALT (Units/L):	*(MRALTRV)* _____ *(xxx)*	*(MRALTULN)* _____ *(xxx)*	*(MRALTDT)* _____ *(mm/dd/yyyy)*
23. AST (Units/L):	*(MRASTRV)* _____ *(xxx)*	*(MRASTULN)* _____ *(xxx)*	*(MRASTDT)* _____ *(mm/dd/yyyy)*
24. Creatinine Clearance (mL/min):	*(MRCCLRRV)* _____ *(xxx)*		*(MRCCLRDT)* _____ *(mm/dd/yyyy)*

	Most Recent Value Corrected for Hemoglobin	Date Sample Obtained
25. DLCO:	*(MRDLCORV)* _____ *(xxx)* %	*(MRDLCODT)* _____ *(mm/dd/yyyy)*
26. FEV1:	*(MRFEVRV)* _____ *(xxx)* %	*(MRFEVDT)* _____ *(mm/dd/yyyy)*

Exclusion Criteria

27. Has the patient had a prior allograft or autograft? *(MRPRALLO)* ☐ 1 - Yes ☐ 2 - No

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

29. Does the patient have a history of leukemic blasts previously detected in the cerebral spinal fluid? *(MRHISTBL)* ☐ 1 - Yes ☐ 2 - No

30. Was leukemia involvement in the CNS cleared within 4 weeks of enrollment? *(MRCLRBL)* ☐ 1 - Yes ☐ 2 - No

31. Date of lumbar puncture: *(MRLPDT)* _____ *(mm/dd/yyyy)*

32. Record patient's Karnofsky performance score: *(MRPRFSCL)*

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

33. Does the patient have symptomatic coronary artery disease? *(MRSYMCAD)* ☐ 1 - Yes ☐ 2 - No

34. Is the patient receiving supplementary continuous oxygen? *(MRSUPPO2)* ☐ 1 - Yes ☐ 2 - No

35. Does the patient have a current uncontrolled bacterial, viral, or fungal infection (currently taking medication with evidence of progression of clinical symptoms)? *(MRVFBACI)* ☐ 1 - Yes ☐ 2 - No

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

37. Does the patient have a history of any malignant diseases other than basal cell carcinoma or cervical carcinoma in situ? *(MRPRIMAL)*

1 - Yes
2 - Yes, Approved by Study Chair or Protocol Officer
3 - No

38. For malignancy treated with curative intent ≤ 5 years ago, date approved by Study Chair or Protocol Officer: *(MRMALDT)* _____ *(mm/dd/yyyy)*

39. Was the malignancy treated with curative intent >5 years previously? *(MRCURMAL)* ☐ 1 - Yes ☐ 2 - No

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

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

42. Is the patient willing to use contraceptive techniques during and for 12 months following treatment? *(MRMFCONT)* ☐ 1 - Yes ☐ 2 - No

Consent for Use of Biological Samples for Research

43. Did the patient give consent to provide blood for future research purposes? *(MRFUTRES)*
☐ 1 - Yes ☐ 2 - No

Donor Inclusion Criteria

44. Record the HCT donor source:*(MRHCTSRC)*
☐ Peripheral Blood ☐ Bone Marrow

Donor Exclusion Criteria

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

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

47. Is the donor currently receiving experimental therapy or investigational agents? *(MRDOEXP)*

1 - Yes
2 - Yes, Approved by Study Chair or Protocol Officer
3 - No

48. Date approved by Study Chair or Protocol Officer:*(MRDOAPDT)*
(mm/dd/yyyy)

Comments:*(MRCOMM)*

Additional Selection Options for ENR

Declared RIC GVHD prophylaxis regimen:
6 - Other, specify

If MDS, record WHO classification at diagnosis:
6 - Refractory Anemia with Excess Blasts - 2 (10-20% blasts)
7 - Myelodysplastic Syndrome, Unclassified
8 - MDS Associated with Isolated Del(5q)

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

Blood and Marrow Transplant Clinical Trials Network

Follow Up Status Form - 0901 (F10)

Web Version: 1.0; 3.01; 10-16-15

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

1. Date of last contact:*(F10LSCTD)* _____ *(mm/dd/yyyy)*

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

2. Has the patient died?*(F10PTDTH)* ☐ 1 - Yes ☐ 2 - No

If Yes, a Death Form must be submitted.

3. Date of patient death:*(F10DTHDT)* _____ *(mm/dd/yyyy)*

4. Has the patient relapsed?*(F10PTRLP)* ☐ 1 - Yes ☐ 2 - No

If Yes, a Relapse Form must be submitted.

5. Date of relapse:*(F10RLPDT)* _____ *(mm/dd/yyyy)*

Any therapy to treat relapsed disease, including DLI or withdrawal of immunosuppressive therapy will be considered evidence of relapse regardless of whether the criteria described in Section 3.2 of the protocol are met.

6. Has the patient received non-protocol AML or MDS therapy?*(F10NPTAM)* ☐ 1 - Yes ☐ 2 - No

7. If Yes, date of initiation of non-protocol AML or MDS therapy:*(F10NPDT)* _____ *(mm/dd/yyyy)*

8. Has immunosuppressive therapy been withdrawn to treat relapsed disease? *(F10WDIMM)* ☐ 1 - Yes ☐ 2 - No

If Yes, a Relapse Form must be submitted.

9. Date of withdrawal from immunosuppressive therapy:*(F10IMMDT)* _____ *(mm/dd/yyyy)*

10. Was a donor leukocyte infusion (DLI) given to treat relapsed disease?*(F10DLI)* ☐ 1 - Yes ☐ 2 - No

If Yes, a Relapse Form must be submitted.

11. Date of DLI:*(F10DLIDT)* _____ *(mm/dd/yyyy)*

12. Has the patient experienced secondary graft failure?*(F10PTSGF)* ☐ 1 - Yes ☐ 2 - No

If Yes, a Secondary Graft Failure Form must be submitted.

13. Date of secondary graft failure:*(F10SGFDT)* _____ *(mm/dd/yyyy)*

14. Has the patient experienced any new, clinically significant infections?*(F10PTINF)* ☐ 1 - Yes ☐ 2 - No

If Yes, an Infection Form must be submitted.

15. Date of infection:*(F10INFDT)* _____ *(mm/dd/yyyy)*

16. Has the patient been hospitalized (other than for transplant)?*(F10PTHSP)* ☐ 1 - Yes ☐ 2 - No

17. Has the patient been hospitalized?*(F10PTHSP)* ☐ 1 - Yes ☐ 2 - No

If Yes, a Re-Admission Form must be submitted.

18. Date of hospitalization:*(F10HSPDT)* _____ *(mm/dd/yyyy)*

19. Has the patient experienced any Unexpected, Grade 3-5 Adverse Events? *(F10PTSAE)* ☐ 1 - Yes ☐ 2 - No

If Yes, an Unexpected, Grade 3 - 5 Adverse Event Form must be submitted.

20. Date of onset of Unexpected, Grade 3-5 Adverse Event:*(F10SAEDT)* _____ *(mm/dd/yyyy)*

21. Has the patient received a non-protocol specified transplant?*(F10NPTXP)* ☐ 1 - Yes ☐ 2 - No

22. Date of non-protocol specified transplant:*(F10NPTDT)* _____ *(mm/dd/yyyy)*

Comments:*(F10CMNTS)*

Blood and Marrow Transplant Clinical Trials Network

FACT-BMT (Version 4) (FCT)

Web Version: 1.0; 3.05; 10-16-15

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

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

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

Physical Well-Being

1. I have a lack of energy*(LCKENRG)*

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

2. I have nausea*(NAUSEA)*

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

3. Because of my physical condition, I have trouble meeting the needs of my family*(FMLYNEED)*

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

4. I have pain*(PAIN)*

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

5. I am bothered by the side effects of treatment*(SIDEFFCT)*

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

6. I feel ill*(FEELILL)*

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

7. I am forced to spend time in bed*(TIMINBED)*

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

Social/Family Well-Being

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

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

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

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

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

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

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

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

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

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

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

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

Did the patient answer the following question?(CHECKBOX)

☐ 1 - Yes ☐ 2 - No

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

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

Emotional Well-Being

15. I feel sad*(FEELSAD)*

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

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

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

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

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

18. I feel nervous*(NERVOUS)*

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

19. I worry about dying*(WORRYDIE)*

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

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

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

Functional Well-Being

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

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

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

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

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

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

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

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

25. I am sleeping well*(SLEEPWEL)*

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

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

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

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

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

Additional Concerns

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

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

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

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

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

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

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

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

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

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

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

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

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

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

35. I get tired easily*(GETTIRED)*

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

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

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

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

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

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

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

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

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

40. I can remember things*(MEMORY)*

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

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

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

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

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

43. My eyesight is blurry*(EYESIGHT)*

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

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

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

45. I have tremors*(TREMORS)*

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

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

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

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

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

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

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

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

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

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

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

English (Universal)

16 November 2007

Additional Selection Options for FCT

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

Blood and Marrow Transplant Clinical Trials Network

Global QOL Baseline Form (GBL)

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

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

Date of Assessment:*(GBLASMDT)* _____ *(mm/dd/yyyy)*

Please tell us about yourself

1. What is your marital status?*(GBLMTLST)*

1 - Married/Living with partner
2 - Single, Never married
3 - Divorced, Separated
4 - Widowed
5 - Other, specify
*Additional Options Listed Below

Other, please specify:*(GBLMTLSP)* _____

2. What is your current work status? (Check all that apply.)

In school:*(GBLWKEDU)*	☐ 1 - Yes	☐ 2 - No
Working full time:*(GBLWKFT)*	☐ 1 - Yes	☐ 2 - No
Working part time:*(GBLWKPT)*	☐ 1 - Yes	☐ 2 - No
Homemaker:*(GBLWKHM)*	☐ 1 - Yes	☐ 2 - No
Disabled:*(GBLWKDIS)*	☐ 1 - Yes	☐ 2 - No
On medical leave from work:*(GBLWKLV)*	☐ 1 - Yes	☐ 2 - No
Unemployed, looking for work:*(GBLWKUNL)*	☐ 1 - Yes	☐ 2 - No
Unemployed, not looking for work:*(GBLWKUNN)*	☐ 1 - Yes	☐ 2 - No
Retired:*(GBLWKRET)*	☐ 1 - Yes	☐ 2 - No
Other:*(GBLWRKSP)*	☐ 1 - Yes	☐ 2 - No

Other, please specify:*(GBLOTHSP)* _____

3. Which category best describes your usual occupation? If you are not currently employed, which category best describes your LAST job?*(GBLOCCUP)*

1 - Professional, technical (teacher/professor, nurse, lawyer, physician, engineer)
2 - Manager, administrator, or proprietor (sales manager, real estate agent, postmater)
3 - Clerical (secretary, clerk, mail carrier)
4 - Sales (salesperson, demonstrator, agent, broker)
5 - Service (police, cook, hairdresser)
*Additional Options Listed Below

Other, please describe:*(GBLJOBSP)* _____

4. What is the highest grade of school you have completed?*(GBLEDU)*

1 - Grade school
2 - Some high school
3 - High school graduate
4 - Some college
5 - College graduate
*Additional Options Listed Below

5. What was your approximate annual family income in the year prior to your diagnosis?*(GBLINCOM)*

1 - Under $15,000
2 - $15,000 - $24,999
3 - $25,000 - $49,999
4 - $50,000 - $74,999
5 - $75,000 - $99,999
*Additional Options Listed Below

6. Which statement describes how you feel most of the time:*(GBLFEEL)*

- 1 - Normal, no difficulties with daily activities
- 2 - Able to carry on normal activities, minor problems
- 3 - Normal activity with effort
- 4 - Able to care for self, but unable to carry on normal activity or active work
- 5 - Require occasional assistance, but able to care for most of needs
- *Additional Options Listed Below

7. In general, would you say your health is:*(GBLHLTH)*

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

8. On a scale of 0 to 100, with zero being death and one-hundred being perfect health, which number would you say best describes your state of health over the **past two weeks? *(GBLSCALE)***

(xxx)

Comments:*(GBLCOMM)*

Additional Selection Options for GBL

What is your marital status?
88 - Not Answered

Which category best describes your usual occupation? If you are not currently employed, which category best describes your LAST job?
6 - Skilled crafts (carpenter, repairer, telephone line worker)
7 - Equipment or vehicle operator (driver, railroad brakeman, sewer worker)
8 - Laborer (helper, longshoreman, warehouse worker)
9 - Farmer (owner, manager, operator, tenant)
10 - Member of the military
11 - Homemaker
12 - Student
13 - Other, please describe
88 - Not Answered

What is the highest grade of school you have completed?
6 - Postgraduate degree
88 - Not Answered

What was your approximate annual family income in the year prior to your diagnosis?
6 - $100,000 or above
88 - Not Answered

Which statement describes how you feel most of the time:
6 - Require considerable assistance and frequent medical care
7 - Disabled, require special care and assistance
8 - Severely disabled, hospitalized
9 - Very sick, hospitalized
88 - Not Answered

In general, would you say your health is:
88 - Not Answered

Blood and Marrow Transplant Clinical Trials Network

Global QOL Follow-Up Form (GFU)

Web Version: 1.0; 1.01; 10-16-15

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

Date of Assessment:*(GFUASMDT)* _____ *(mm/dd/yyyy)*

Please tell us about yourself

1. Which statement describes how you feel most of the time:*(GFUFEEL)*

- 1 - Normal, no difficulties with daily activities
- 2 - Able to carry on normal activities, minor problems
- 3 - Normal activity with effort
- 4 - Able to care for self, but unable to carry on normal activity or active work
- 5 - Require occasional assistance, but able to care for most of needs
- *Additional Options Listed Below

2. In general, would you say your health is:*(GFUHLTH)*

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

3. On a scale of 0 to 100, with zero being death and one-hundred being perfect health, which number would you say best describes your state of health over the **past two weeks**?*(GFUSCALE)* _____ *(xxx)*

4. Overall, how would you rate the severity of your chronic graft-versus-host disease?*(GFUCGVHD)*

- 1 - None
- 2 - Mild
- 3 - Moderate
- 4 - Severe
- 88 - Not Answered

Comments:*(GFUCOMM)*

Additional Selection Options for GFU

Which statement describes how you feel most of the time:
6 - Require considerable assistance and frequent medical care
7 - Disabled, require special care and assistance
8 - Severely disabled, hospitalized
9 - Very sick, hospitalized
88 - Not Answered

In general, would you say your health is:
88 - Not Answered

Blood and Marrow Transplant Clinical Trials Network

Acute GVHD Form (GVH)

Web Version: 1.0; 10.12; 06-16-16

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

1. Date of staging:*(STAGEDT)* _____ *(mm/dd/yyyy)*

   Start of GVHD Assessment Period:*(GVASSTDT)* _____ *(mm/dd/yyyy)*

   End of GVHD Assessment Period:*(GVASENDT)* _____ *(mm/dd/yyyy)*

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

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

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

3. Record most recent blood level of immunosuppressant (prophylaxis): *(TROUGHLV)* _____ *(xxxx.x)* ng/mL

4. Record date blood sample obtained:*(TROUGHDT)* _____ *(mm/dd/yyyy)*

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

5. Skin abnormalities:*(GVHSKINA)*

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

6. Skin etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(SETGVHD) ☐ 1 - Yes ☐ 2 - No	*(SETDRGRX)* ☐ 1 - Yes ☐ 2 - No	*(SETCRTOX)* ☐ 1 - Yes ☐ 2 - No

Infection	Other
(SETINFCT) ☐ 1 - Yes ☐ 2 - No	*(SETOTHER)* ☐ 1 - Yes ☐ 2 - No

Specify other skin etiologies:*(GVHSKNSP)* _____

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

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

8. Upper GI abnormalities:*(GVHUPGIA)*

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

9. Upper intestinal tract etiologies:

GVHD	Drug Reaction	Conditioning Regimen Toxicity
(UGIETGVH) ☐ 1 - Yes ☐ 2 - No	*(UGIETDRG)* ☐ 1 - Yes ☐ 2 - No	*(UGIETCON)* ☐ 1 - Yes ☐ 2 - No

TPN	Infection	Other
(UGIETTPN) ☐ 1 - Yes ☐ 2 - No	*(UGIETINF)* ☐ 1 - Yes ☐ 2 - No	*(UGIETOTH)* ☐ 1 - Yes ☐ 2 - No

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

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

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

11. Lower GI abnormalities:*(GVHINTA)*

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

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

12. Lower intestinal tract etiologies:

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

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

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

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

14. Liver abnormalities:*(GVHLIVRA)*

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

15. Liver etiologies:

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

Specify other liver etiologies:*(GVHLIVRS)*

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

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

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

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

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

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

Specify other agent:*(GVHAGNSP)*

19. Indicate treatment modification:*(GVHTRMOD)*

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

Comments:*(GVHCOMM)*

Additional Selection Options for GVH

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

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

Blood and Marrow Transplant Clinical Trials Network

Hematopoiesis Form (HF1)

Web Version: 1.0; 3.00; 10-16-15

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

1. Did the patient's ANC drop below 500/mm^3 after the initiation of the conditioning regimen?*(ANCDRP)* ☐ 1 - Yes ☐ 2 - No

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

3. Record absolute neutrophil counts and dates obtained:

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

4. If 'No', record the most recent absolute neutrophil count:*(RECNTANC)* *(xxxxx)* /mm^3

5. Date most recent absolute neutrophil count obtained:*(RCTANCDT)* *(mm/dd/yyyy)*

Record Chimerism Assay Data for Marrow and/or Blood

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

Marrow:

6. Was a chimerism assay performed on a marrow sample during this assessment period?*(MRWCHIM)* ☐ 1 - Yes ☐ 2 - No

7. Record date specimen collected:*(MRWCHIDT)* *(mm/dd/yyyy)*

8. Record method of evaluation:*(MRWMTHD)*

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

9. Specify other method of evaluation:*(MRWMTHSP)*

10. Record marrow chimerism cell type:*(MRWTYPE)* ☐ 1 - Unmanipulated ☐ 2 - Granulocytes

11. Record marrow assay results:*(MRWRSLT)*

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

12. Record % donor:*(MRWPCTD)* *(xx)* %

Blood:

13. Was a chimerism assay performed on a blood sample during this assessment period?*(BLDCHIM)* ☐ 1 - Yes ☐ 2 - No

14. Record date specimen collected:*(BLDCHIDT)* *(mm/dd/yyyy)*

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

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

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

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

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

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

19. Record % donor:*(BLDPCTD)*

(xx) %

T Cell (CD3+):

20. Was a chimerism assay performed on a T cell sample during this assessment period?*(TCLCHIM)*

☐ 1 - Yes ☐ 2 - No

21. Record date specimen collected:*(TCLCHIDT)*

(mm/dd/yyyy)

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

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

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

24. Record the type of T cell sample:*(TCLTYPE)*

☐ 1 - Blood ☐ 2 - Marrow

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

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

26. Record % donor:*(TCLPCTD)*

(xx) %

Comments:*(HTPCOMM)*

Additional Selection Options for HF1

Record method of evaluation:
9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

Immune Reconstitution Form - 0901 (IMC)

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

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

Start of Assessment Period:*(IMCSTDT)* *(mm/dd/yyyy)*
End of Assessment Period:*(IMCENDT)* *(mm/dd/yyyy)*

Flow Cytometry

1. Date flow cytometry was performed:*(IMCFCYDT)* *(mm/dd/yyyy)*
2. White blood cell count:*(IMCWBC)* *(xxxxxx)* /uL
3. Percent lymphocyte of CD45+ cells:*(IMCLYMPH)* *(xxx)* %
4. CD3:*(IMC3CT)* *(xxxx)* cells/uL
5. CD4:*(IMC4CT)* *(xxxx)* cells/uL
6. CD8:*(IMC8CT)* *(xxxx)* cells/uL
7. CD19:*(IMC19CT)* *(xxxx)* cells/uL
8. CD56+:*(IMC56CT)* *(xxxx)* cells/uL

Comments:*(IMCCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Infection Form (INF)

Web Version: 1.0; 4.01; 10-16-15

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

INFECTION I

1. Type of infection:*(INFTYP01)*

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

2. Organism I:*(ORGN01)*

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

?

If other specify:*(INFSPEC1)*

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

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

4. Severity of infection:*(SVRTY01)*

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

INFECTION II

5. Type of infection:*(INFTYP02)*

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

6. Organism II:*(ORGN02)*

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

If other specify:*(INFSPEC2)*

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

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

8. Severity of infection:*(SVRTY02)*

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

INFECTION III

9. Type of infection:*(INFTYP03)*

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

10. Organism Ill:*(ORGN03)*

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

If other specify:*(INFSPEC3)*

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

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

12. Severity of infection:*(SVRTY03)*

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

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

Provide agent(s) administered for this infectious period:

14. 1st agent:*(AGENT1)*

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

If other specify:*(AGTSPEC1)*

15. 2nd agent:*(AGENT2)*

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

If other specify:*(AGTSPEC2)*

16. 3rd agent:*(AGENT3)*

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

If other specify:*(AGTSPEC3)*

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

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

Comments:*(INFCOM)*

Additional Selection Options for INF

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

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

MAC Conditioning Regimen Form - 0901 (MCR)

Web Version: 1.0; 4.01; 12-08-15

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

1. Was a bone marrow assessment repeated?*(MCBMAR)* ☐ 1 - Yes ☐ 2 - No
   2. Date repeat bone marrow assessment performed:*(MCBMRDT)* _____ *(mm/dd/yyyy)*
   3. Did the repeat bone marrow assessment indicate < 5% myeloblasts? *(MCBM5MB)* ☐ 1 - Yes ☐ 2 - No
4. Was a peripheral blood assessment repeated?*(MCPBAR)* ☐ 1 - Yes ☐ 2 - No
   5. Date of repeat peripheral blood assessment:*(MCPBRDT)* _____ *(mm/dd/yyyy)*
   6. Were there leukemic myeloblasts in the peripheral blood on morphologic analysis?*(MCPBLMB)* ☐ 1 - Yes ☐ 2 - No

If a repeat bone marrow assessment revealed ≥ 5% myeloblasts or morphologic analysis of the peripheral blood revealed leukemic myeloblasts, a Relapse form is required.

7. Record the patient's Body Surface Area (BSA):*(MCBSA)* _____ *(x.xx)* m^2
8. Record the date the BSA was obtained:*(MCBSADT)* _____ *(mm/dd/yyyy)*
9. Record the patient's weight used to calculate dose:*(MCPTWT)* _____ *(xxx.x)* kg
10. Record the date the weight was obtained:*(MCPTWDT)* _____ *(mm/dd/yyyy)*
11. Record the conditioning regimen that the patient received:*(MCCONRG)*
    - 1 - Busulfan/Fludarabine (Bu/Flu)
    - 2 - Busulfan/Cyclophosphamide (Bu/Cy)
    - 3 - Cyclophosphamide/TBI (Cy/TBI)
    - 4 - Other

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

	Busulfan Dose	Date Given
Dose 1:	*(MCBU11D)* _____ *(xxx)* mg	*(MCBU11DT)* _____ *(mm/dd/yyyy)*
Dose 2:	*(MCBU12D)* _____ *(xxx)* mg	*(MCBU12DT)* _____ *(mm/dd/yyyy)*
Dose 3:	*(MCBU13D)* _____ *(xxx)* mg	*(MCBU13DT)* _____ *(mm/dd/yyyy)*
Dose 4:	*(MCBU14D)* _____ *(xxx)* mg	*(MCBU14DT)* _____ *(mm/dd/yyyy)*
	Fludarabine Dose	**Date Given**
Dose 1:	*(MCFL11D)* _____ *(xxx)* mg	*(MCFL11DT)* _____ *(mm/dd/yyyy)*
Dose 2:	*(MCFL12D)* _____ *(xxx)* mg	*(MCFL12DT)* _____ *(mm/dd/yyyy)*
Dose 3:	*(MCFL13D)* _____ *(xxx)* mg	*(MCFL13DT)* _____ *(mm/dd/yyyy)*
Dose 4:	*(MCFL14D)* _____ *(xxx)* mg	*(MCFL14DT)* _____ *(mm/dd/yyyy)*

13. Record the dose and date of Bu/Cy administration:

	Busulfan Dose	Date Given
Dose 1:	*(MCBU21D)* _____ *(xxx)* mg	*(MCBU21DT)* _____ *(mm/dd/yyyy)*
Dose 2:	*(MCBU22D)* _____ *(xxx)* mg	*(MCBU22DT)* _____ *(mm/dd/yyyy)*
Dose 3:	*(MCBU23D)* _____ *(xxx)* mg	*(MCBU23DT)* _____ *(mm/dd/yyyy)*
Dose 4:	*(MCBU24D)* _____ *(xxx)* mg	*(MCBU24DT)* _____ *(mm/dd/yyyy)*

	Cyclophosphamide Dose	Date Given
Dose 1:	*(MCCY11D)* *(xxxxx)* mg	*(MCCY11DT)* *(mm/dd/yyyy)*
Dose 2:	*(MCCY12D)* *(xxxxx)* mg	*(MCCY12DT)* *(mm/dd/yyyy)*

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

	TBI Dose	Date Given
Dose 1:	*(MCTBI1D)* *(xxxx)* cGy	*(MCTBI1DT)* *(mm/dd/yyyy)*
Dose 2:	*(MCTBI2D)* *(xxxx)* cGy	*(MCTBI2DT)* *(mm/dd/yyyy)*
Dose 3:	*(MCTBI3D)* *(xxxx)* cGy	*(MCTBI3DT)* *(mm/dd/yyyy)*
Dose 4:	*(MCTBI4D)* *(xxxx)* cGy	*(MCTBI4DT)* *(mm/dd/yyyy)*
	Cyclophosphamide Dose	Date Given
Dose 1:	*(MCCY21D)* *(xxxxx)* mg	*(MCCY21DT)* *(mm/dd/yyyy)*
Dose 2:	*(MCCY22D)* *(xxxxx)* mg	*(MCCY22DT)* *(mm/dd/yyyy)*

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

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

Agent	Date	Other Agent	Specify Other Agent	Total Dose	Unit
1.	*(MCR1DT)* *(mm/dd/yyyy)*	*(MC1AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(MC1OTHER)*	*(MC1DOSE)* *(xxxxx)*	*(MC1UNIT)* 1 - mg 2 - cGy
2.	*(MCR2DT)* *(mm/dd/yyyy)*	*(MC2AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(MC2OTHER)*	*(MC2DOSE)* *(xxxxx)*	*(MC2UNIT)* 1 - mg 2 - cGy
3.	*(MCR3DT)* *(mm/dd/yyyy)*	*(MC3AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(MC3OTHER)*	*(MC3DOSE)* *(xxxxx)*	*(MC3UNIT)* 1 - mg 2 - cGy
4.	*(MCR4DT)* *(mm/dd/yyyy)*	*(MC4AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(MC4OTHER)*	*(MC4DOSE)* *(xxxxx)*	*(MC4UNIT)* 1 - mg 2 - cGy
5.	*(MCR5DT)* *(mm/dd/yyyy)*	*(MC5AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(MC5OTHER)*	*(MC5DOSE)* *(xxxxx)*	*(MC5UNIT)* 1 - mg 2 - cGy

6.	*(MCR6DT)* (mm/dd/yyyy)	*(MC6AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(MC6OTHER)*	*(MC6DOSE)* (xxxxx)	*(MC6UNIT)* 1 - mg 2 - cGy
7.	*(MCR7DT)* (mm/dd/yyyy)	*(MC7AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(MC7OTHER)*	*(MC7DOSE)* (xxxxx)	*(MC7UNIT)* 1 - mg 2 - cGy
8.	*(MCR8DT)* (mm/dd/yyyy)	*(MC8AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(MC8OTHER)*	*(MC8DOSE)* (xxxxx)	*(MC8UNIT)* 1 - mg 2 - cGy
9.	*(MCR9DT)* (mm/dd/yyyy)	*(MC9AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(MC9OTHER)*	*(MC9DOSE)* (xxxxx)	*(MC9UNIT)* 1 - mg 2 - cGy

16. Record the Busulfan administration route:*(MCBURT)* ☐ 1 - IV ☐ 2 - PO

17. Was a pharmacokinetic assessment done to calculate exposure to Busulfan? *(MCBUEX)* ☐ 1 - Yes ☐ 2 - No

18. Was the Busulfan dose adjusted based on the results from the PK assessment? *(MCDSADJ)* ☐ 1 - Yes ☐ 2 - No

19. If the dose was modified based on PK results, what was the overall exposure to Bu?*(MCCSS)* Concentration at Steady State (CSS): *(xxx.x)* Units:*(MCCSSUT)*
1 - ng/mL
2 - umol*min

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

21. If yes, indicate which source of ATG was used as part of the conditioning regimen:*(MCATGSRC)*
1 - Thymoglobulin (rabbit)
2 - ATGAM (horse)

22. If yes, specify the total dose of ATG:*(MCATGDOS)* *(xxxxx)* mg

23. Record the start date of ATG administration:*(MCSTAMDT)* *(mm/dd/yyyy)*

24. Record the end date of ATG administration:*(MCEDAMDT)* *(mm/dd/yyyy)*

Comments:*(MCRCOMM)*

Additional Selection Options for MCR

CR Agent 1
6 - ATGAM (horse)
7 - TBI
8 - Other

Blood and Marrow Transplant Clinical Trials Network

M.D. Anderson Symptom Inventory (MDA)

Web Version: 1.0; 3.04; 10-16-15

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

Date M.D. Anderson Symptom Inventory was completed by the patient: *(MDACOMDT)* _____ *(mm/dd/yyyy)*

Date M.D. Anderson Symptom Inventory was completed by the patient: *(MDACOMDT)* _____ *(mm/dd/yyyy)*

Is the patient ≥ 18 years old?*(MDA18OLD)* ☐ 1 - Yes ☐ 2 - No

If no, please indicate if the form was completed by the patient or the patient's guardian:*(MDAPAREN)* ☐ 1 - Patient ☐ 2 - Guardian

Part I. How severe are the reported symptoms?

Complete the following questions regarding the patient's symptoms within 24 hours. Please rate the symptoms on a scale of 0 (not present) to 10 (as bad as imaginable).

1. Pain at its worst?*(MDAPAIN)*
2. Fatigue at its worst?*(MDAFATIG)*
3. Nausea at its worst?*(MDANAUSE)*
4. Disturbed sleep at its worst?*(MDASLEEP)*
5. Feelings of being distressed at its worst?*(MDADISTR)*
6. Shortness of breath at its worst?*(MDASOB)*

For each of the above, select from:

0
1
2
3
4
*Additional Options Listed Below

7. Problem with remembering things at its worst?*(MDAREMEM)*

0
1
2
3
4
*Additional Options Listed Below

8. Problem with lack of appetite at its worst?*(MDAAPPET)*

0
1
2
3
4
*Additional Options Listed Below

9. Feeling drowsy at its worst?*(MDADROWS)*

0
1
2
3
4
*Additional Options Listed Below

10. Having a dry mouth at its worst?*(MDADRYM)*

0
1
2
3
4
*Additional Options Listed Below

11. Feeling sad at its worst?*(MDASAD)*

0
1
2
3
4
*Additional Options Listed Below

12. Vomiting at its worst?*(MDAVOMIT)*

0
1
2
3
4
*Additional Options Listed Below

13. Numbness or tingling at its worst?*(MDANUMB)*

0
1
2
3
4
*Additional Options Listed Below

Part II. How have symptoms interfered with the patient's life?

Complete the following questions regarding the frequency of interference in the patient's life within 24 hours. Please rate the level of interference on a scale of 0 (did not interfere) to 10 (interfered completely).

14. General activity?*(MDAGENAC)*

0
1
2
3
4
*Additional Options Listed Below

15. Mood?*(MDAMOOD)*

0
1
2
3
4
*Additional Options Listed Below

16. Work (including work around the house)?*(MDAWORK)*

0
1
2
3
4
*Additional Options Listed Below

17. Relations with other people?*(MDARELA)*

0
1
2
3
4
*Additional Options Listed Below

18. Walking?*(MDAWALK)*

0
1
2
3
4
*Additional Options Listed Below

19. Enjoyment of life?*(MDAENJOY)*

0
1
2
3
4
*Additional Options Listed Below

Additional Selection Options for MDA

Pain at its worst?
5
6
7
8
9
10

General activity?
5
6
7
8
9
10

Blood and Marrow Transplant Clinical Trials Network

Occupational Functioning Items (OFX)

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

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

Date of assessment:*(OFXASTDT)* *(mm/dd/yyyy)*

The next set of questions has to do with your working at a job or in the home.

1. Which of the following best describes your current job status?*(OFXJOBST)*

1 - Employed outside the home, full-time
2 - Employed outside the home, part-time
3 - Homemaker
4 - Retired
5 - Unemployed, looking for work
*Additional Options Listed Below

2. What kind of work do you do at the present time? (Include work done in the home.)*(OFXTYWRK)*

3. At the present time, how many hours do you work each week for which you are paid?*(OFXHRSWK)* *(xx.xx)* paid hours

How many for which you are not paid?*(OFXNOTPD)* *(xx.xx)* unpaid hours

4. Have you attempted to work/go to school but found that you weren't able to?*(OFXATTWK)* ☐ 1 - Yes ☐ 2 - No ☐ 88 - Not Answered

(If yes) What prevents you from working/going to school at the present time?*(OFXPVTWK)*

5. Is your work/school work as important to you now as it was before your diagnosis?*(OFXIMPWK)*

1 - More important
2 - About the same importance
3 - Less important
88 - Not Answered

6. Have you changed your goals concerning your work/education as a result of your diagnosis?*(OFXGOALS)*

1 - My goals haven't changed
2 - My goals have changed slightly
3 - My goals have changed quite a bit
4 - My goals have changed completely
88 - Not Answered

Comments:*(OFXCOMM)*

Additional Selection Options for OFX

Which of the following best describes your current job status?
6 - Temporarily disabled
7 - Permanently disabled
8 - Student
9 - Other (e.g. volunteer)
88 - Not Answered

Blood and Marrow Transplant Clinical Trials Network

RIC Conditioning Regimen Form - 0901 (RCR)

Web Version: 1.0; 4.02; 12-08-15

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

1. Was a bone marrow assessment repeated?*(RCBMAR)* ☐ 1 - Yes ☐ 2 - No
   2. Date repeat bone marrow assessment performed:*(RCBMRDT)* _____ *(mm/dd/yyyy)*
   3. Did the repeat bone marrow assessment indicate < 5% myeloblasts? *(RCBM5MB)* ☐ 1 - Yes ☐ 2 - No
4. Was a peripheral blood assessment repeated?*(RCPBAR)* ☐ 1 - Yes ☐ 2 - No
   5. Date of repeat peripheral blood assessment:*(RCPBRDT)* _____ *(mm/dd/yyyy)*
   6. Were there leukemic myeloblasts in the peripheral blood on morphologic analysis?*(RCPBLMB)* ☐ 1 - Yes ☐ 2 - No

If a repeat bone marrow assessment revealed ≥ 5% myeloblasts or morphologic analysis of the peripheral blood revealed leukemic myeloblasts, a Relapse form is required.

7. Record the patient's Body Surface Area (BSA):*(RCBSA)* _____ *(x.xx)* m^2
8. Record the date the BSA was obtained:*(RCBSADT)* _____ *(mm/dd/yyyy)*
9. Record the patient's weight used to calculate the dose:*(RCPTWT)* _____ *(xxx.x)* kg
10. Record the date the weight was obtained:*(RCPTWDT)* _____ *(mm/dd/yyyy)*
11. Record the conditioning regimen that the patient received:*(RCCONRG)*
    1 - Fludarabine/Busulfan (Flu/Bu)
    2 - Fludarabine/Melphalan (Flu/Mel)
    3 - Other

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

	Fludarabine Dose	Date Given
Dose 1:	*(RCFL11D)* _____ *(xxx)* mg	*(RCFL11DT)* _____ *(mm/dd/yyyy)*
Dose 2:	*(RCFL12D)* _____ *(xxx)* mg	*(RCFL12DT)* _____ *(mm/dd/yyyy)*
Dose 3:	*(RCFL13D)* _____ *(xxx)* mg	*(RCFL13DT)* _____ *(mm/dd/yyyy)*
Dose 4:	*(RCFL14D)* _____ *(xxx)* mg	*(RCFL14DT)* _____ *(mm/dd/yyyy)*
Dose 5:	*(RCFL15D)* _____ *(xxx)* mg	*(RCFL15DT)* _____ *(mm/dd/yyyy)*
	Busulfan Dose	**Date Given**
Dose 1:	*(RCBU1D)* _____ *(xxx)* mg	*(RCBUD1DT)* _____ *(mm/dd/yyyy)*
Dose 2:	*(RCBU2D)* _____ *(xxx)* mg	*(RCBUD2DT)* _____ *(mm/dd/yyyy)*

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

	Fludarabine Dose	Date Given
Dose 1:	*(RCFL21D)* _____ *(xxx)* mg	*(RCFL21DT)* _____ *(mm/dd/yyyy)*
Dose 2:	*(RCFL22D)* _____ *(xxx)* mg	*(RCFL22DT)* _____ *(mm/dd/yyyy)*
Dose 3:	*(RCFL23D)* _____ *(xxx)* mg	*(RCFL23DT)* _____ *(mm/dd/yyyy)*
Dose 4:	*(RCFL24D)* _____ *(xxx)* mg	*(RCFL24DT)* _____ *(mm/dd/yyyy)*
	Melphalan Dose	**Date Given**
Dose:	*(RCMELD)* _____ *(xxx)* mg	*(RCMELDT)* _____ *(mm/dd/yyyy)*

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

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

Agent	Date	Other Agent	Specify Other Agent	Total Dose	Unit
1.	*(RC1DT)* *(mm/dd/yyyy)*	*(RC1AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(RC1OTHSP)*	*(RC1DOSE)* *(xxxxx)*	*(RC1UNIT)* 1 - mg 2 - cGy
2.	*(RC2DT)* *(mm/dd/yyyy)*	*(RC2AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(RC2OTHSP)*	*(RC2DOSE)* *(xxxxx)*	*(RC2UNIT)* 1 - mg 2 - cGy
3.	*(RC3DT)* *(mm/dd/yyyy)*	*(RC3AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(RC3OTHSP)*	*(RC3DOSE)* *(xxxxx)*	*(RC3UNIT)* 1 - mg 2 - cGy
4.	*(RC4DT)* *(mm/dd/yyyy)*	*(RC4AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(RC4OTHSP)*	*(RC4DOSE)* *(xxxxx)*	*(RC4UNIT)* 1 - mg 2 - cGy
5.	*(RC5DT)* *(mm/dd/yyyy)*	*(RC5AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(RC5OTHSP)*	*(RC5DOSE)* *(xxxxx)*	*(RC5UNIT)* 1 - mg 2 - cGy
6.	*(RC6DT)* *(mm/dd/yyyy)*	*(RC6AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(RC6OTHSP)*	*(RC6DOSE)* *(xxxxx)*	*(RC6UNIT)* 1 - mg 2 - cGy
7.	*(RC7DT)* *(mm/dd/yyyy)*	*(RC7AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(RC7OTHSP)*	*(RC7DOSE)* *(xxxxx)*	*(RC7UNIT)* 1 - mg 2 - cGy
8.	*(RC8DT)* *(mm/dd/yyyy)*	*(RC8AGENT)*	*(RC8OTHSP)*	*(RC8DOSE)* *(xxxxx)*	*(RC8UNIT)* 1 - mg 2 - cGy

		1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below			
9.	*(RC9DT)* *(mm/dd/yyyy)*	*(RC9AGENT)* 1 - Busulfan 2 - Fludarabine 3 - Cyclophosphamide 4 - Melphalan 5 - Thymoglobulin (rabbit) *Additional Options Listed Below	*(RC9OTHSP)*	*(RC9DOSE)* *(xxxxx)*	*(RC9UNIT)* 1 - mg 2 - cGy

15. Record the Busulfan administration route:*(RCBURT)* ☐ 1 - IV ☐ 2 - PO

16. Was a pharmakokinetic assessment done to calculate exposure to Busulfan? *(RCBUEX)* ☐ 1 - Yes ☐ 2 - No

17. Was the Busulfan dose adjusted based on the results from the PK assessment? *(RCDSADJ)* ☐ 1 - Yes ☐ 2 - No

18. If the dose was modified based on PK results, what was the overall exposure to Bu:*(RCCSS)* Concentration at Steady State (CSS): *(xxx.x)* Units:*(RCCSSUT)*
1 - ng/mL
2 - umol*min

19. Did the patient receive ATG?*(RCATG)* ☐ 1 - Yes ☐ 2 - No

20. If yes, indicate which source of ATG was used as part of the conditioning regimen:*(RCATGSRC)*
1 - Thymoglobulin (rabbit)
2 - ATGAM (horse)

21. If yes, specify the total dose of ATG:*(RCATGDOS)* *(xxxxx)* mg

22. Record the start date of ATG administration:*(RCSTATDT)* *(mm/dd/yyyy)*

23. Record the end date of ATG administration:*(RCENDDT)* *(mm/dd/yyyy)*

Comments:*(RCRCOMM)*

Additional Selection Options for RCR

CR Agent 1
6 - ATGAM (horse)
7 - TBI
8 - Other

Blood and Marrow Transplant Clinical Trials Network

Relapse Form - 0901 (RPS)

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

Disease *(RELDIS)*:

Date of Relapse:*(RPSRELDT)* _____ *(mm/dd/yyyy)*

Acute Leukemia

Institution of any therapy to treat relapsed disease, including withdrawal of immunosuppressive therapy or DLI, will be considered evidence of relapse regardless of whether the criteria below are met.

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

If yes, indicate the following:

2. Type of sample:*(RPSTYPE)* ☐ 1 - Blood ☐ 2 - Bone Marrow
3. Date blasts documented:*(RPSPDT)* _____ *(mm/dd/yyyy)*
4. % leukemic blasts documented:*(RPSPR)* _____ *(xxx)* %
5. Was cytogenetic testing done?*(RPSCYT)* ☐ 1 - Yes ☐ 2 - No
6. Date of cytogenetic testing:*(RPSCYDT)* _____ *(mm/dd/yyyy)*
7. Have pre-transplant cytogenetic abnormalities reappeared?*(RPSCYTAB)* ☐ 1 - Yes ☐ 2 - No
8. Was leukemia detected at an extramedullary site?*(RPSEXTR)* ☐ 1 - Yes ☐ 2 - No
9. Indicate date disease first detected:*(RPSEXDT)* _____ *(mm/dd/yyyy)*

Myelodysplastic Syndrome (MDS)

Institution of any therapy to treat relapsed disease, including withdrawal of immunosuppressive therapy or DLI, will be considered evidence of relapse regardless of whether the criteria below are met.

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

If yes, indicate the following:

11. Date specimen obtained:*(RPSMD1DT)* _____ *(mm/dd/yyyy)*
12. Have the abnormalities reappeared on a second bone marrow specimen?*(RPSMD2AB)* ☐ 1 - Yes ☐ 2 - No
13. Indicate date second specimen obtained:*(RPSMD2DT)* _____ *(mm/dd/yyyy)*
14. Was cytogenetic testing done?*(RPSCYTO)* ☐ 1 - Yes ☐ 2 - No
15. Date of cytogenetic testing:*(RPSCYTDT)* _____ *(mm/dd/yyyy)*
16. Have pre-transplant cytogenetic abnormalities reappeared?*(RPSMD1CY)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate the following:

17. Date of cytogenetic analysis:*(RPSMC1DT)* _____ *(mm/dd/yyyy)*
18. Number of metaphases analyzed:*(RPSMD1MA)* _____ *(xxx)*
19. Number of metaphases exhibiting pre-transplant cytogenetic abnormalities:*(RPSM1ABN)* _____ *(xxx)*
20. Have pre-transplant cytogenetic abnormalities reappeared on a second analysis?*(RPSMD2CY)* ☐ 1 - Yes ☐ 2 - No

If yes, indicate the following:

21. Date of second cytogenetic analysis:*(RPSMC2DT)* _____ *(mm/dd/yyyy)*
22. Number of metaphases analyzed on second analysis:*(RPSMD2MA)* _____ *(xxx)*
23. Number of metaphases exhibiting pre-transplant cytogenetic abnormalities on second analysis:*(RPSM2ABN)* _____ *(xxx)*

Comments:*(RPSCOMM)*

Additional Selection Options for RPS

Disease *(RELDIS)* (key field):
1 - Acute Myelogenous Leukemia
2 - Myelodysplastic Syndrome

Blood and Marrow Transplant Clinical Trials Network

Specimen Acquisition Form - 0901 (SA6)

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

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

Future Research Studies

1. Was a sample for future research collected?*(SA6FRS)* ☐ 1 - Yes ☐ 2 - No

   Date sample was collected:*(SA6FRSDT)* _____ *(mm/dd/yyyy)*

Blood Samples for Busulfan Pharmacokinetics

2. Were Busulfan Pharmacokinetic samples collected?*(SA6BPKCL)* ☐ 1 - Yes ☐ 2 - No

Bu PK Sample	Date of Collection	Time of Collection
Sample 1:	*(SA6B1DT)* _____ *(mm/dd/yyyy)*	*(SA6B1TM)* _____ *(hh:mm)*
Sample 2:	*(SA6B2DT)* _____ *(mm/dd/yyyy)*	*(SA6B2TM)* _____ *(hh:mm)*
Sample 3:	*(SA6B3DT)* _____ *(mm/dd/yyyy)*	*(SA6B3TM)* _____ *(hh:mm)*
Sample 4:	*(SA6B4DT)* _____ *(mm/dd/yyyy)*	*(SA6B4TM)* _____ *(hh:mm)*
Sample 5:	*(SA6B5DT)* _____ *(mm/dd/yyyy)*	*(SA6B5TM)* _____ *(hh:mm)*
Sample 6:	*(SA6B6DT)* _____ *(mm/dd/yyyy)*	*(SA6B6TM)* _____ *(hh:mm)*
Sample 7:	*(SA6B7DT)* _____ *(mm/dd/yyyy)*	*(SA6B7TM)* _____ *(hh:mm)*
Sample 8:	*(SA6B8DT)* _____ *(mm/dd/yyyy)*	*(SA6B8TM)* _____ *(hh:mm)*
Sample 9:	*(SA6B9DT)* _____ *(mm/dd/yyyy)*	*(SA6B9TM)* _____ *(hh:mm)*
Sample 10:	*(SA6B10DT)* _____ *(mm/dd/yyyy)*	*(SA6B10TM)* _____ *(hh:mm)*

Comments:*(SA6COMM)* _____

Blood and Marrow Transplant Clinical Trials Network

SF36 Quality of Life (SFH)

Web Version: 1.0; 3.06; 12-08-15

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

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

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

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

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

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

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

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

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

f. Bending, kneeling, or stooping

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

g. Walking more than one mile

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

h. Walking several hundred yards

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

i. Walking one hundred yards

(WALK1BLK)
1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

j. Bathing or dressing yourself

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

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

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

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

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

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

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

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

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

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

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

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

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

b. Accomplished less than you would like

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

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

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

(WORKLMT)

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

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

(PRFMDIFF)

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

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

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

(ECUTTIME)

b. Accomplished less than you would like

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

(ELESSACC)

c. Did work or other activities less carefully than usual

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

(ECARELES)

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

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

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

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

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

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

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

a. Did you feel full of pep?

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

(FULLPEP)

b. Have you been a very nervous person?

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

(NERVOUS)

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

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

(DUMPS)

d. Have you felt calm and peaceful?

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

(CALM)

e. Did you have a lot of energy?

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

(LOTSNRG)

f. Have you felt downhearted and blue?

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

(BLUE)

g. Did you feel worn out?

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

(WORNOUT)

h. Have you been a happy person?

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

(HAPPY)

i. Did you feel tired?

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

(TIRED)

j. Did you feel full of life?

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

(FULLLIFE)

k. Have you been very nervous?

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

(FEELNERV)

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

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

(FEELDOWN)

m. Have you felt calm and peaceful?

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

(FEELCALM)

n. Did you have a lot of energy?

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

(FLENERGY)

o. Have you felt downhearted and depressed?

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

(FEELDEPR)

p. Did you feel worn out?

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

(FEELWORN)

q. Have you been happy?

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

(FEELHAP)

r. Did you feel tired?

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

(FEELTIR)

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

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

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

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

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

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

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

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

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

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

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

d. My health is excellent*(EXCLNT)*

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

(SF-36v2 Standard, US Version 2.0)

Additional Selection Options for SFH

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

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

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

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

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

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

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

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

Blood and Marrow Transplant Clinical Trials Network

Secondary Graft Failure Form (SGF)

Web Version: 1.0; 3.02; 10-16-15

Segment *(PROTSEG)*:

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

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

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

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

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

Comments:*(SGFCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Toxicity Form - 0901 (T19)

Web Version: 1.0; 2.01; 12-08-15

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

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

Record the highest grade of toxicity diagnosed since the previous evaluation. If this is the first evaluation, record the highest toxicity diagnosed since Day 0. The toxicity grades are based on the NCI CTCAE Version 4.02.

GI Disorders

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

Renal Disorders

3. Cystitis noninfective:*(CYSTNINF)*
   - 0 - Grades 0-2
   - 3 - Gross hematuria; transfusion, IV meds or hosp indicated;
   - 4 - Life-threatening consequences; urgent radiologic or operative intervention indicated
   - 5 - Death

4. Acute kidney injury:*(ACKIDINJ)*
   - 0 - Grades 0-2
   - 3 - Creatinine >3x baseline; >4.0 mg/dL; hospitalization indicated
   - 4 - Life-threatening consequences; dialysis indicated
   - 5 - Death

5. Chronic kidney disease:*(CHKIDDIS)*
   - 0 - Grades 0-2
   - 3 - eGFR or CrCl 29-15 ml/min/1.73 m^2
   - 4 - eGFR <15 ml/min/1.73 m^2; dialysis or renal transplant indicated
   - 5 - Death

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

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

Hemorrhagic Disorders

8. Hemorrhage:*(HEMORRHG)*
   - 0 - Grades 0-2
   - 3 - Transfusion, radiologic, endoscopic, or elective operative intervention indicated
   - 4 - Life-threatening consequences; urgent intervention indicated
   - 5 - Death

9. Which organ system was the hemorrhage associated with?*(ORGSYHEM)*
   - 1 - CNS
   - 2 - Gastrointestinal
   - 3 - Genitourinary
   - 4 - Pulmonary, Upper Respiratory
   - 5 - Other

Specify other organ system:*(ORGSYHSP)* _____

Cardiac Disorders

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

11. Specify arrhythmia:*(CRDARRSP)* _____

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

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

Nervous System Disorders

13. Somnolence:*(SOMNOLN)*

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

14. Seizure:*(TXSEIZR)*

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

Blood and Lymphatic Disorders

15. Thrombotic thrombocytopenic purpura:*(THRMBPUR)*

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

Vascular Disorders

16. Hypotension:*(HYPOTEN)*

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

17. Capillary leak syndrome:*(CAPLKSYN)*

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

Respiratory, Thoracic and Mediastinal Disorders

18. Hypoxia:*(TXHYPXIA)*

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

19. Dyspnea:*(TXDYSPNA)*

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

Hepatic Disorders

20. ALT:*(TXALT)*

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

21. AST:*(TXAST)*

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

22. Bilirubin:*(TXBILIRB)*

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

23. Alkaline Phosphatase:*(TXALKPH)*

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

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

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

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

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

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

Indicate the etiology of the abnormal liver function:

	Etiology	Biopsy Results	Doppler Ultrasound Results
28. VOD:	*(VODETIOL)* 1 - Yes 2 - No	*(VODBIOP)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(VODDOPP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
29. GVHD:	*(GVHETIOL)* 1 - Yes 2 - No	*(GVHBIOP)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(GVHDOPP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
30. Infection:	*(INFETIOL)* 1 - Yes 2 - No	*(INFBIOP)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(INFDOPP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
31. Other:	*(OTHETIOL)* 1 - Yes 2 - No	*(OTHBIOP)* 1 - Positive 2 - Negative 3 - Equivocal 4 - Not Done	*(OTHDOPP)* 1 - Confirmed 2 - Not Confirmed 3 - Not Done
32. Unknown:	*(UNKETIOL)* 1 - Yes 2 - No	N/A	N/A

Specify other etiology:*(OTHETSP)*

Comments:*(T19COMM)*

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

Web Version: 1.0; 16.00; 06-22-16

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

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

Comments:*(COMMTXP1)* _____

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

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

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

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

   Specify secondary race:*(RACE2SP)*

Comments:*(DEMCOMM1)*

Additional Selection Options for DEM

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

Blood and Marrow Transplant Clinical Trials Network

09010 (ENR)

Web Version: 1.0; 3.00; 10-16-15

RIC vs MAC in MDS/AML Enrollment Form - Segment 0

Please verify this patient is to be enrolled on the BMT CTN 0901 trial prior to completing the form below.

1. Patient's date of birth:*(MRPATBDT)* 12/07/1977 *(mm/dd/yyyy)*
2. Date BMT CTN 0901 informed consent form signed:*(MRCONSDT)* *(mm/dd/yyyy)*
3. Record patient's donor type:*(MRDNRLTD)* ☐ 1 - Related Donor ☐ 2 - Unrelated Donor
   a. If related, is the donor an identical twin of the recipient?*(MRTWIN)* ☐ 1 - Yes ☐ 2 - No

   Comments:*(MR0COMM)*

Blood and Marrow Transplant Clinical Trials Network

Regimen Intensity HLA (Page 1) (RH1)

Web Version: 1.0; 2.02; 10-16-15

Segment *(PROTSEG)*: 0
Visit Number *(VISNO)*:

HLA Typing

Type of HLA Match required by this protocol:*(HT1MATCH)*

- Loci A, B: Low Level DNA, Locus DRB1: High Level DNA
- Loci A, B: Serologic, Locus DRB1: High Level DNA
- Loci A, B: Serologic, Locus DRB1: Low Level DNA
- Loci A, B, C: Low Level DNA, Locus DRB1: High Level DNA
- Loci A, B, C: Serologic, Locus DRB1: High Level DNA
- *Additional Options Listed Below

1. Recipient HLA Typing

Upload HLA-typing source documents. Be sure to remove patient identifiers prior to uploading.

HLA-A

Typing method:*(HLAAMET)*

- 1 - DNA Technology
- 2 - Serology

Antigens/alleles provided:*(HLAANUM)*

- 1 - One
- 2 - Two

1st: *(HLAA11X)* *(HLAA12X)* / *(HLAA13X)* / *(HLAA14X)* /
(HLAA15X) *(HLAA16X)* / *(HLAA17X)* / *(HLAA18X)* /
2nd: *(HLAA21X)* *(HLAA22X)* / *(HLAA23X)* / *(HLAA24X)* /
(HLAA25X) *(HLAA26X)* / *(HLAA27X)* / *(HLAA28X)* /

HLA-B

Typing method:*(HLABMET)*

- 1 - DNA Technology
- 2 - Serology

Antigens/alleles provided:*(HLABNUM)*

- 1 - One
- 2 - Two

1st: *(HLAB11X)* *(HLAB12X)* / *(HLAB13X)* / *(HLAB14X)* /
(HLAB15X) *(HLAB16X)* / *(HLAB17X)* / *(HLAB18X)* /
2nd: *(HLAB21X)* *(HLAB22X)* / *(HLAB23X)* / *(HLAB24X)* /
(HLAB25X) *(HLAB26X)* / *(HLAB27X)* / *(HLAB28X)* /

HLA-C

Typing method:*(HLACMET)*

- 1 - DNA Technology
- 2 - Serology

Antigens/alleles provided:*(HLACNUM)*

- 1 - One
- 2 - Two

1st: *(HLAC11X)* *(HLAC12X)* / *(HLAC13X)* / *(HLAC14X)* /
(HLAC15X) *(HLAC16X)* / *(HLAC17X)* / *(HLAC18X)* /

2nd: *(HLAC21X)* | *(HLAC22X)* / | *(HLAC23X)* / | *(HLAC24X)* /

(HLAC25X) | *(HLAC26X)* / | *(HLAC27X)* / | *(HLAC28X)* /

HLA-DRB1

Typing method:*(HLADMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLADNUM)*

1 - One
2 - Two

1st: *(HLAD11X)* | *(HLAD12X)* / | *(HLAD13X)* / | *(HLAD14X)* /

(HLAD15X) | *(HLAD16X)* / | *(HLAD17X)* / | *(HLAD18X)* /

2nd: *(HLAD21X)* | *(HLAD22X)* / | *(HLAD23X)* / | *(HLAD24X)* /

(HLAD25X) | *(HLAD26X)* / | *(HLAD27X)* / | *(HLAD28X)* /

Comments:*(RH1COMM)*

Additional Selection Options for RH1

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

Blood and Marrow Transplant Clinical Trials Network

Regimen Intensity HLA (Page 2) (RH2)

Web Version: 1.0; 2.02; 10-16-15

Segment *(PROTSEG)*: 0
Visit Number *(VISNO)*:

HLA Typing

Type of HLA Match required by this protocol:*(HT2MATCH)*

- Loci A, B: Low Level DNA, Locus DRB1: High Level DNA
- Loci A, B: Serologic, Locus DRB1: High Level DNA
- Loci A, B: Serologic, Locus DRB1: Low Level DNA
- Loci A, B, C: Low Level DNA, Locus DRB1: High Level DNA
- Loci A, B, C: Serologic, Locus DRB1: High Level DNA
- *Additional Options Listed Below

1. Donor HLA Typing

Upload HLA-typing source documents. Be sure to remove patient identifiers prior to uploading.

HLA-A

Typing method:*(HLAAMET)*

- 1 - DNA Technology
- 2 - Serology

Antigens/alleles provided:*(HLAANUM)*

- 1 - One
- 2 - Two

1st: *(HLAA11X)* / *(HLAA12X)* / *(HLAA13X)* / *(HLAA14X)* /

(HLAA15X) / *(HLAA16X)* / *(HLAA17X)* / *(HLAA18X)* /

2nd: *(HLAA21X)* / *(HLAA22X)* / *(HLAA23X)* / *(HLAA24X)* /

(HLAA25X) / *(HLAA26X)* / *(HLAA27X)* / *(HLAA28X)* /

HLA-B

Typing method:*(HLABMET)*

- 1 - DNA Technology
- 2 - Serology

Antigens/alleles provided:*(HLABNUM)*

- 1 - One
- 2 - Two

1st: *(HLAB11X)* / *(HLAB12X)* / *(HLAB13X)* / *(HLAB14X)* /

(HLAB15X) / *(HLAB16X)* / *(HLAB17X)* / *(HLAB18X)* /

2nd: *(HLAB21X)* / *(HLAB22X)* / *(HLAB23X)* / *(HLAB24X)* /

(HLAB25X) / *(HLAB26X)* / *(HLAB27X)* / *(HLAB28X)* /

HLA-C

Typing method:*(HLACMET)*

- 1 - DNA Technology
- 2 - Serology

Antigens/alleles provided:*(HLACNUM)*

- 1 - One
- 2 - Two

1st: *(HLAC11X)* / *(HLAC12X)* / *(HLAC13X)* / *(HLAC14X)* /

(HLAC15X) / *(HLAC16X)* / *(HLAC17X)* / *(HLAC18X)* /

2nd: *(HLAC21X)* / *(HLAC22X)* / *(HLAC23X)* / *(HLAC24X)* /

(HLAC25X) (HLAC26X) / (HLAC27X) / (HLAC28X) /

HLA-DRB1

Typing method:*(HLADMET)*

1 - DNA Technology
2 - Serology

Antigens/alleles provided:*(HLADNUM)*

1 - One
2 - Two

1st: (HLAD11X) (HLAD12X) / (HLAD13X) / (HLAD14X) /

(HLAD15X) (HLAD16X) / (HLAD17X) / (HLAD18X) /

2nd: (HLAD21X) (HLAD22X) / (HLAD23X) / (HLAD24X) /

(HLAD25X) (HLAD26X) / (HLAD27X) / (HLAD28X) /

Recipient-to-Donor HLA Match Scores

Recipient-to-Donor HLA Match Score required by this protocol:*(HT2HRQD)*

Recipient-to-Donor Locus A calculated HLA Match Score*(HT2SCRA)*

Recipient-to-Donor Locus B calculated HLA Match Score*(HT2SCRB)*

Recipient-to-Donor Locus C calculated HLA Match Score*(HT2SCRC)*

Recipient-to-Donor Locus DRB1 calculated HLA Match Score*(HT2SCRD)*

Recipient-to-Donor total calculated HLA Match Score*(HT2HLA)*

Indicate your institution's HLA Match Score for Recipient-to-Donor:*(HT2SISC)*

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

Comments:*(RH2COMM)*

Additional Selection Options for RH2

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

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