Blood and Marrow Transplant
Clinical Trials Network

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

Web Version: 1.0; 3.01; 06-17-09

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

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

   If Other, specify reason for deactivation: *(AESPEC1)*

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

Comments: *(AE1COMM)*

Additional Selection Options for AE1

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

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

Web Version: 1.0; 3.00; 06-17-09

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

1. Report activation status: *(AVSTAT_A)*

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

Relevant Past Medical History

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

☐ 1- Yes ☐ 2 - No

(SEMEDHX)

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

(SESUMM)

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4. Initial submitter: *(SEISUBBY)*

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

5. Authorized submitter: *(SEASUBBY)*

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

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

Web Version: 1.0; 3.00; 06-17-09

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

1. Report activation status: *(AVSTAT_B)*

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

Study Product/Suspect Medication Data

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

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

Study Product Name (Note: If blinded, indicate as such)	Dose of Study Product(s) at SAE Onset	Route of Study Product(s) at SAE Onset	Schedule of Study Product(s) at SAE Onset
(SPNAME1)	*(SP1DOSE)*	*(SP1ROUTE)*	*(SP1SCHED)*
(SPNAME2)	*(SP2DOSE)*	*(SP2ROUTE)*	*(SP2SCHED)*
(SPNAME3)	*(SP3DOSE)*	*(SP3ROUTE)*	*(SP3SCHED)*
(SPNAME4)	*(SP4DOSE)*	*(SP4ROUTE)*	*(SP4SCHED)*
(SPNAME5)	*(SP5DOSE)*	*(SP5ROUTE)*	*(SP5SCHED)*

Concomitant Medications

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

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

Medication	Start Date *(mm/dd/yyyy)*	Stop Date *(mm/dd/yyyy)*	Dose, Route, Schedule
(CONMED1)	*(CM1STDT)*	*(CM1SPDT)*	*(CM1DOSE)*
(CONMED2)	*(CM2STDT)*	*(CM2SPDT)*	*(CM2DOSE)*
(CONMED3)	*(CM3STDT)*	*(CM3SPDT)*	*(CM3DOSE)*
(CONMED4)	*(CM4STDT)*	*(CM4SPDT)*	*(CM4DOSE)*
(CONMED5)	*(CM5STDT)*	*(CM5SPDT)*	*(CM5DOSE)*

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

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

Comments: *(AE3COMM)*

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

Web Version: 1.0; 3.00; 06-23-09

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

1. Report activation status: *(AVSTAT_C)*

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

Laboratory Test Results

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

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

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

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

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

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

Test	Date Performed *(mm/dd/yyyy)*	Results/Comments
(ADDTS1)	*(AD1DTDAT)*	*(AD1DTRES)*
(ADDTS2)	*(AD2DTDAT)*	*(AD2DTRES)*

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

Comments: *(AE4COMM)*

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

Web Version: 1.0; 3.00; 06-17-09

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

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

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

Web Version: 1.0; 4.00; 08-10-09

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

1. Adverse event status: *(AVSTAT_E)*

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

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

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

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

Comments: *(AE6COMM)*

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Demographics (DEM)

Web Version: 1.0; 5.00; 06-10-09

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

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

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

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

7. Race: *(RACE)*

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

Specify race: *(RACESP)*

8. Secondary Race: *(RACE2)*

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

Specify secondary race: *(RACE2SP)*

Comments: *(DEMCOMM1)*

Additional Selection Options for DEM

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

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0101A (ENR)

Web Version: 1.0; 6.00; 06-26-09

Fungal Prophylaxis Protocol Enrollment Form - Segment A

1. Has the patient had a prior allogeneic or autologous transplant? *(PRIORTX)* ☐ 1- Yes ☐ 2 - No
2. Record the proposed or actual date of initiation of conditioning: *(CONDTDTA)* _____ *(mm/dd/yyyy)*
3. Patient's birthdate: *(BIRTHDT)* *(mm/dd/yyyy)*

Inclusion Criteria

4. Record the donor source: *(DNRSRCA)*
   - 1-1 - Related Donor Marrow
   - 2-2 - Unrelated Donor Marrow
   - 3-3 - Related PBSC
   - 4-4 - Unrelated PBSC
   - 5-5 - Related Donor Umbilical Cord Blood
   - *Additional Options Listed Below
5. Record the patient's underlying disease: *(PRIMDZA)*
   - 1-1 - Acute Myelogenous Leukemia (AML)
   - 2-2 - Acute Lymphoblastic Leukemia (ALL)
   - 3-3 - Chronic Myelogenous Leukemia (CML)
   - 4-4 - Myelodysplastic Syndrome (MDS)
   - 5-5 - Acute Undifferentiated Leukemia (AUL)
   - *Additional Options Listed Below
6. If AML, what is the patient's disease stage? *(AMLSTG)*
   - 1-1 - 1st Complete Remission
   - 2-2 - 2nd Complete Remission
   - 3-3 - Early Relapse
   - 4-4 - Other
7. If ALL, what is the patient's disease stage? *(ALLSTG)*
   - 1-1 - 1st Complete Remission
   - 2-2 - 2nd Complete Remission
   - 3-3 - Other
8. If CML, what is the patient's disease stage? *(CMLSTG)*
   - 1-1 - Chronic Phase
   - 2-2 - Accelerated Phase
   - 3-3 - Blast Crisis
9. If MDS, what is the patient's disease stage? *(MDSSTG)*
   - 1-1 - Refractory Anemia
   - 2-2 - Refractory Anemia with Ringed Sideroblasts
   - 3-3 - Refractory Cytopenia with Multilineage Dysplasia
   - 4-4 - Refractory Cytopenia with Multilineage Dysplasia and Ringed Sideroblasts
   - 5-5 - Refractory Anemia with Excess Blasts - 1 (5-10% blasts)
   - *Additional Options Listed Below
10. If AUL, what is the patient's disease stage? *(AULSTG)*
    - 1-1 - 1st Complete Remission
    - 2-2 - 2nd Complete Remission
    - 3-3 - Other
11. If Acute Biphenotypic Leukemia, what is the patient's disease stage? *(ACBIPHST)*
    - 1-1 - 1st Complete Remission
    - 2-2 - 2nd Complete Remission
    - 3-3 - Other
12. If Lymphoma, has the disease demonstrated chemosensitivity? *(LYCMSENS)* ☐ 1- Yes ☐ 2 - No
13. Will the patient receive a myeloablative conditioning regimen? *(CNDREGMN)* ☐ 1- Yes ☐ 2 - No

14. Does the patient have symptomatic cardiac disease? *(CRDCDZ1A)* ☐ 1- Yes ☐ 2 - No

15. Record the type of fraction test performed: *(FRACTYPE)*
1-1 - Left Ventricular Ejection Fraction (LVEF)
2-2 - Shortening Fraction

16. Left Ventricular Ejection Fraction (LVEF): *(EJCTFRAC)* _____ *(xxx)* % Date ejection fraction performed: *(EJCTFRDT)* _____ *(mm/dd/yyyy)*

17. Does the LVEF improve with exercise? *(EJCTIMPR)* ☐ 1- Yes ☐ 2 - No

18. Record the shortening fraction at rest: *(SHRTFRAC)* _____ *(xxx)* % Date shortening fraction performed: *(SHRTFRDT)* _____ *(mm/dd/yyyy)*

	Most Recent Value	LLN for your Institution	ULN for your Institution	Date Sample Obtained
19. Creatinine (mg/dL):	*(SCR1A)* _____ *(x.x)*	*(SCRLLN1A)* _____ *(x.x)*	*(SCRULN1A)* _____ *(x.x)*	*(SCRDT1A)* _____ *(mm/dd/yyyy)*
20. Creatinine Clearance (mL/min):	*(SCRCLRNA)* _____ *(xxx)*	*(SCRLLN2A)* _____ *(xxx)*		*(SCRCLDTA)* _____ *(mm/dd/yyyy)*
21. ALT (Units/L):	*(ALT1A)* _____ *(xxx)*		*(ALTULN1A)* _____ *(xx)*	*(ALTDT1A)* _____ *(mm/dd/yyyy)*
22. Bilirubin (mg/dL):	*(BILIA)* _____ *(x.x)*			*(BILIDTA)* _____ *(mm/dd/yyyy)*

23. Were Pulmonary Function Tests performed? *(PFTYESNO)* ☐ 1- Yes ☐ 2 - No

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

	Most Recent Value Corrected for Hemoglobin	Date Sample Obtained
24. DLCO:	*(DLCO)* _____ *(xxx)* % of predicted value	*(DLCO1DT)* _____ *(mm/dd/yyyy)*
25. FEV1:	*(FEV1)* _____ *(xxx)* % of predicted value	*(FEV1DT)* _____ *(mm/dd/yyyy)*
26. FVC:	*(FVC)* _____ *(xxx)* % of predicted value	*(FVC1DT)* _____ *(mm/dd/yyyy)*

27. O_2 saturation on room air: *(OXYSATUR)* _____ *(xxx)* % Date O_2 saturation was obtained: *(OXYSATDT)* _____ *(mm/dd/yyyy)*

Exclusion Criteria

28. Has the patient had an invasive yeast infection within the eight weeks prior to the proposed date of initiation of conditioning? *(INFYEAST)* ☐ 1- Yes ☐ 2 - No

29. Does the patient have a history of candidemia > eight weeks prior to the proposed date of initiation of conditioning? *(INFCAND)* ☐ 1- Yes ☐ 2 - No

30. Date blood sample obtained: *(BLDCTRDT)* _____ *(mm/dd/yyyy)*

31. Results of blood culture: *(BLDCLTRA)* ☐ 1 - Positive ☐ 2 - Negative

32. Are there clinical signs of candidemia? *(CNDSIGNS)* ☐ 1- Yes ☐ 2 - No

33. Does the patient currently require anti-fungal therapy? *(FNGLRX)* ☐ 1- Yes ☐ 2 - No

34. Has the patient had a proven or probable aspergillus or other mold infection or deep mycoses (including hepatosplenic candidemia) within 4 months prior to the proposed date of initiation of conditioning? *(INFASPRA)* ☐ 1- Yes ☐ 2 - No

35. Does the patient have an uncontrolled viral or bacterial infection? *(VIBACINF)* ☐ 1- Yes ☐ 2 - No

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

37. Performance status scale used to evaluate patient (Lansky for patients <16 years old; Karnofsky for patient ≥16): *(KARNLANS)* ☐ 1 - Karnofsky ☐ 2 - Lansky

38. Record patient's performance status? *(PSA)*

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

39. Does the patient have a history of allergies or intolerance to azoles? *(ALLERGY)* ☐ 1- Yes ☐ 2 - No

40. Does the patient require therapy with rifampin, rifabutin, carbamazepine, cisapride, terfenadin, astemizole, ergot alkaloids, or long-acting barbiturates? *(MEDSA)* ☐ 1- Yes ☐ 2 - No

41. Has the patient received >3 days treatment with rifampin or carbamazepine within 7 days prior to the proposed date of the initiation of conditioning? *(MEDRXA)* ☐ 1- Yes ☐ 2 - No

42. Is the patient taking therapeutic anticoagulation with coumadin? *(COUMADIN)* ☐ 1- Yes ☐ 2 - No

43. Is the patient taking 1 mg/day of coumadin for port prophylaxis? *(PRTPROPH)* ☐ 1- Yes ☐ 2 - No

44. Is the patient currently receiving sirolimus? *(SIR0RXA)* ☐ 1- Yes ☐ 2 - No

45. Does the patient have prolonged QTc syndrome? *(QTCSYNDR)* ☐ 1- Yes ☐ 2 - No

46. Is the patient HIV positive? *(HIVPOSA)* ☐ 1- Yes ☐ 2 - No

47. Is the patient receiving an investigational drug? *(INVDRGS)*

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

48. Date confirmed by study chair/medical monitor: *(MMOKDT)* *(mm/dd/yyyy)*

49. Does the patient have active CNS disease? *(CNSDSEAS)* ☐ 1- Yes ☐ 2 - No

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

51. Does the patient have a cancer treated with curative intent ≤ 5 years previously? *(HXLT5YRS)*

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

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

HLA Typing

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

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

53. ## Recipient HLA Typing

HLA-A

Typing method: *(RHLAAMET)*

1-1 - DNA Technology
2-2 - Serology

Antigens/alleles provided: *(RHLAANUM)*

1-1 - One
2-2 - Two

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

(RHLAA25X) *(RHLAA26X)* / *(RHLAA27X)* / *(RHLAA28X)* /

HLA-B

Typing method: *(RHLABMET)*

1-1 - DNA Technology
2-2 - Serology

Antigens/alleles provided: *(RHLABNUM)*

1-1 - One
2-2 - Two

1st: *(RHLAB11X)* *(RHLAB12X)* / *(RHLAB13X)* / *(RHLAB14X)* /

(RHLAB15X) *(RHLAB16X)* / *(RHLAB17X)* / *(RHLAB18X)* /

2nd: *(RHLAB21X)* *(RHLAB22X)* / *(RHLAB23X)* / *(RHLAB24X)* /

(RHLAB25X) *(RHLAB26X)* / *(RHLAB27X)* / *(RHLAB28X)* /

HLA-DRB1

Typing method: *(RHLADMET)*

1-1 - DNA Technology
2-2 - Serology

Antigens/alleles provided: *(RHLADNUM)*

1-1 - One
2-2 - Two

1st: *(RHLAD11X)* *(RHLAD12X)* / *(RHLAD13X)* / *(RHLAD14X)* /

(RHLAD15X) *(RHLAD16X)* / *(RHLAD17X)* / *(RHLAD18X)* /

2nd: *(RHLAD21X)* *(RHLAD22X)* / *(RHLAD23X)* / *(RHLAD24X)* /

(RHLAD25X) *(RHLAD26X)* / *(RHLAD27X)* / *(RHLAD28X)* /

54. ## Donor HLA Typing

HLA-A

Typing method: *(DHLAAMET)*

1-1 - DNA Technology
2-2 - Serology

Antigens/alleles provided: *(DHLAANUM)*

1-1 - One
2-2 - Two

1st: *(DHLAA11X)* *(DHLAA12X)* / *(DHLAA13X)* / *(DHLAA14X)* /

(DHLAA15X) *(DHLAA16X)* / *(DHLAA17X)* / *(DHLAA18X)* /

2nd: *(DHLAA21X)* *(DHLAA22X)* / *(DHLAA23X)* / *(DHLAA24X)* /

(DHLAA25X) *(DHLAA26X)* / *(DHLAA27X)* / *(DHLAA28X)* /

HLA-B

Typing method: *(DHLABMET)*

1-1 - DNA Technology
2-2 - Serology

Antigens/alleles provided: *(DHLABNUM)*

1-1 - One
2-2 - Two

1st: *(DHLAB11X)* *(DHLAB12X)* / *(DHLAB13X)* / *(DHLAB14X)* /

(DHLAB15X) *(DHLAB16X)* / *(DHLAB17X)* / *(DHLAB18X)* /

2nd: *(DHLAB21X)* *(DHLAB22X)* / *(DHLAB23X)* / *(DHLAB24X)* /

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

HLA-DRB1

Typing method: *(DHLADMET)*

1-1 - DNA Technology
2-2 - Serology

Antigens/alleles provided: *(DHLADNUM)*

1-1 - One
2-2 - Two

1st:	*(DHLAD11X)*		*(DHLAD12X)* /		*(DHLAD13X)* /		*(DHLAD14X)* /	
	(DHLAD15X)		*(DHLAD16X)* /		*(DHLAD17X)* /		*(DHLAD18X)* /	
2nd:	*(DHLAD21X)*		*(DHLAD22X)* /		*(DHLAD23X)* /		*(DHLAD24X)* /	
	(DHLAD25X)		*(DHLAD26X)* /		*(DHLAD27X)* /		*(DHLAD28X)* /	

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

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

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

Total calculated HLA Match Score *(HLASCORE)*

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

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

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

Comments *(COMMENTS)*

Additional Selection Options for ENR

Record the donor source:
6-6 - Unrelated Donor Umbillical Cord Blood

Record the patient's underlying disease:
6-6 - Acute Biphenotypic Leukemia
7-7 - Lymphoma

If MDS, what is the patient's disease stage?
6-6 - Refractory Anemia with Excess Blasts - 2 (10-20% blasts)
7-7 - Myelodysplastic Syndrome, Unclassified
8-8 - MDS Associated with Isolated Del(5q)

Record patient's performance status?
06-06 - 50 (Requires Considerable Assistance/No Active Play)
07-07 - 40 (Disabled/Able to Initiate Quiet Activities)
08-08 - 30 (Severely Disabled/Needs Assistance for Quiet Play)
09-09 - 20 (Very Sick/Limited to Very Passive Activity)
10-10 - 10 (Moribund; Completely Disabled)
99-99 - Karnofsky <70% or Lansky <50% with Approval by Study Chair/MM

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

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

Blood and Marrow Transplant
Clinical Trials Network

Termination Form (TRM)

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

Segment *(PROTSEG)*:

1. Date of termination: *(TRMDATE)* *(mm/dd/yyyy)*

2. Record reason for termination: *(TRMRSN1)*

01-01 - Death
02-02 - Fungal Infection
03-03 - Uncontrolled Infection (Other than Fungal Infection)
04-04 - Disease Stage
05-05 - Ineligible ALT Value
*Additional Options Listed Below

If Death, a Death form must be submitted.

Specify other termination reason: *(TRMSPEC1)*

Comments: *(TRMCOMM)*

Additional Selection Options for TRM

Record reason for termination:
06-06 - Inadequate Organ Function
07-07 - Patient Became Pregnant
08-08 - Patient Refused/Withdrew Consent
09-09 - Other, Specify