

# Cord Blood Transplantation Study (COBLT)

## Transplants Data

Study Case Report Forms  
Annotated with Variable Names  
Per Final Study SAS Data Files



4. Record CBU typing (continued)

HLA-DRB1

**DTYPMETH**

**DAPROVID**

Typing Method: 1  Serology 2  DNA Technology

Antigens/alleles provided: 1  One 2  Two

1st: 1       /2       /3       /4

**D1STRING** 5       /6       /7       /8

2nd: 1       /2       /3       /4

**D2STRING** 5       /6       /7       /8

5. Has Confirmatory HLA Typing Report-Recipient from the COBLT HLA Typing Lab been received? 1  Yes 2  No **CONF SUB**

6. Record proposed starting date for conditioning therapy: **CONDTHDT**        
M D Y

Patient Status

7. Date of birth: **BIRTHDT**        
M D Y

8. Sex 1  Male  
**SEX** 2  Female

9. Is the patient pregnant or breastfeeding? **PREGBRST** 1  Yes 2  No

10. Has the patient had a previous allogeneic stem cell transplant with cytoablative preparative therapy?

**PREVALLO**  
1  Yes  
2  No

11. Date of allogeneic stem cell transplant: **ALLODATE**        
M D Y

12. Has the patient had a previous autologous stem cell transplant?

**PREVAUTO**  
1  Yes  
2  No

13. Date of autologous stem cell transplant: **AUTODATE**        
M D Y

14. Does the patient have a consenting, 5 of 6 or 6 of 6 HLA-matched related donor? **RELDONOR** 1  Yes 2  No

15. Date Informed Consent Form signed: **CONSENT**        
M D Y

Patient Clinical Status

16. Does the primary disease include active CNS leukemia involvement at the time of enrollment?

**ACTIVCNS**  
1  Yes  
2  No

17. Does the cerebrospinal fluid contain > 5 WBC/ $\mu$ L? **FLUIDWBC** 1  Yes 2  No

18. Have malignant cells been found as a result of cytopsin? **MALCYTOS** 1  Yes 2  No

19. What is the patient's Karnofsky (Lansky for patients < 16 years old) performance status? **PS**    %

20. Does the patient have an uncontrolled viral, bacterial, or fungal infection at the time of enrollment? **INFECT** 1  Yes 2  No

21. Is the patient HIV seropositive? **HIVPOS** 1  Yes 2  No

22. Does the patient have myelofibrosis?

**MYELOF**

- 1  Yes  
2  No



23. Record grade of myelofibrosis: **MYELOFGD**

24. Does the patient have primary myelofibrosis? **MYELOFP** 1  Yes 2  No

25. Has the patient been diagnosed with dyskeratosis congenita? **DISKCONG** 1  Yes 2  No

26. Does the patient have symptomatic cardiac disease?

**CARDIAC**

- 1  Yes  
2  No



27. a. Record the left ventricular ejection fraction at rest: **EJFRACT**    %

OR

b. Record the shortening fraction at rest: **SNFR REST**    %

28. Does left ventricular ejection fraction improve with exercise? **IMPROVE** 1  Yes 2  No 3  N/A

29. Does the patient have any pulmonary disease symptoms?

**PULMON**

- 1  Yes  
2  No



30. a. Record DLCO, FEV1 or FEC (Diffusion capacity): **DLCO**    %  
of predicted (corrected for hemoglobin)

OR

b. Record O<sub>2</sub> saturation on room air: **OXYGSAT**    %

31. Provide the most recent values for the following tests:

Serum Creatinine **CR**     mg/dL **ULN for your institution** **CRULN**     mg/dL **LLN for your institution** **CRLLN**     mg/dL

SGOT **SGOT**    Units/L **ULN** **SGOTULN**    Units/L

Total Serum Bilirubin **BILI**     mg/dL

32. Is the serum creatinine level greater than the institution's ULN?

**CRNORM**

- 1  Yes  
2  No



33. Record creatinine clearance **CRCLR**    mL/min/1.73m<sup>2</sup> **LLN for your institution** **CRCLRLLN**    mL/min/1.73m<sup>2</sup>

34. Record GFR **GFR**     mL/min **GFRLLN**     mL/min

Continue with Question #35

Continue with Question #35

35. What is the patient's primary disease?

- DISPRIM**  
 1  Acute Myelogenous Leukemia (with or without history of MDS)

36. Is the patient in first complete remission ( $\leq$  5% blasts in marrow) with translocations t(8;21) and inv (16)? **AMLCRT8**  
 1  Yes  $\rightarrow$  2  No

37. Has the patient failed first line induction therapy? **AMLFIT8**  
 1  Yes 2  No

38. Is the patient in first complete remission ( $\leq$  5% blasts in marrow) with translocation t(15;17)? **AMLCRT15**  
 1  Yes  $\rightarrow$  2  No

39. Has the patient failed first line induction therapy? **AMLFIT15**  
 1  Yes 2  No

40. Does the patient have molecular evidence of persistent disease? **AMLMOLEC**  
 1  Yes 2  No

41. Is the patient in first complete remission with Down Syndrome? **AMLDOWN**  
 1  Yes 2  No

42. Is the patient in  $\geq$  3 medullary relapse? **ALLMEDUR**  
 1  Yes 2  No

43. Does the patient have refractory disease (other than primary induction failure)? **ALLREDIS**  
 1  Yes 2  No

Skip to Question #85 on Page 7

- 2  Acute Lymphoblastic Leukemia

44. Is the patient in first complete remission ( $\leq$  5% blasts in marrow)? **ALLCR**  
 1  Yes  $\rightarrow$  2  No

45. Does the patient have hypoploidy as measured by flow cytometry? **HYPO**  
 1  Yes 2  No

46. Does the patient have pseudodiploidy with translocations t(9;22), 11q23, or t(8;14) or +MLL gene rearrangement? **PSEUDO**  
 1  Yes 2  No

47. Record the WBC at presentation: **WBC**  / $\mu$ L

48. Did the patient achieve a complete remission after 4 weeks of induction therapy? **ALLINDUCT**  
 1  Yes 2  No

49. Has the patient been diagnosed with B-ALL? **BALL**  
 1  Yes  $\rightarrow$  2  No

50. Does the patient have translocation t(8;14)? **BALLTRAN**  
 1  Yes 2  No

51. Do blasts have surface immunoglobulins? **BALLBLAS**  
 1  Yes 2  No

52. Is the patient CD10+? **BALLCD10**  
 1  Yes 2  No

53. Is the patient in  $\geq$  3 medullary relapse? **ALLMEDUR**  
 1  Yes 2  No

54. Does the patient have refractory disease (other than primary induction failure)? **ALLREDIS**  
 1  Yes 2  No

Skip to Question #85 on Page 7

**DISPRIM (contd)**

3  Chronic Myelogenous Leukemia

**CML DATE**

M D Y

55. Record date of diagnosis: .....

56. Record the phase of CML:  
 1  Chronic → 57. Does the patient have an adequately matched unrelated bone marrow donor identified? **CMLMATCH** 1  Yes 2  No  
 2  Accelerated  
 3  Blast crisis 58. Has the patient been unresponsive to interferon? ..... **CMLUNRES** 1  Yes 2  No  
 ↓  
 59. Is the patient unable to tolerate interferon? ..... **CMLUNTDL** 1  Yes 2  No

*Skip to Question #85 on Page 7*

**CMLPHASE**

4  Undifferentiated Leukemia  
 5  Bi-phenotypic Leukemia

60. Is the patient in ≥ 3 medullary relapse? ..... **UNLMEDUR** 1  Yes 2  No

61. Does the patient have refractory disease (other than primary induction failure)? ..... **UNLREDIS** 1  Yes 2  No

*Skip to Question #85 on Page 7*

6  Juvenile Myelomonocytic Leukemia

62. Is the Philadelphia chromosome present? ..... **JMLPHILA** 1  Yes 2  No

63. Record % marrow blasts: ..... **JMLMARBL** \_\_\_\_\_ %

64. Record peripheral blood monocytes: ..... **JMLMONOC** \_\_\_\_\_ /μL

65. Is there spontaneous growth of peripheral blood and/or GM-CSF hypersensitivity? ..... **JMLSPONT** 1  Yes 2  No

66. Does the patient have an increased hemoglobin F for his/her age? ..... **JMLINCHG** 1  Yes 2  No

67. Does the patient have clonal abnormalities present? ..... **JMLCLOAB** 1  Yes 2  No

68. Are myeloid precursors present in the peripheral blood? ..... **JMLMYPRE** 1  Yes 2  No

69. Record the WBC count at diagnosis: ..... **JMLWBC** \_\_\_\_\_ /μL

*Skip to Question #85 on Page 7*

**DISPRM (contd)**

7  Myelo-dysplastic Syndrome

70. Indicate the patient's disease using the disease definitions in the COBLT Protocol:

1  Refractory Anemia **MDSDIS**

2  Refractory Anemia with Ringed Sideroblasts

3  Refractory Anemia with Excess Blasts

4  Refractory Anemia with Excess Blasts in Transformation

5  Chronic Myelomonocytic Leukemia

6  Paroxysmal Nocturnal Hemoglobinuria (PNH)

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8  Hodgkins Disease

9  Non-Lymphoblastic Non-Hodgkins Lymphomas

10  Lymphoblastic Non-Hodgkins Lymphomas

71. Is the patient in first complete remission? **HODCR** 1  Yes 2  No

72. Was the patient a primary induction failure? **HODINDCT** 1  Yes 2  No

73. Have tumors demonstrated chemosensitivity (defined as > 50% reduction in mass size) after most recent therapy? **HODTUMOR** 1  Yes 2  No

74. Does the patient have a history of bone marrow involvement? **HODBMINV** 1  Yes 2  No

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11  Acquired Severe Aplastic Anemia

75. Record granulocyte count: **ASAGRAN**    cells/ $\mu$ L

76. Record platelet count: **ASA PLATE**     $\times 10^3/\mu$ L

77. Record absolute reticulocyte count (after correction for hematocrit): **ASARETIC**     $\times 10^3/\mu$ L

78. Is the patient unresponsive to medical therapy with anti-thymocyte globulin and/or cyclosporine? **ASA UNRES** 1  Yes 2  No

Skip to Question #85 on Page 7

12  Hurler's Syndrome

13  Adrenoleukodystrophy

14  Maroteaux-Lamy Syndrome

15  Globoid Cell Leukodystrophy

16  Metachromatic Leukodystrophy

17  Fucosidosis

18  Mannosidosis

19  Other Metabolic Disorder, Specify \_\_\_\_\_

**METIQ**

79a. If GREATER THAN 5 years of age, record the patient's IQ:

b. If LESS THAN or EQUAL to 5 years of age **METDEVEL** Does the patient's developmental quotient or clinical neurodevelopmental exam demonstrate potential for stabilization at a level of functioning where continuous life support would not be predicted to be required in the year following transplantation? 1  Yes 2  No

Skip to Question #85 on Page 7

20  Fanconi Anemia

80. Have increased chromosomal fragility assays to mitomycin C and DEB been documented? **FANCHRFR** 1  Yes 2  No

81. Indicate if the patient has been diagnosed with any of the following:

a. Severe pancytopenia **RANCYPOP** 1  Yes 2  No

b. Myelodysplastic syndrome with morphological evidence **MYELSYND** 1  Yes 2  No

c. Leukemic transformation **LEUKTRAN** 1  Yes 2  No

Skip to Question #85 on Page 7

**DISPRIM (contd)**

- 21  Severe Combined Immunodeficiency (SCID)
- 22  Wiskott-Aldrich Syndrome
- 23  Leukocyte Adhesion Defect (LAD)
- 24  Chediak-Higashi Disease
- 25  X-Linked Lymphoproliferative Disease
- 26  Adenosine Deaminase (ADA) Deficiency
- 27  Purine Nucleoside Phosphorylase (PNP) Deficiency
- 28  X-Linked SCID
- 29  Common Variable Immune Deficiency (VID)
- 30  Nezeloff's Syndrome
- 31  Cartilage Hair Hypoplasia
- 32  Other Combined Immune Deficiency, Specify: \_\_\_\_\_

**SCIDCYTO**

82. Does the patient require cyto reduction? 1  Yes 2  No

*Skip to Question #85 below*

- 33  Familial Erythrophagocytic Lymphohistiocytosis (FEL)

83. Is the cerebrospinal fluid currently positive for disease as defined by abnormal brain MRI or neurologic symptoms or >7/mm<sup>3</sup> lymphocytes plus monocytes? **FELCERE** 1  Yes 2  No

*Skip to Question #85 below*

- 34  Langerhans Cell Histiocytosis
- 35  Blackfan-Diamond (Congenital Pure Red Cell Aplasia)
- 36  Kostmann's Congenital Agranulocytosis
- 37  Congenital Amegakaryocytic Thrombocytopenia
- 38  Infantile Osteopetrosis
- 39  Thalassemia, specify: \_\_\_\_\_
- 40  Sickle Cell Disease
- 99  Other, specify: \_\_\_\_\_

84. Is disease unresponsive to medical therapy? **DISUNRES** 1  Yes 2  No

*Skip to Question #85 below*

85. Indicate COBLT strata for this recipient: **STRATUM**

- 1  Malignant disease, 5/6 or 6/6 HLA match, ≤ 18 years of age
- 2  Malignant disease, 4/6 HLA match, ≤ 18 years of age
- 3  Malignant disease, 3/6 HLA match, ≤ 18 years of age
- 5  Severe aplastic anemia, Fanconi anemia and other marrow failure syndromes
- 6  Inborn errors of metabolism/storage diseases and other non-malignant diseases
- 7  Malignant disease alternative conditioning regimen (busulfan/busulfex and melphalan)
- 8  Adult patients (> 18 years of age)
- 9  Expanded Access Protocol







6. Were cells from the waste-bag supernatant recovered and infused? <sup>N</sup> **RECIPUS** 1  Yes 2  No → go to Question 9

7. Were recovered cells added to the Transplant Bag for infusion? **RECADDED**  
 1  Yes → Report final volume infused, cell viability, and cell count from Transplant Bag for Question 8.  
 2  No → Report volume infused, cell viability, and cell count from second bag for Question 8.

8. Record infusion data for recovered cells.

Volume infused .  ml **VOLRECOV**

Cell viability  % **VIARECOV** Automated nucleated cell count .  X10<sup>6</sup>/ml **NCCRECOV**

*Continue with Question 9*

9. Calculate final infused viable cell recovery.

Total viable nucleated cell count .  x 10<sup>6</sup> **NCCFINAL**

Viable cell recovery .  % **VIAFINAL**

10. Recipient's actual body weight on day of transplant **BODYWGT** .  kg

11. Were there performance issues with the cryo bag or cell wash/infusion bag set? ... 1  Yes 2  No → go to Question 12  
**PERFISS**

Specify problem(s):

12. Thawing procedure performed by ..... a. Study ID  **THAWER1** b. Study ID  **THAWER2**

13. Results of sterility assay **RESSTER** ..... 1  Negative 2  Positive 3  Not performed 4  Pending  
Specify, if positive: \_\_\_\_\_

Comments: \_\_\_\_\_

**FAX COMPLETED FORM TO THE COBLT DATA COORDINATOR  
AT THE MEDICAL COORDINATING CENTER  
301-251-1355**

**SEND A COPY OF THE COMPLETED FORM TO THE  
COBLT TRANSPLANT COORDINATOR  
AT YOUR CENTER**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Study ID

MCC Use Only  
Date Recd.:

COBLT Recipient ID:

ID

COBLT Name Code:

Center Code:

TCCODE

1. Date of infusion

INFDATE

2. Time of infusion Start:

:  hr/min [24hr]

INFTMBEG

Finish: :  hr/min [24hr]

INFTMEND

3. Were pre-infusion medications administered within 2 hours of infusion?

PREINFUS

1  Yes →

2  No

↓  
Continue with question 5

4. Record Medication:

PREBENAD Benadryl 1  Yes 2  No  
 PREHYDRO Hydrocortisone 1  Yes 2  No  
 PREMETH Methylprednisolone 1  Yes 2  No  
 PREMANN Mannitol 1  Yes 2  No  
 PREOTNER Other, specify \_\_\_\_\_ 1  Yes 2  No

5. Were emergency medications administered during or within 2 hours of infusion?

EMERGENC

1  Yes →

2  No

↓  
Continue with question 7

6. Record Medication:

EMEBENAD Benadryl 1  Yes 2  No  
 EMEHYDRO Hydrocortisone 1  Yes 2  No  
 EMEMETH Methylprednisolone 1  Yes 2  No  
 EMEMANN Mannitol 1  Yes 2  No  
 EMEOTNER Other, specify \_\_\_\_\_ 1  Yes 2  No

7. Record highest grade of complication/toxicity within 24 hours of infusion.

Toxicity	Grade				
	0	1	2	3	4
Allergy reaction/ hypersensitivity (including drug fever)  <b>ALLERGY</b>	<input type="checkbox"/> none	<input type="checkbox"/> transient rash, drug fever <38 °C (<100.4 °F)	<input type="checkbox"/> urticaria, drug fever 38 °C (100.4°) and/or asymptomatic brochospasm	<input type="checkbox"/> systematic brochospasm, requiring parenteral medication(s), with or without urticaria; allergy-related edema/angioedema	<input type="checkbox"/> anaphylaxis
Sinus bradycardia  <b>SINUSBRA</b>	<input type="checkbox"/> none	<input type="checkbox"/> asymptomatic, not requiring treatment	<input type="checkbox"/> symptomatic, but not requiring treatment	<input type="checkbox"/> symptomatic and requiring treatment	<input type="checkbox"/> life-threatening (e.g. arrhythmia associated with CHF, hypotension syncope, shock)
Sinus tachycardia  <b>SINUSTAC</b>	<input type="checkbox"/> none	<input type="checkbox"/> asymptomatic, not requiring treatment	<input type="checkbox"/> symptomatic, but not requiring treatment	<input type="checkbox"/> symptomatic and requiring treatment of underlying cause	
Hypertension  <b>HYPERTEN</b>	<input type="checkbox"/> none	<input type="checkbox"/> asymptomatic, transient increase by >20 mmHg (diastolic) or to >150/100* if previously WNL; not requiring treatment	<input type="checkbox"/> recurrent or persistent symptomatic increase by >20 mmHg(diastolic) or to >150/100* if previously WNL; not requiring treatment	<input type="checkbox"/> requiring therapy or more intensive therapy than previously	<input type="checkbox"/> hypertensive crisis

\*Note: For pediatric patients, use age and sex appropriate normal values > 95th percentile ULN.

Toxicity	Grade				
	0	1	2	3	4
<b>Hypotension</b> <b>HYPOTEN</b>	<input type="checkbox"/> none	<input type="checkbox"/> changes, but not requiring therapy (including transient orthostatic hypotension)	<input type="checkbox"/> requiring brief fluid replacement or other therapy but not hospitalization; no physiologic consequences	<input type="checkbox"/> requiring therapy and sustained medical attention, but resolves without persisting physiologic consequences	<input type="checkbox"/> shock (associated with acidemia and impairing vital organ function due to tissue hypoperfusion)
<i>For pediatric patients, systolic BP 65mmHg or less in infants up to 1 year old and 70 mmHg or less in children older than 1 year of age, use two successive or three measurements in 24 hours</i>					
<b>Fever (in the absence of neutropenia, where neutropenia is defined as ANC &lt; 1.0 x 10<sup>9</sup>/L)</b> <b>FEVER</b>	<input type="checkbox"/> none	<input type="checkbox"/> 38.0 - 39.0 °C (100.4 - 102.2 °F)	<input type="checkbox"/> 39.1 - 40.0 °C (102.3 - 104.0 °F)	<input type="checkbox"/> >40.0 °C (>104.0 °F) for <24hrs	<input type="checkbox"/> >40.0 °C (>104.0 °F) for >24hrs
<i>Note: The temperature measurements listed above are oral or tympanic</i>					
<b>Rigors, chills</b> <b>RIGCHILL</b>	<input type="checkbox"/> none	<input type="checkbox"/> mild, requiring symptomatic treatment (e.g., blanket) or non-narcotic medication	<input type="checkbox"/> severe and/or prolonged, requiring narcotic medication	<input type="checkbox"/> not responsive to narcotic medication	-
<b>Nausea</b> <b>NAUSEA</b>	<input type="checkbox"/> none	<input type="checkbox"/> not able to eat	<input type="checkbox"/> oral intake significantly decreases	<input type="checkbox"/> no significant intake, requiring IV fluids	-
<b>Vomiting</b> <b>VOMITING</b>	<input type="checkbox"/> none	<input type="checkbox"/> 1 episode in 24 hours over pre-treatment	<input type="checkbox"/> 2-5 episodes in 24 hours over pre-treatment	<input type="checkbox"/> >6 episodes in 24 hours over pre-treatment; or need for IV fluids	<input type="checkbox"/> Requiring parenteral nutrition; or physiologic consequences requiring intensive care; hemodynamic collapse
<b>Infection with unknown ANC</b> <b>UNKANC</b>	<input type="checkbox"/> none	-	-	<input type="checkbox"/> Present	<input type="checkbox"/> life-threatening sepsis (e.g., septic shock)
<i>Note: This toxicity criterion is used in the rare case when ANC is unknown</i>					
<b>Dyspnea (shortness of breath)</b> <b>DYSPNEA</b>	<input type="checkbox"/> normal	-	<input type="checkbox"/> dyspnea on exertion	<input type="checkbox"/> dyspnea at normal level or activity	<input type="checkbox"/> dyspnea at rest or requiring ventilator support
<b>Hypoxia</b> <b>HYPOXIA</b>	<input type="checkbox"/> normal	-	<input type="checkbox"/> decreased O <sub>2</sub> saturation with exercise	<input type="checkbox"/> decreased O <sub>2</sub> saturation at rest, requiring supplemental oxygen	<input type="checkbox"/> decreased O <sub>2</sub> saturation, requiring pressure support (CPAP) or assisted ventilation
<b>Hemoglobinuria</b>	<input type="checkbox"/> none	<input type="checkbox"/> present	<b>HEMOGLOB</b>	-	-

Comments: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Study ID



ACUTE GVHD WEEKLY ASSESSMENT FORM

MCC Use Only
Date Recd::

COBLT Recipient ID: ID [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]
COBLT Name Code: [ ] [ ] [ ]
Center Code: TCCODE [ ] [ ] [ ]
Assessment Number: ASSNUM [ ] [ ]

1. Date of staging ..... STAGEDT [ ] [ ] [ ] [ ] [ ] [ ]
M D Y

2. Record immunosuppressant received: IMMUNREC
1 [ ] Cyclosporine 2 [ ] Tacrolimus 3 [ ] Not given during assessment period

3. Record trough level and date. CSALVL [ ] [ ] [ ] [ ] [ ] ng/mL [ ] [ ] [ ] [ ] [ ] [ ]
M D Y

4. Record the highest level of organ abnormalities during the assessment period:
Skin 1 [ ] No rash 2 [ ] Maculopapular rash < 25% of body surface 3 [ ] Maculopapular rash, 25-50% of body surface 4 [ ] Generalized erythroderma 5 [ ] Generalized erythroderma with bullous formation and desquamation
ORGABSKN CSALVLDT

Intestinal tract (use mL/day for adult patients and mL/m² for pediatric patients)

ORGABIT 0 [ ] No diarrhea 1 [ ] Diarrhea ≤ 500 mL/day or < 280 mL/m² 2 [ ] Diarrhea > 500 but ≤ 1000 mL/day or 280-555 mL/m² 3 [ ] Diarrhea > 1000 but ≤ 1500 mL/day or 556-833 mL/m² 4 [ ] Diarrhea > 1500 mL/day or > 833 mL/m² 5 [ ] Severe abdominal pain with or without ileus, or stool with frank blood or melena

ORGABLVR Liver 1 [ ] Bilirubin < 2.0 mg/dl 2 [ ] Bilirubin 2.0-3.0 mg/dl 3 [ ] Bilirubin 3.1-6.0 mg/dl 4 [ ] Bilirubin 6.1-15.0 mg/dl 5 [ ] Bilirubin > 15.0 mg/dl

ORGABUGI Upper GI 1 [ ] No protracted nausea and vomiting 2 [ ] Persistent nausea, vomiting or anorexia

5. Within this assessment period, or within the subsequent 7-day period, what etiologies contributed to above symptoms? ETIOSKN Skin 0 [ ] No symptoms 1 [ ] GVHD 2 [ ] Drug Reaction 3 [ ] Cond. Regimen Toxicity 4 [ ] TPN 5 [ ] Infection 9 [ ] Other, specify:
ETIOIT Intestinal Tract (upper or lower) 0 [ ] No symptoms 1 [ ] GVHD 2 [ ] Drug Reaction 3 [ ] Cond. Regimen Toxicity 4 [ ] TPN 5 [ ] Infection 9 [ ] Other, specify:
ETIOLVR Liver 0 [ ] No symptoms 1 [ ] GVHD 2 [ ] Drug Reaction 3 [ ] Cond. Regimen Toxicity 4 [ ] TPN 5 [ ] Infection 6 [ ] VOD 9 [ ] Other, specify:

6. Record biopsy results pertaining to GVHD for this assessment period:
BIOPSKN Skin 1 [ ] Positive 2 [ ] Negative 3 [ ] Equivocal 4 [ ] Not Done
BIOPIT Intestinal Tract (upper or lower) 1 [ ] Positive 2 [ ] Negative 3 [ ] Equivocal 4 [ ] Not Done
BIOPLVR Liver 1 [ ] Positive 2 [ ] Negative 3 [ ] Equivocal 4 [ ] Not Done

7. Was primary or secondary treatment for GVHD initiated? RXINIT [ ] [ ] [ ] [ ] [ ] [ ] 1 [ ] Yes 2 [ ] No
If 1-Yes, specify treatment: \_\_\_\_\_

Comments: \_\_\_\_\_

Signature

Date

Study ID

[ ] [ ] [ ] [ ] [ ] [ ]

MCC Use Only  
Date Recd.:

COBLT Recipient ID: **ID**

COBLT Name Code:

Center Code: **TTCODE**

Assessment Period: 1  Day 28 Post-CBT 2  Day 42 Post-CBT **ASSESSPD**

1. Date of evaluation ..... **EVALDT** .....     
M D Y

2. Record the highest grade of toxicity diagnosed by the day of evaluation. Use the grading scale on the back of page 2 to determine the grade.

	<u>Grade 0</u>	<u>Grade I</u>	<u>Grade II</u>	<u>Grade III</u>	<u>Grade IV</u>
<b>TG CARD</b> Cardiac	0 <input type="checkbox"/> No EKG abnormality	1 <input type="checkbox"/> Mild EKG abnormality	2 <input type="checkbox"/> Moderate EKG abnormality	3 <input type="checkbox"/> Severe EKG abnormality	4 <input type="checkbox"/> Fatal toxicity
<b>TG BLAD</b> Bladder	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Macro. hem. 2d. from last chemo	2 <input type="checkbox"/> Macro. hem. 7d. after last chemo	3 <input type="checkbox"/> Hem. cystitis with frank blood	4 <input type="checkbox"/> Fatal toxicity
<b>TG RENAL</b> Renal	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Creat. increase up to 2 x baseline	2 <input type="checkbox"/> Creat. above 2 x baseline	3 <input type="checkbox"/> Dialysis required	4 <input type="checkbox"/> Fatal toxicity
<b>TG PULM</b> Pulmonary	0 <input type="checkbox"/> None	1 <input type="checkbox"/> See scale	2 <input type="checkbox"/> See scale	3 <input type="checkbox"/> See scale	4 <input type="checkbox"/> Fatal toxicity
<b>TG HEPT</b> Hepatic	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Mild hep. dysfunction	2 <input type="checkbox"/> Mod. hep. dysfunction	3 <input type="checkbox"/> Severe hep. dysfunction	4 <input type="checkbox"/> Fatal toxicity
<b>TG CNS</b> CNS	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Somnolence + arousable	2 <input type="checkbox"/> Somnolence + confusion	3 <input type="checkbox"/> Seizures or coma	4 <input type="checkbox"/> Fatal toxicity
<b>TG STDM</b> Stomatitis	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Pain and/or ulceration, no IV narc. drug	2 <input type="checkbox"/> Pain and/or ulceration with IV narc. drug	3 <input type="checkbox"/> Severe ulcer. and/or mucositis - see scale	4 <input type="checkbox"/> Fatal toxicity
<b>TG GITX</b> GI Toxicity	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Watery stools >500 mL but ≤2,000 mL every d.	2 <input type="checkbox"/> Watery stools >2,000 mL every d.	3 <input type="checkbox"/> Ileus require nasogastric suction	4 <input type="checkbox"/> Fatal toxicity

3. Did the patient have an allergic reaction?  
0  None 1  Bronchospasm, no parenteral therapy needed 2  Anaphylaxis  
**ALLGRCT**

4. Did the patient have persistent nausea and vomiting?  
0  None 1  Nausea 2  Transient vomiting  
**NAUSEA** 3  Vomiting requiring therapy 4  Intractable vomiting

**If assessment period #1 (Day 28), continue with question 5; otherwise, sign and submit form.**

CASSMETH

5. Record cyclosporine or tacrolimus assay method: 1  TDX 2  HPLC 3  Other, specify: \_\_\_\_\_

6. Was patient treated for hyperacute GVHD ("cytokine storm")?

CYT STORM

1  Yes →

2  No



7. Date symptoms first appeared ... CYTDATE ...     
M D Y

8. Record maximum fever ... CYT. ...  •  °F

9. Was erythoderma present? ... CYTERYTH ... 1  Yes 2  No

10. Record total dose of Solumedrol given ... CYTSOLUM ...

11. Was other treatment given? 1  Yes, specify: CYTOTHER \_\_\_\_\_  
2  No

Comments: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Study ID



## TOXICITY GRADING SCALE

	<u>GRADE I</u>	<u>GRADE II</u>	<u>GRADE III</u>
Cardiac toxicity	Mild EKG abnormality, not requiring medical intervention; or noted heart enlargement on CXR with no clinical symptoms	Moderate EKG abnormalities requiring and responding to medical intervention; or requiring continuous monitoring without treatment; or congestive heart failure responsive to digitals or diuretics	Severe EKG abnormalities with no or only partial response to medical intervention; or heart failure with no or only minor response to medical intervention; or decrease in voltage by more than 50%
Bladder toxicity	Macroscopic hematuria after 2 d from last chemotherapy dose with no subjective symptoms of cystitis and not caused by infection	Macroscopic hematuria after 7 d from last chemotherapy dose not caused by infection; or hematuria after 2 d with subjective symptoms of cystitis not caused by infection	Hemorrhagic cystitis with frank blood, necessitating invasive local intervention with installation of sclerosing agents, nephrostomy or other surgical procedure
Renal toxicity	Increase in creatinine up to twice the baseline value (usually the last recorded before start of conditioning)	Increase in creatinine above twice baseline but not requiring dialysis	Requirement of dialysis
Pulmonary toxicity	Dyspnea without CXR changes not caused by infection or congestive heart failure; or CXR showing isolated infiltrate or mild interstitial changes without symptoms not caused by infection or congestive heart failure	CXR with extensive localized infiltrate or moderate interstitial changes combined with dyspnea and not caused by infection or CHF, or decrease of PO <sub>2</sub> (> 10% from baseline) but not requiring mechanical ventilation or > 50% O <sub>2</sub> on mask and not caused by infection or CHF	Interstitial changes requiring mechanical ventilatory support or > 50% oxygen on mask and not caused by infection or CHF
Hepatic toxicity	Mild hepatic dysfunction with 2.0 mg% ≤ bilirubin ≤ 6.0 mg%; or weight gain > 2.5% and < 5% from baseline, of noncardiac origin; or SGOT increase more than 2-fold but less than 5-fold from lowest pre-conditioning	Moderate hepatic dysfunction bilirubin > 6 mg% < 20 mg%, or SGOT increase > 5-fold from pre-conditioning; or clinical ascites or image documented ascites > 100mL; or weight gain > 5% from baseline of noncardiac origin	Severe hepatic dysfunction with bilirubin > 20mg%; or hepatic encephalopathy; or ascites compromising respiratory function
CNS toxicity	Somnolence but the patient is easily arousable and oriented after arousal	Somnolence with confusion after arousal; or other new objectives CNS symptoms with no loss of consciousness not more easily explained by other medication, bleeding, or CNS infection	Seizures or coma not explained (documented) by other medication, CNS infection, or bleeding
Stomatitis	Pain and/or ulceration not requiring a continuous IV narcotic drug	Pain and/or ulceration requiring a continuous IV narcotic drug (morphine drip)	Severe ulceration and/or mucositis requiring preventive intubation; or resulting in documented aspiration pneumonia with or without intubation
GI toxicity	Watery stools > 500 ml but < 2,000 mL every d not related to infection	Watery stools > 2,000 ml every d not related to infection, or macroscopic hemorrhagic stools with no affect on cardiovascular status not caused by infection; or subileus not related to infection	Ileus requiring nasogastric suction and/or surgery and not related to infection; or hemorrhagic enterocolitis affecting cardiovascular status and requiring transfusion

Note: Grade IV regimen-related toxicity is defined as fatal toxicity.

Abbreviations: CXR, chest x-ray, IV, intravenous

Reference: Bearman SI, Appelbaum FR, Bucker CD, Peterson FB, Fisher LD, Clift RA, Thomas ED. (1988). Regimen-related toxicity in patients undergoing bone marrow transplantation. *Journal of Clinical Oncology* **6**(10):1562-1568.

**HEMATOP**

MCC Use Only  
Date Recd.:

COBLT Recipient ID: ID   
COBLT Name Code:   
Center Code: TCCODE

**ASSESSPD**

Assessment Period: 1  Day 42 Post-CBT 2  Day 100 Post-CBT 3  Secondary Graft Failure

1. Did the patient engraft as evidenced by an ANC  $\geq$  500/mm<sup>3</sup> on 3 consecutive days?

- 1  Yes →
- 2  No
- 3  Previously reported

2. Record ANC values and dates:

<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> /mm <sup>3</sup> .....	<input type="text"/> <input type="text"/> M <input type="text"/> <input type="text"/> D <input type="text"/> <input type="text"/> Y
<b>ANC1</b>	<b>ANC1DT</b>
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> /mm <sup>3</sup> .....	<input type="text"/> <input type="text"/> M <input type="text"/> <input type="text"/> D <input type="text"/> <input type="text"/> Y
<b>ANC2</b>	<b>ANC2DT</b>
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> /mm <sup>3</sup> .....	<input type="text"/> <input type="text"/> M <input type="text"/> <input type="text"/> D <input type="text"/> <input type="text"/> Y
<b>ANC3</b>	<b>ANC3DT</b>

*Continue with question 3*

3. Did the patient have severe neutropenia (ANC < 500/mm<sup>3</sup>) without subsequent improvement?

- 1  Yes →
- 2  No

4. Record % of marrow cellularity ..... **BMCELL**  %  
1  Cellularity not quantified, but less than 25% **BMCELLNQ**

**IMPNEUT**

5. Date marrow obtained ..... **BMCELLDT**  M  D  Y

6. Record chimerism assay data for marrow and/or blood.

	Date	Primary Method Use codes below.	Assay Results
<b>Marrow</b>	<input type="text"/> <input type="text"/> M <input type="text"/> <input type="text"/> D <input type="text"/> <input type="text"/> Y <b>← BMCHMDT →</b>	<input type="checkbox"/> <b>BMCHMMTH</b> If Other, specify: _____	<b>BMCHMRES</b> 1 <input type="checkbox"/> All host cells 2 <input type="checkbox"/> All donor cells 3 <input type="checkbox"/> Host and donor → <input type="text"/> <input type="text"/> % donor <b>BMCTDNR</b>
<input type="checkbox"/> Marrow chimerism not done			
<b>Blood</b>	<input type="text"/> <input type="text"/> M <input type="text"/> <input type="text"/> D <input type="text"/> <input type="text"/> Y <b>← BLCHMDT →</b>	<input type="checkbox"/> <b>BLCHMMTH</b> If Other, specify: _____	<b>BLCHMRES</b> 1 <input type="checkbox"/> All host cells 2 <input type="checkbox"/> All donor cells 3 <input type="checkbox"/> Host and donor → <input type="text"/> <input type="text"/> % donor <b>BLPCTDNR</b>
<input type="checkbox"/> Blood chimerism not done			

Primary method codes: 1 - Standard cytogenetics 2 - Fluorescent in situ hybridization (FISH) 3 - Restriction fragment-length polymorphisms (RFLP) 4 - Polymerase chain reaction (PCR) 5 - HLA serotyping 9 - Other

7. Did the patient receive stem cell re-infusion due to inadequate hematopoietic function?

**STEMCELL**  
1  Yes →

8. Record date of infusion ..... **SCINFSDT**  M  D  Y

- 2  No

Comments: \_\_\_\_\_

\_\_\_\_\_  
Signature Date Study ID



**POST-TRANSPLANT INFECTION FORM**

MCC Use Only  
 Date Recd.:

COBLT Recipient ID: **ID**

COBLT Name Code:

Center Code: **TCCODE**

**INFECTDT**        
M D Y

1. Starting date of infection episode/visit date confirming an infection-free period. ....

2. Does this form document an infection episode? ..... **DOCIN FCT** ..... 1  Yes 2  No → Sign and submit form

Continue with question 3

3. Record all clinically important infections present.

		Site	Organism	Severity Scale
Bacteria <b>BACINF</b>	1 <input type="checkbox"/> Yes →	<input type="text"/> <input type="text"/>	<b>BACSITE1</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>BACORC1</b> <input type="text"/> <input type="text"/> <b>BACSEV1</b>
	2 <input type="checkbox"/> No	<input type="text"/> <input type="text"/>	<b>BACSITE2</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>BACORC2</b> <input type="text"/> <input type="text"/> <b>BACSEV2</b>
	↓	If Other, specify: _____		
Fungal <b>FNGINF</b>	1 <input type="checkbox"/> Yes →	<input type="text"/> <input type="text"/>	<b>FNGSITE1</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>FNGORC1</b> <input type="text"/> <input type="text"/> <b>FNGSEV1</b>
	2 <input type="checkbox"/> No	<input type="text"/> <input type="text"/>	<b>FNGSITE2</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>FNGORC2</b> <input type="text"/> <input type="text"/> <b>FNGSEV2</b>
	↓	If Other, specify: _____		
Viral <b>VIRINF</b>	1 <input type="checkbox"/> Yes →	<input type="text"/> <input type="text"/>	<b>VIRSITE1</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>VIRORC1</b> <input type="text"/> <input type="text"/> <b>VIRSEV1</b>
	2 <input type="checkbox"/> No	<input type="text"/> <input type="text"/>	<b>VIRSITE2</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>VIRORC2</b> <input type="text"/> <input type="text"/> <b>VIRSEV2</b>
	↓	If Other, specify: _____		
Protozoal <b>PROINF</b>	1 <input type="checkbox"/> Yes →	<input type="text"/> <input type="text"/>	<b>PROSITE1</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>PROORC1</b> <input type="text"/> <input type="text"/> <b>PROSEV1</b>
	2 <input type="checkbox"/> No	<input type="text"/> <input type="text"/>	<b>PROSITE2</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>PROORC2</b> <input type="text"/> <input type="text"/> <b>PROSEV2</b>
	↓	If Other, specify: _____		
Other <b>OTHINF</b>	1 <input type="checkbox"/> Yes →	<input type="text"/> <input type="text"/>	<b>OTHSITE1</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>OTHORC1</b> <input type="text"/> <input type="text"/> <b>OTHSEV1</b>
	2 <input type="checkbox"/> No	<input type="text"/> <input type="text"/>	<b>OTHSITE2</b> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <b>OTHORC2</b> <input type="text"/> <input type="text"/> <b>OTHSEV2</b>
	↓	If Other, specify: _____		

4. Was the only diagnosis for this episode "Fever of Undetermined Origin"? ..... **FUO** ..... 1  Yes 2  No

5. Was infection treated in addition to ongoing prophylaxis? ..... **INF TREAT** ..... 1  Yes 2  No

If Yes, specify: \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Date

Study ID

## Common Sites of Infection

01 Blood/Buffy Coat	
02 Disseminated - Generalized, isolated at 3 or more distinct sites	
<b>Central Nervous System</b>	
03 Brain	
04 Spinal Cord	
05 Meninges and CSF	
06 Central Nervous System unspecified	
<b>Gastrointestinal Tract</b>	
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	
<b>Respiratory Tract</b>	
18 Upper Airway and Nasopharynx	
19 Laryngitis/Larynx	
20 Lower Respiratory Tract (lung)	
21 Pleural Cavity, Pleural Fluid	
22 Sinuses	
23 Respiratory Tract unspecified	
	<b>Genito-Urinary Tract</b>
	24 Kidneys, Renal Pelvis, Ureters, and Bladder
	25 Prostate
	26 Testes
	27 Fallopian Tubes, Uterus, Cervix
	28 Vagina
	29 Genito-Urinary Tract unspecified
	<b>Skin</b>
	30 Genital Area
	33 Rash, Pustules, or Abscesses not typical of any of the above
	34 Skin unspecified
	<b>Other</b>
	35 Central Venous Catheter, not otherwise specified
	36 Woundsite or Catheter Tip
	37 Eyes
	38 Ears
	39 Joints
	40 Bone Marrow
	41 Bone Cortex (Osteomyelitis)
	42 Muscle (excluding Cardiac)
	43 Cardiac (Endocardium, Myocardium, Pericardium)
	44 Lymph Nodes
	45 Spleen
	46 Other unspecified

## Severity Scale

1. Mild, no active treatment (e.g., viral syndromes)
2. Moderate, requires outpatient PO antibiotic
3. Severe, requires IV antibiotic or antifungal or hospitalization
4. Life-threatening (e.g., septic shock)
5. Caused or contributed to death

## Commonly Reported Organisms

### Bacterial Infections

B19 Acinetobacter (baumanii, calcoaceticus, calcoaceticus- baumannii, Iwoffii, other species)	B34 Lactobacillus (bulgaricus, acidophilus, other species)
B20 Agrobacterium radiobacter	B2 Legionella
B21 Alcaligenes xylosoxidans	B3 Leptospira
B44 Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)	B35 Leptotrichia buccalis
B22 Bacillus (cereus, other species)	B36 Leuconostoc (all species)
B23 Bacteroides (gracilis, uniformis, vulgaris, other species)	B4 Listeria
B45 Borrelia (Lyme disease)	B55 Methylobacterium
B24 Branhamella or Moraxella catarrhalis (other species)	B37 Micrococcus (NOS)
B17 Campylobacter (all species)	B10 Mycobacteria (avium, bovis, haemophilum, intercellulare)
B25 Capnocytophaga	B5 Mycoplasma
B11 Chlamydia	B38 Neisseria (gonorrhoea, meningitidis, other species)
B26 Citrobacter (freundii, other species)	B6 Nocardia
B27 Clostridium (bifermentans, septicum, other species except difficile)	B54 Pharyngeal/Respiratory Flora
B18 Clostridium difficile	B39 Propionibacterium (acnes, avidum, granulatum, other species)
B28 Corynebacterium (all non-diphtheria species)	B16 Pseudomonas (all species except cepacia and maltophilia)
B47 Corynebacterium diphtheria	B46 Pseudomonas or Burkholderia cepacia
B1 Coxiella	B42 Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia
B14 Enterobacter	B56 Rhodococcus
B48 Enterococcus (all species)	B7 Rickettsia
B29 Escherichia (also E. coli)	B57 Salmonella (all species)
B30 Flavimonas oryzihabitans	B41 Serratia marcescens
B31 Flavobacterium	B58 Shigella
B32 Fusobacterium nucleatum	B12 Staphylococcus (coag - )
B52 Gram Negative Diplococci (NOS)	B59 Staphylococcus aureus (coag +)
B53 Gram Negative Rod (NOS)	B43 Stomatococcus mucilaginosus
B50 Gram Positive Cocci (NOS)	B13 Streptococcus (all species except Enterococcus)
B51 Gram Positive Rod (NOS)	B60 Treponema (syphilis)
B49 Haemophilus (all species including influenzae)	B8 Tuberculosis (NOS, AFB, acid fast bacillus, Koch bacillus)
B33 Helicobacter pylori	B9 Typical tuberculosis (TB, Tuberculosis)
B15 Klebsiella	B61 Vibrio (all species)
	<b>B99 Other Bacteria (NOS)</b>

### Fungal Infections

F1 Candida Albicans	F9 Aspergillus Niger
F2 Candida Krusei	F10 Aspergillus (NOS)
F3 Candida Parasitosis	F11 Cryptococcus Species
F4 Candida Tropicalis	F12 Fusarium Species
F5 Torulopsis Galbrata (a subspecies of Candida)	F13 Mucormycosis (Zygomycetes, Rhizopus)
F6 Candida (NOS)	F14 Yeast (NOS)
F7 Aspergillus Flavus	<b>F15 Other Fungus</b>
F8 Aspergillus Fumigatus	

### Viral Infections

V1 Herpes Simplex (HSV1, HSV2)	V12 Mumps
V2 Herpes Zoster (Chicken pox, Varicella)	V13 Papovavirus
V3 Cytomegalovirus (CMV)	V14 Respiratory Syncytial Virus (RSV)
V4 Adenovirus	V15 Rubella (German Measles)
V5 Enterovirus (Coxsackie, Echo, Polio)	V16 Parainfluenza
V6 Hepatitis A (HAV)	V17 HHV-6 (Human Herpes Virus)
V7 Hepatitis B (HBV, Australian antigen)	V18 Epstein-Barr Virus (EBV)
V8 Hepatitis C (includes non-A and non-B, HCV)	V19 Polyomavirus
V9 HIV-1, HTLV-III	V20 Rotavirus
V10 Influenza (Flu)	V21 Rhinovirus (Common Cold)
V11 Measles (Rubeola)	<b>V22 Other Viral</b>

### Protozoal (Parasite) Infections

P1 Pneumocystis (PCP)	P6 Echinococcal cyst
P2 Toxoplasma	P7 Trichomonas -- either vaginal or gingivitis
P3 Giardia	<b>P8 Other Protozoal (Parasite)</b>
P4 Cryptosporidium	
P5 Amebiasis	

### Other Infections

O1 Mycobacterium Tuberculosis	O4 Mycoplasma
O2 Other Mycobacterium	O5 Other Organism
O3 Legionella	<b>O6 No Organism Identified</b>

COBLT Recipient ID:

**ID**

COBLT Name Code:

**TCCODE**

Center Code:

MCC Use Only

Date Rec'd.:

1. What is the patient's primary diagnosis?

**PRIMDX**

3  CML →

2. Have immature hematopoietic cells been documented in the peripheral blood?

**IMMATHEM**

1  Yes →

2  No

3. Date first documented:

**IMMHEMDT**

M D Y

4. Has myeloid hyperplasia in the bone marrow been documented (in the absence of infection or growth factor therapy)?

**MYELHYPR**

1  Yes →

2  No

5. Date first documented:

**MYELHYDT**

M D Y

6. Have host cells reappeared?

**CMLHOST**

1  Yes →

2  No

3  No test performed

7. Record method(s) used:

Standard cytogenetics

**CMLMCTYO**

1  Yes 2  No

FISH

**CMLM FISH**

1  Yes 2  No

RFLP

**CMLMRFLP**

1  Yes 2  No

PCR

**CMLM PCR**

1  Yes 2  No

HLA serotyping

**CMLM HLA**

1  Yes 2  No

Other, specify

**CMLMOTH**

1  Yes 2  No

8. Has the 9;22 translocation reappeared?

**T922**

1  Yes → Continue with Question 9

2  No → Sign and submit form

3  N/A → Sign and submit form

9. Record date of cytogenetic analysis:

**CYTODT**

M D Y

10. Record number of metaphases analyzed:

**META**

11. Record number of metaphases exhibiting 9;22 translocation:

**METATRN**

12. List all molecular (BCR/ABL) examinations of blood or bone marrow post-transplant:

**BCRABDT1**

a.   
M D Y

Source of Cells

BCR/ABL+

1  Blood

1  Yes

2  Marrow

2  No

**BCRSOUR1**

**BCRPOS1**

**BCRABDT2**

b.   
M D Y

1  Blood

1  Yes

2  Marrow

2  No

**BCRSOUR2**

**BCRPOS2**

**BCRABDT3**

c.   
M D Y

1  Blood

1  Yes

2  Marrow

2  No

**BCRSOUR3**

**BCRPOS3**

**Go to Question 52 if the number of metaphases analyzed is ≥ 10 and ≥ 50% exhibit the 9;22 translocation; otherwise continue with Question 13**



**Patient with Non-Lymphoblastic Non-Hodgkin's Lymphoma, Hodgkin's Disease, or Lymphoblastic Non-Hodgkins Lymphoma complete Questions 28-41**

28. Has there been a progression more than 25% in the product of the two largest diameters of any measurable lesion?  
**PROG25**  
 1  Yes →  
 2  No  
 ↓

29. Record method(s) used:  
 Chest x-ray ..... **PRM1XRAY** 1  Yes 2  No  
 CT ..... **PRM1CT** 1  Yes 2  No  
 MRI ..... **PRM1MRI** 1  Yes 2  No  
 Other, specify **PRM1OTH** 1  Yes 2  No

**PRD1LES1** 30. Diameter of lesion one pre-transplant (cm): ....

**PRD1LES2** 31. Diameter of lesion two pre-transplant (cm): ....

**PRD1DATE** 32. Date of measurement: ..        
 M D Y

33. Record method(s) used:  
 Chest x-ray ..... **PRM2XRAY** 1  Yes 2  No  
 CT ..... **PRM2CT** 1  Yes 2  No  
 MRI ..... **PRM2MRI** 1  Yes 2  No  
 Other, specify **PRM2OTH** 1  Yes 2  No

**PRD2LES1** 34. Current diameter of lesion one: .....

**PRD2LES2** 35. Current diameter of lesion two: .....

**PRD2DATE** 36. Date of measurement: ..        
 M D Y

37. Have new definitive lesions appeared?  
**NEWLAPP** 1  Yes →  
 2  No  
 ↓

38. Have lesions been confirmed by biopsy?  
**NEWLCONF**  
 1  Yes →  
 2  No  
 ↓  
 Date:        
 M D Y  
**NEWLDATE**

39. Were bone marrow specimens obtained?  
**BMSPCOBT** 1  Yes →  
 2  No  
 ↓

40. Record method used:  
 1  Biopsy  
 2  Aspirate **BMMETH**  
 3  Both

41. Was there an appearance of lymphoma?  
**BMLYMPH**  
 1  Yes →  
 2  No  
 ↓  
 Date:        
 M D Y  
**BMLYMDAT**

**Continue with Question 52**



PRIMEDX (Cont'd)

6  JMML →

JMMHOST

42. Have host cells reappeared?

- 1  Yes →  
 2  No  
 8  No test performed

43. Record method(s) used:

- |                       |         |                                |                               |
|-----------------------|---------|--------------------------------|-------------------------------|
| Standard cytogenetics | JMMCYTO | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No |
| FISH                  | JMMFISH | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No |
| RFLP                  | JMMRFLP | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No |
| PCR                   | JMMPCR  | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No |
| HLA serotyping        | JMMHLA  | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No |
| Other, specify        | JMMOTH  | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No |

44. Are there clinical and laboratory features present which are consistent with the patient's original disease? ..... JIMPRES ..... 1  Yes 2  No

45. Has there been a reappearance of an abnormal cytogenetic marker which was present at diagnosis? ..... JMMPREAPP ..... 1  Yes 2  No

If yes, specify marker \_\_\_\_\_

46. Does the patient have GM-CSF hypersensitivity or spontaneous growth of CFU-GM in peripheral blood? ..... JMMGM ..... 1  Yes 2  No

Continue with Question 52

7  MDS →

MDSABNYYN

47. Have MDS-associated morphologic abnormalities reappeared?

- 1  Yes →  
 2  No

48. Record dates of two consecutive marrow specimens and % cells of host origin. MDSS1DT

Date of 1st specimen: .....      
 M D Y

% cells host origin: ..... HOSTORG1 .....  %

Date of 2nd specimen: ..... MDSS2DT .....     
 M D Y

% cells host origin: ..... HOSTORG2 .....  %

49. Has there been a reappearance of an abnormal cytogenetic marker which was present at diagnosis? ..... MDSREAPP ..... 1  Yes 2  No

Continue with Question 52

33  FEL →

34  LCH →

50. Has erythrophagocytosis been documented by biopsy or is infiltrative disease consistent with FEL or LCH? ..... FELLCH ..... 1  Yes 2  No

51. Has host hematopoiesis reappeared? ..... HEMREAPP ..... 1  Yes 2  No

Continue with Question 52

52. Have the following therapies been initiated for relapse reversal?

Infusion of donor lymphocytes <b>INFDON</b>	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No	Date first performed <b>INFDONDT</b>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>																								
Interferon use <b>INTERF</b>	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No	Date first performed <b>INTERFDT</b>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>																								
Second transplant <b>SECOTR</b>	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No	Date first performed <b>SECOTRDT</b>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>																								
Other, specify: <b>OTHERT</b> →	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No	Date first performed <b>OTHERTDT</b>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>																								

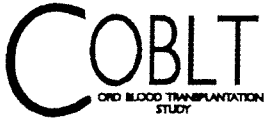
Comments: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Study ID





HOSPITAL

RE-ADMISSION FORM

MCC Use Only
Date Recd.:

COBLT Recipient ID: [ ] [ ] [ ] [ ] [ ] [ ]
COBLT Name Code: [ ] [ ] [ ]
Center Code: [ ] [ ] [ ]
Date of Re-admission: [ ] [ ] [ ] [ ] [ ] [ ]
M D Y
HOSPDT

1. Date of Discharge ..... DISCRGDT ..... [ ] [ ] [ ] [ ] [ ] [ ]
M D Y

2. Patient status at discharge ..... PATSTAT ..... 1 [ ] Alive 2 [ ] Dead
If 2-Dead, complete NMDP 190 - Recipient Death Information Form.

3. Record one primary reason for hospitalization and indicate other contributing reasons.
GVHD ..... RSN GVHD ..... 1 [ ] Primary 2 [ ] Contributing 3 [ ] Non-contributing
Relapse ..... RSN RLPS ..... 1 [ ] Primary 2 [ ] Contributing 3 [ ] Non-contributing
Graft Failure ..... RSN GF ..... 1 [ ] Primary 2 [ ] Contributing 3 [ ] Non-contributing
Infection ..... RSN INF ..... 1 [ ] Primary 2 [ ] Contributing 3 [ ] Non-contributing
Fever ..... RSN FEVER ..... 1 [ ] Primary 2 [ ] Contributing 3 [ ] Non-contributing
Other ..... RSN OTHER ..... 1 [ ] Primary 2 [ ] Contributing 3 [ ] Non-contributing
Specify: \_\_\_\_\_

4. Record the number of days on a ventilator during this hospitalization period ..... VENTDAYS ..... [ ] [ ]

Comments: \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_ Study ID [ ] [ ] [ ] [ ] [ ]

