Cord Blood Transplantation Study (COBLT)

Transplants Data

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

COBLT
CORD BLOOD TRANSPLANTATION STUDY

ELIGIBLE

ELIGIBILITY FORM

MCC Use Only
Date Rec'd.:

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

1. Indicate source of cord blood unit (CBU) selected for transplant: SOURCE

1 ☐ COBLT Cord Blood Bank Record COBLT Cord Blood Bank unit ID number: RESCBUNO

W☐☐☐☐☐☐☐☐☐☐☐☐ 00☐

Skip to Question #5 on page 2

2 ☐ New York Blood Center

3 ☐ NMDP-approved Cord Blood Bank. Specify_____

4 ☐ Other source. Specify_____

↓ *If choices 2, 3 or 4 selected, complete box below* ↓

2a. Record CBU identification number ..... CBUIDENT ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

b. Record CBU post-processing/pre-cryopreservation total nucleated cell count ..... CBUTNCC ☐☐.☐☐ x 10^8

c. Record patient weight used to select CBU ..... PTWEIGHT ☐☐☐.☐ kg

3. Has a sample from CBU been sent to COBLT HLA Typing Lab? ..... SAMP2LAB 1 ☐ Yes 2 ☐ No

4. Record CBU HLA typing

HLA-A

Typing Method: ATYPMETH 1☐ Serology 2☐ DNA Technology Antigens/alleles provided: AAPROVID 1☐ One 2☐ Two

1st: 1☐☐☐☐☐☐/2☐☐☐☐☐☐/3☐☐☐☐☐☐/4☐☐☐☐☐☐
A1STRING 5☐☐☐☐☐☐/6☐☐☐☐☐☐/7☐☐☐☐☐☐/8☐☐☐☐☐☐

2nd: 1☐☐☐☐☐☐/2☐☐☐☐☐☐/3☐☐☐☐☐☐/4☐☐☐☐☐☐
A2STRING 5☐☐☐☐☐☐/6☐☐☐☐☐☐/7☐☐☐☐☐☐/8☐☐☐☐☐☐

HLA-B

Typing Method: BTYPMETH 1☐ Serology 2☐ DNA Technology Antigens/alleles provided: BAPROVID 1☐ One 2☐ Two

1st: 1☐☐☐☐☐☐/2☐☐☐☐☐☐/3☐☐☐☐☐☐/4☐☐☐☐☐☐
B1STRING 5☐☐☐☐☐☐/6☐☐☐☐☐☐/7☐☐☐☐☐☐/8☐☐☐☐☐☐

2nd: 1☐☐☐☐☐☐/2☐☐☐☐☐☐/3☐☐☐☐☐☐/4☐☐☐☐☐☐
B2STRING 5☐☐☐☐☐☐/6☐☐☐☐☐☐/7☐☐☐☐☐☐/8☐☐☐☐☐☐

Continue on Page 2

4. Record CBU typing (continued)

HLA-DRB1

Typing Method: DTYPMETH 1☐ Serology 2☐ DNA Technology Antigens/alleles provided: DAPROVID 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? CONFSUB 1☐ Yes 2☐ No

6. Record proposed starting date for conditioning therapy: CONDTHDT ☐☐ ☐☐ ☐☐ (M D Y)

Patient Status

7. Date of birth: BIRTHDT ☐☐ ☐☐ ☐☐ (M D Y)

8. Sex SEX 1☐ Male 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 cytoreductive 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/μL? FLUIDWBC 1☐ Yes 2☐ No

18. Have malignant cells been found as a result of cytospin? 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: SHFRREST ☐☐☐ %

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, FEVI or FEC (Diffusion capacity): DLCO ☐☐☐ %
of predicted (corrected for hemoglobin)

OR

b. Record O_2 saturation on room air: OXYGSAT ☐☐☐ %

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

		ULN for your institution	LLN for your institution
Serum Creatinine	CR ☐☐.☐ mg/dL	CRULN ☐☐.☐ mg/dL	CRLLN ☐☐.☐ mg/dL
SGOT	SGOT ☐☐☐ Units/L	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 ↓

Continue with Question #35

33. Record creatinine clearance CRCLR ☐☐☐ mL/min/1.73m² CRCLRLNN LLN for your institution ☐☐☐ mL/min/1.73m²

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

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 (≤ 5% blasts in marrow) with translocations t(8;21) and inv (16)?
AMLCRT8
1 ☐ Yes →
2 ☐ No

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

38. Is the patient in first complete remission (≤ 5% blasts in marrow) with translocation t(15;17)?
AMLCRT15
1 ☐ Yes →
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 ≥ 3 medullary relapse? AMLMEDUR 1 ☐ Yes 2 ☐ No

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

Skip to Question #85 on Page 7

2 ☐ Acute Lymphoblastic Leukemia

44. Is the patient in first complete remission (≤ 5% blasts in marrow)?
ALLCR
1 ☐ Yes →
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 ⌊⌊⌊⌊⌊⌊⌋ /µL

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 →
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 ≥ 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

55. Record date of diagnosis: CMLDATE ☐☐ ☐☐ ☐☐ (M D Y)

56. Record the phase of CML: CMLPHASE
1 ☐ Chronic →
2 ☐ Accelerated
3 ☐ Blast crisis
↓

57. Does the patient have an adequately matched unrelated bone marrow donor identified? CMLMATCH 1 ☐ Yes 2 ☐ No

58. Has the patient been unresponsive to interferon? CMLUNRES 1 ☐ Yes 2 ☐ No

59. Is the patient unable to tolerate interferon? CMLUNTOL 1 ☐ Yes 2 ☐ No

Skip to Question #85 on Page 7

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

DISPRIM (contd)

7☐ Myelo-dysplastic Syndrome

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

1 ☐ Refractory Anemia
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 Noctural Hemoglobinuria (PNH)

Skip to Question #85 on Page 7

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

Skip to Question #85 on Page 7

11☐ Acquired Severe Aplastic Anemia

75. Record granulocyte count: ASAGRAN ..... ⌊⌋⌋⌋ cells/μL
76. Record platelet count: ASAPLATE ..... ⌊⌋⌋⌋ x10³/μL
77. Record absolute reticulocyte count (after correction for hematocrit): ASARETIC ..... ⌊⌋⌋⌋ x10³/μL
78. Is the patient unresponsive to medical therapy with anti-thymocyte globulin and/or cyclosporine? ASAUNRES .. 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

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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 Phosphoylase (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 cytoreduction? 1 ☐ Yes 2 ☐ No
Skip to Question #85 below

33☐ Familial Erythrophagocytic Lymphohistiocytosis (FEL)

FELCEREB
83. Is the cerebrospinal fluid currently positive for disease as defined by abnormal brain MRI or neurologic symptoms or >7/mm^3 lymphocytes plus monocytes? ..... 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: _____

DISUNRES
84. Is disease unresponsive to medical therapy? ..... 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

86. Indicate planned conditioning regimen: PCREGIM

1 ☐ TBI/Cyclophosphamide
2 ☐ Busulfan (Busulfex)/Cyclophosphamide
3 ☐ Busulfan (Busulfex)/Melphalan *Complete Questions 87 - 91*
4 ☐ Other, specify_____

If choices 1, 2 or 4 selected, sign and submit form

87. Was the patient diagnosed with infant acute leukemia when less than 2 years old? INFLKYN
1 ☐ Yes → 88. Date of diagnosis . . . . . INFLKDT ☐☐ ☐☐ ☐☐
M D Y
2 ☐ No
↓

89. Does the patient have a malignant disease and is unable to tolerate TBI? TBIYN
1 ☐ Yes → 90. Reason patient is unable to tolerate TBI: TBIDOSE
TBIREAS
2 ☐ No
1 ☐ Prior dose-limiting radiation; Specify prior dose: ☐☐☐☐ cGy
2 ☐ Prior significant cardiac toxicity
3 ☐ Other, specify_____

91. Has the patient been diagnosed with leukemia or myelodysplastic syndrome due to prior therapy? . . . . . LEUKMYSY . . . . . 1 ☐ Yes 2 ☐ No

Sign and submit form

Comments:_____

_____

_____ _____ ☐☐☐☐☐
Signature Date Study ID

For MCC Use:
☐/☐ HLA Match

THAWING

COBLT

CORD BLOOD TRANSPLANTATION STUDY

CBU THAWING FORM

MCC Use Only
Date Recd.:

COBLT Recipient ID: ID

COBLT Name Code:

Center Code: TCCODE

COBLT CBU ID : CBUID W 00

For CBUs thawed for certification, record 999 999 6 for Recipient ID and CRT for Name Code.

1. Date and starting time of CBU thaw . . . . . THAWDT (M D Y) THAWTM *hr/min [24hr]*

2. Total viable NCC of CBU recorded on Transplant Center Feedback Sheet . . . . . NCCTCFS . X 10^8

3. Reagent and supply data.

	LOT NUMBER	EXPIRATION DATE (MM/YY)	MANUFACTURER (Specify)
Cell wash/Infusion bag set	CELLLOT		
Dextran 40	DEXTLOT	DEXTEXP	
Stock Albumin Bottle 1	ALB1LOT	ALB1EXP	
Bottle 2	ALB2LOT	ALB2EXP	

4. Weight of washed and resuspended cells in Transplant Bag from tared scale . . . . . WGTWASH . gm

(NOTE: Record the weight after resuspending the cells and prior to the removal of QC sample.)

5. Cell count and viability of washed and resuspended CBU in Transplant Bag.

Volume for infusion . ml VOLWASH

Cell viability % VIAWASH

Automated nucleated cell count NCCWASH . $x10^6$/ml

Calculate cell recovery using the formula:

$$\frac{\textit{Total viable nucleated cells in resuspended CBU}}{\textit{Total viable nucleated cells in prefreeze CBU}}$$

Continue with Question 6

6. Were cells from the waste-bag supernatant recovered and infused? RECIPNUS 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 NCCRECOV ☐☐☐.☐ X10⁶/ml

Continue with Question 9

9. Calculate final infused viable cell recovery.
   Total viable nucleated cell count ☐☐☐.☐☐ x 10⁸ 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

COBLT
CORD BLOOD TRANSPLANTATION STUDY

INFUSION

CBU INFUSION FORM

COBLT Recipient ID: ID ☐☐☐☐☐☐☐

MCC Use Only
Date Recd.:

COBLT Name Code: ☐☐☐

Center Code: TCCODE ☐☐☐

1. Date of infusion ..... INFDATE ☐☐ ☐☐ ☐☐ (M D Y)

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
PREOTHER	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:

EMERENAD	Benadryl	1☐Yes	2☐No
EMEHYDRO	Hydrocortisone	1☐Yes	2☐No
EMEMETH	Methylprednisolone	1☐Yes	2☐No
EMEMANN	Mannitol	1☐Yes	2☐No
EMEOTHER	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) ALLERGY	☐ none	☐ transient rash, drug fever <38 °C (<100.4 °F)	☐ urticaria, drug fever 38 °C (100.4°) and/or asymptomatic brochospasm	☐ systematic brochospasm, requiring parenteral medication(s), with or without urticaria; allergy-related edema/angioedema	☐ anaphylaxis
Sinus bradycardia SINUSBRA	☐ none	☐ asymptomatic, not requiring treatment	☐ symptomatic, but not requiring treatment	☐ symptomatic and requiring treatment	☐ life-threatening (e.g. arrhythmia associated with CHF, hypotension syncope, shock
Sinus tachycardia SINUSTAC	☐ none	☐ asymptomatic, not requiring treatment	☐ symptomatic, but not requiring treatment	☐ symtomatic and requiring treatment of underlying cause	-
Hypertension HYPERTEN	☐ none	☐ asymptomatic, transcient increase by >20 mmHg (diastolic) or to >150/100* if previously WNL; not requiring treatment	☐ recurrent or persistent symptomatic increase by >20 mmHg(diastolic) or to >150/100* if previously WNL; not requiring treatment	☐ requiring therapy or more intensive therapy than previously	☐ hypertensive crisis

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

Toxicity	Grade 0	1	2	3	4
Hypotension HYPOTEN	☐ none	☐ changes, but not requiring therapy (including transient orthostatic hypotension)	☐ requiring brief fluid replacement or other therapy but not hospitalization; no physiologic consequences	☐ requiring therapy and sustained medical attention, but resolves without persisting physiologic consequences	☐ shock (associated with acidemia and impairing vital organ function due to tissue hypoperfusion)
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					
Fever (in the absence of neutropenia, where neutropenia is defined as ANC<1.0 x 10^9/L) FEVER	☐ none	☐ 38.0 - 39.0 °C (100.4 - 102.2 °F)	☐ 39.1 - 40.0 °C (102.3 - 104.0°F)	☐ >40.0 °C (>104.0 °F) for <24hrs	☐ >40.0 °C (>104.0 °F) for>24hrs
Note: The temperature measurements listed above are oral or tympanic					
Rigors, chills RIGCHILL	☐ none	☐ mild, requiring symptomatic treatment (e.g., blanket) or non-narcotic medication	☐ severe and/or prolonged, requiring narcotic medication	☐ not responsive to narcotic medication	-
Nausea NAUSEA	☐ none	☐ not able to eat	☐ oral intake significantly decreases	☐ no significant intake, requiring IV fluids	-
Vomiting VOMITING	☐ none	☐ 1 episode in 24hours over pre-treatment	☐ 2-5 episodes in 24 hours over pre-treatment	☐ ≥6 episodes in 24 hours over pre-treatment; or need for IV fluids	☐ Requiring parenteral nutrition; or physiologic consequences requiring intensive care; hemodynamic collapse
Infection with unknown ANC UNKANC	☐ none	-	-	☐ Present	☐ life-threatening sepsis (e.g., septic shock)
Note: This toxicity criterion is used in the rare case when ANC is unknown					
Dyspnea (shortness of breath) DYSPNEA	☐ normal	-	☐ dyspnea on exertion	☐ dyspnea at normal level or activity	☐ dyspnea at rest or requiring ventilator support
Hypoxia HYPOXIA	☐ normal	-	☐ decreased 0_2 saturation with exercise	☐ decreased 0_2 saturation at rest, requiring supplemental oxygen	☐ decreased 0_2 saturation, requiring pressure support (CPAP) or assisted ventilation
Hemoglobinuria	☐ none	☐ present HEMOGLOB	-	-	-

Comments: _____

_____ _____ ☐☐☐☐☐

Signature Date Study ID

GVHD

COBLT
CORD BLOOD TRANSPLANTATION STUDY

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 8 ☐ Not given during assessment period

3. Record trough level and date..... CSALVL ☐☐☐☐.☐ ng/mL ..... ☐☐ ☐☐ ☐☐ (M D Y) CSALVLDT

4. Record the highest level of organ abnormalities during the assessment period:

Skin ORGABSKN
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

Intestinal tract (use mL/day for adult patients and mL/m^2 for pediatric patients)

ORGABIT
0 ☐ No diarrhea
1 ☐ Diarrhea ≤ 500 mL/day or < 280 mL/m^2
2 ☐ Diarrhea > 500 but ≤ 1000 mL/day or 280-555 mL/m^2
3 ☐ Diarrhea > 1000 but ≤ 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

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

COBLT
CORD BLOOD TRANSPLANTATION STUDY

TOXICITY FORM

TOXIC

COBLT Recipient ID: ID ☐☐☐☐☐☐☐☐

COBLT Name Code: ☐☐☐

Center Code: TTCODE ☐☐☐

MCC Use Only
Date Recd.:

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.

	Grade 0	Grade I	Grade II	Grade III	Grade IV
Cardiac TGCARD	0 ☐ No EKG abnormality	1 ☐ Mild EKG abnormality	2 ☐ Moderate EKG abnormality	3 ☐ Severe EKG abnormality	4 ☐ Fatal toxicity
Bladder TGBLAD	0 ☐ None	1 ☐ Macro. hem. 2d. from last chemo	2 ☐ Macro. hem. 7d. after last chemo	3 ☐ Hem. cystitis with frank blood	4 ☐ Fatal toxicity
Renal TGRENAL	0 ☐ None	1 ☐ Creat. increase up to 2 x baseline	2 ☐ Creat. above 2 x baseline	3 ☐ Dialysis required	4 ☐ Fatal toxicity
Pulmonary TGPULM	0 ☐ None	1 ☐ See scale	2 ☐ See scale	3 ☐ See scale	4 ☐ Fatal toxicity
Hepatic TGHEPT	0 ☐ None	1 ☐ Mild hep. dysfunction	2 ☐ Mod. hep. dysfunction	3 ☐ Severe hep. dysfunction	4 ☐ Fatal toxicity
CNS TGCNS	0 ☐ None	1 ☐ Somnolence + arousable	2 ☐ Somnolence + confusion	3 ☐ Seizures or coma	4 ☐ Fatal toxicity
Stomatitis TGSTOM	0 ☐ None	1 ☐ Pain and/or ulceration, no IV narc. drug	2 ☐ Pain and/or ulceration with IV narc. drug	3 ☐ Severe ulcer. and/or mucositis - see scale	4 ☐ Fatal toxicity
GI Toxicity TGGITX	0 ☐ None	1 ☐ Watery stools >500 mL but ≤2,000 mL every d.	2 ☐ Watery stools >2,000 mL every d.	3 ☐ Ileus require nasogastric suction	4 ☐ 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 →

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

2☐ No

↓

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

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

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

CYTOTHER

11. Was other treatment given? 1☐ Yes, specify: _____
2☐ No

Comments: _____

_____ _____ ☐☐☐☐☐
Signature Date Study ID

TOXICITY GRADING SCALE

	GRADE I	GRADE II	GRADE III
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_2 (> 10% from baseline) but not requiring mechanical ventilation or > 50% O_2 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% form 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 escites or image documented escites > 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.

COBLT
CORD BLOOD TRANSPLANTATION STUDY

HEMATOP

HEMATOPOIESIS ASSESSMENT FORM - NEUTROPHILS

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 ≥ 500/mm³ on 3 consecutive days?

1 ☐ Yes→
2 ☐ No
3 ☐ Previously reported ↓

2. Record ANC values and dates:

☐☐☐☐☐ /mm³ ..... ANC1 ☐☐ ☐☐ ☐☐ ANC1DT (M D Y)
☐☐☐☐☐ /mm³ ..... ANC2 ☐☐ ☐☐ ☐☐ ANC2DT (M D Y)
☐☐☐☐☐ /mm³ ..... ANC3 ☐☐ ☐☐ ☐☐ ANC3DT (M D Y)

Continue with question 3

3. Did the patient have severe neutropenia (ANC < 500/mm³) without subsequent improvement?

1 ☐ Yes→ IMPNEUT
2 ☐ No

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

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
Marrow	←BMCHMDT→ ☐☐ ☐☐ ☐☐ (M D Y)	☐ BMCHMMTH If Other, specify: _____	BMCHMRES 1 ☐ All host cells 2 ☐ All donor cells 3 ☐ Host and donor→ BMPCTDNR ☐☐ %donor
☐ Marrow chimerism not done			
Blood	←BLCHMDT→ ☐☐ ☐☐ ☐☐ (M D Y)	☐ BLCHMMTH If Other, specify: _____	BLCHMRES 1 ☐ All host cells 2 ☐ All donor cells 3 ☐ Host and donor→ BLPCTDNR ☐☐ %donor
☐ Blood chimerism not done			

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

REDHEMAT

COBLT
CORD BLOOD TRANSPLANTATION STUDY

HEMATOPOIESIS ASSESSMENT FORM - RED CELL

MCC Use Only
Date Recd.:

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

Assessment Period: ASSESSPD 1 ☐ Day 100 Post-CBT 2 ☐ 6 Mo. Post-CBT 3 ☐ 12 Mo. Post-CBT

1. Did the patient engraft as evidenced by an absolute reticulocyte count ≥ 30,000/mm^3 for 2 consecutive measurements?

ENGRAFT
1 ☐ Yes→
2 ☐ No
3 ☐ Previously reported

2. Record absolute reticulocyte count values and dates:

ARC1 ☐☐☐☐☐☐ /mm^3 ..... ARC1DT ☐☐ ☐☐ ☐☐ (M D Y)

ARC2 ☐☐☐☐☐☐ /mm^3 ..... ARC2DT ☐☐ ☐☐ ☐☐ (M D Y)

continue with question #3

3. Date of most recent red cell transfusion ..... RCTDATE ☐☐ ☐☐ ☐☐ (M D Y)

4. Date cyclosporine ended ..... CYCDATE ☐☐ ☐☐ ☐☐ (M D Y)

Comments: _____

_____ Signature

_____ Date

☐☐☐☐☐ Study ID

INFECT

COBLT
CORD BLOOD TRANSPLANTATION STUDY

POST-TRANSPLANT INFECTION FORM

COBLT Recipient ID: ID ☐☐☐ ☐☐☐☐

MCC Use Only
Date Recd.:

COBLT Name Code: ☐☐☐

Center Code: TCCODE ☐☐☐

1. Starting date of infection episode/visit date confirming an infection-free period. . . . . INFECTDT ☐☐ ☐☐ ☐☐
   M D Y

2. Does this form document an infection episode? . . . . . DOCINFCT . . . . 1 ☐ Yes 2 ☐ No → *Sign and submit form*
   ↓
   Continue with question 3

3. Record all clinically important infections present.

		Site	Organism	Severity Scale
Bacteria BACINF	1 ☐ Yes → 2 ☐ No ↓	One	BACSITE1 ☐☐ B ☐☐	BACORG1 ☐ BACSEV1
		Two	BACSITE2 ☐☐ B ☐☐	BACORG2 ☐ BACSEV2
		If Other, specify: _____		
Fungal FNGINF	1 ☐ Yes → 2 ☐ No ↓	One	FNGSIT1 ☐☐ F ☐☐	FNGORG1 ☐ FNGSEV1
		Two	FNGSIT2 ☐☐ F ☐☐	FNGORG2 ☐ FNGSEV2
		If Other, specify: _____		
Viral VIRINF	1 ☐ Yes → 2 ☐ No ↓	One	VIRSIT1 ☐☐ V ☐☐	VIRORG1 ☐ VIRSEV1
		Two	VIRSIT2 ☐☐ V ☐☐	VIRORG2 ☐ VIRSEV2
		If Other, specify: _____		
Protozoal PROINF	1 ☐ Yes → 2 ☐ No ↓	One	PROSIT1 ☐☐ P ☐☐	PROORG1 ☐ PROSEV1
		Two	PROSIT2 ☐☐ P ☐☐	PROORG2 ☐ PROSEV2
		If Other, specify: _____		
Other OTHINF	1 ☐ Yes → 2 ☐ No ↓	One	OTHSIT1 ☐☐ O ☐☐	OTHORG1 ☐ OTHSEV1
		Two	OTHSIT2 ☐☐ O ☐☐	OTHORG2 ☐ OTHSEV2
		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? . . . . . INFTREAT . . . . 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

Central Nervous System

03 Brain
04 Spinal Cord
05 Meninges and CSF
06 Central Nervous System unspecified

Gastrointestinal Tract

07 Lips
08 Tongue, Oral Cavity, and Oro- Pharynx
09 Esophagus
10 Stomach
11 Gallbladder and Bilinary Tree (not Hepatitis), Pancreas
12 Small Intestine
13 Large Intestine
14 Feces/Stool
15 Peritoneum
16 Liver
17 Gastrointestinal Tract unspecified

Respiratory Tract

18 Upper Airway and Nasopharynx
19 Laryngitis/Larynx
20 Lower Respiratory Tract (lung)
21 Pleural Cavity, Pleural Fluid
22 Sinuses
23 Respiratory Tract unspecified

Genito-Urinary Tract

24 Kidneys, Renal Pelvis, Ureters, and Bladder
25 Prostate
26 Testes
27 Fallopian Tubes, Uterus, Cervix
28 Vagina
29 Genito-Urinary Tract unspecified

Skin

30 Genital Area
33 Rash, Pustules, or Abscesses not typical of any of the above
34 Skin unspecified

Other

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

Fungal Infections

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

Viral Infections

V1 Herpes Simplex (HSV1, HSV2)
V2 Herpes Zoster (Chicken pox, Varicella)
V3 Cytomegalovirus (CMV)
V4 Adenovirus
V5 Enterovirus (Coxsackie, Echo, Polio)
V6 Hepatitis A (HAV)
V7 Hepatitis B (HBV, Australian antigen)
V8 Hepatitis C (includes non-A and non-B, HCV)
V9 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

Protozoal (Parasite) Infections

P1 Pneumocystis (PCP)
P2 Toxoplasma
P3 Giardia
P4 Cryptosporidium
P5 Amebiasis
P6 Echinocoocalcyst
P7 Trichomonas -- either vaginal or gingivitis
P8 Other Protozoal (Parasite)

Other Infections

O1 Mycobacterium Tuberculosis
O2 Other Mycobacterium
O3 Legionella
O4 Mycoplasma
O5 Other Organism
O6 No Organism Identified

COBLT
CORD BLOOD TRANSPLANTATION STUDY

RELAPSE FORM

RELAPSE

COBLT Recipient ID: ID ☐☐☐☐☐☐☐☐

MCC Use Only
Date Rec'd.:

COBLT Name Code: ☐☐☐

Center Code: TCCODE ☐☐☐

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:

		Source of Cells	BCR/ABL+
a.	BCRABDT1 ☐☐ ☐☐ ☐☐ (M D Y)	1 ☐ Blood, 2 ☐ Marrow — BCRSOUR1	1 ☐ Yes, 2 ☐ No — BCRPOS1
b.	BCRABDT2 ☐☐ ☐☐ ☐☐ (M D Y)	1 ☐ Blood, 2 ☐ Marrow — BCRSOUR2	1 ☐ Yes, 2 ☐ No — BCRPOS2
c.	BCRABDT3 ☐☐ ☐☐ ☐☐ (M D Y)	1 ☐ Blood, 2 ☐ Marrow — BCRSOUR3	1 ☐ Yes, 2 ☐ No — 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

PRIMDX(contd)

1 ☐ AML →

2 ☐ ALL

4 ☐ Undifferentiated Leukemia

5 ☐ Bi-phenotypic Leukemia

8 ☐ Hodgkins Disease

9 ☐ Non-Lymphoblastic Non-Hodgkins Lymphoma

10 ☐ Lymphoblastic Non-Hodgkins Lymphoma

13. Record date of second cytogenetic analysis: CYTO2DT ☐☐ ☐☐ ☐☐ (M D Y)

14. Record number of metaphases exhibiting 9;22 translocation: ☐☐ METATRN2

Continue with Question 52

15. Were leukemic blasts documented in the marrow or peripheral blood?

	% Leukemic Blasts	Date Blasts First Observed
BMBLSYN Marrow 1 ☐ Yes → / 2 ☐ No	☐☐.☐ BMPCT	☐☐ ☐☐ ☐☐ BMBLSDT (M D Y)
PBBLSYN Blood 1 ☐ Yes → / 2 ☐ No	☐☐.☐ PBPCT	☐☐ ☐☐ ☐☐ PBBLSDT (M D Y)

If leukemia blasts ≤ 25%, repeat test and document results below. Otherwise, continue with Question 16

BM2BLSYN Marrow 1 ☐ Yes → / 2 ☐ No	☐☐.☐ BM2PCT	☐☐ ☐☐ ☐☐ BM2BLSDT (M D Y)
PB2BLSYN Blood 1 ☐ Yes → / 2 ☐ No	☐☐.☐ PB2PCT	☐☐ ☐☐ ☐☐ PB2BLSDT (M D Y)

16. Have host cells reappeared? ACHOST 1 ☐ Yes 2 ☐ No 8 ☐ No test performed

17. Have cytogenetic abnormalities reappeared? CYTOABN 1 ☐ Yes → 2 ☐ No 3 ☐ N/A 4 ☐ No test performed ↓

18. Record method(s) used:

Standard cytogenetics	CABMCYTO	1 ☐ Yes 2 ☐ No
FISH	CABMFISH	1 ☐ Yes 2 ☐ No
RFLP	CABMRFLP	1 ☐ Yes 2 ☐ No
PCR	CABMPCR	1 ☐ Yes 2 ☐ No
HLA serotyping	CABMHLA	1 ☐ Yes 2 ☐ No
Other, specify _____	CABMOTH	1 ☐ Yes 2 ☐ No

19. Date disease first detected: ABNORMDT ☐☐ ☐☐ ☐☐ (M D Y)

20. Was disease detected at an extramedullary site? 1 ☐ Yes → 2 ☐ No ↓ EXTRAMED

21. Date disease first detected: EMDISDT ☐☐ ☐☐ ☐☐ (M D Y)

22. Was disease confirmed by pathology? PATHCONF 1 ☐ Yes 2 ☐ No

23. Has a new extramedullary mass been documented? EMNEWDOC → 1 ☐ Physical exam 2 ☐ Radiographic 3 ☐ Both

24. Have previous masses demonstrated an increase in size? EMPRVINC → 1 ☐ Physical exam 2 ☐ Radiographic 3 ☐ Both

25. Were blasts present in the cerebrospinal fluid? EMBLCER 1 ☐ Yes → 2 ☐ No ↓

26. Record the white blood cell count in the cerebrospinal fluid: EMWBCCER ☐☐☐ %

27. Date WBC recorded: EMWDTCER ☐☐ ☐☐ ☐☐ (M D Y)

If primary disease is Non-Lymphoblastic Non-Hodgkin's Lymphoma, Hodgkin's Disease, or Lymphoblastic Non-Hodgkins Lymphoma, continue with Question 28; otherwise go to Question 52

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 apppeared?

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 (Contd)

6 ☐ JMML →

42. Have host cells reappeared? JMMHOST
1 ☐ Yes →
2 ☐ No
8 ☐ No test performed ↓

43. Record method(s) used:

Standard cytogenetics	JMMCYTO	1 ☐ Yes	2 ☐ No
FISH	JMMFISH	1 ☐ Yes	2 ☐ No
RFLP	JMMRFLP	1 ☐ Yes	2 ☐ No
PCR	JMMPCR	1 ☐ Yes	2 ☐ No
HLA serotyping	JMMHLA	1 ☐ Yes	2 ☐ No
Other, specify_____	JMMMOTH	1 ☐ Yes	2 ☐ No

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

45. Has there been a reappearance of an abnormal cytogenetic marker which was present at diagnosis? JMMREAPP 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 →

47. Have MDS-associated morphologic abnormalities reappeared? MDSABNYN
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 ☐☐☐ %

MDSS2DT
Date of 2nd specimen: ☐☐ ☐☐ ☐☐ (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 INFDON	1 ☐ Yes →	Date first performed INFDONDT	☐☐ M	☐☐ D ☐☐ Y
	2 ☐ No			
Interferon use INTERF	1 ☐ Yes →	Date first performed INTERFDT	☐☐ M	☐☐ D ☐☐ Y
	2 ☐ No			
Second transplant SECOTR	1 ☐ Yes →	Date first performed SECOTRDT	☐☐ M	☐☐ D ☐☐ Y
	2 ☐ No			
Other, specify: OTHERT → _____	1 ☐ Yes →	Date first performed OTHERTDT	☐☐ M	☐☐ D ☐☐ Y
	2 ☐ No			

Comments: _____

_____ Signature

_____ Date

☐☐☐☐☐ Study ID

ADVERSE

COBLT
CORD BLOOD TRANSPLANTATION STUDY

ADVERSE EXPERIENCE FORM

MCC Use Only
Date Rec'd.:

COBLT Recipient ID: ID ☐☐☐☐☐☐☐☐

COBLT Name Code: ☐☐☐

Center Code: TCCODE ☐☐☐

Date of Onset: ONSETDT ☐☐ ☐☐ ☐☐
M D Y

Complete the form and attach a narrative description of the event and patient status.
Submit the form to the MCC as described in the COBLT MOP, Chapter 3, Section 3.2.

1. Document adverse experience: DOCADEXP (50)

2. Is this an unexpected serious adverse experience? ..... UNEXP ..... 1 ☐ Yes 2 ☐ No

3. Severity of the adverse experience ..... SEV 1 ☐ Mild 2 ☐ Moderate 3 ☐ Severe 4 ☐ Life-threatening 5 ☐ Fatal

4. Suspected relationship to study therapy ... RELATN 1 ☐ Definite 2 ☐ Probable 3 ☐ Possible 4 ☐ Remote 5 ☐ None

5. Effect on study therapy ..... EFFECT ..... 1 ☐ No Change 2 ☐ Reduced 3 ☐ Held 4 ☐ Discontinued

6. Was treatment required? ..... RXREQD ..... 1 ☐ Required Med(s) 2 ☐ None 9 ☐ Other, specify: _____

7. Status of adverse experience ..... STATUS ..... 1 ☐ Resolved 2 ☐ Continuing

8. Date of resolution (if known) ..... RESLDT ..... ☐☐ ☐☐ ☐☐
M D Y

9. Has this adverse experience been reported to your Institutional Review Board? ..... AEREPORT 1 ☐ Yes 2 ☐ No
If yes, attach report.

Comments: _____

_____ _____ ☐☐☐☐☐
Coordinator Signature Date Study ID

_____ _____
Principal Investigator Signature Date

HOSPITAL

COBLT
CORD BLOOD TRANSPLANTATION STUDY

RE-ADMISSION FORM

MCC Use Only
Date Recd.:

COBLT Recipient ID: ☐☐☐ ☐☐☐☐

COBLT Name Code: ☐☐☐

Center Code: ☐☐☐

Date of Re-admission: HOSPDT ☐☐ M ☐☐ D ☐☐ Y

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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	RSNGVHD	1 ☐ Primary	2 ☐ Contributing	3 ☐ Non-contributing
Relapse	RSNRLPS	1 ☐ Primary	2 ☐ Contributing	3 ☐ Non-contributing
Graft Failure	RSNGF	1 ☐ Primary	2 ☐ Contributing	3 ☐ Non-contributing
Infection	RSNINF	1 ☐ Primary	2 ☐ Contributing	3 ☐ Non-contributing
Fever	RSNFEVER	1 ☐ Primary	2 ☐ Contributing	3 ☐ Non-contributing
Other	RSNOTHER	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

COBLT
CORD BLOOD TRANSPLANTATION STUDY

SPECSUB

SPECIMEN SUBMISSION FORM

[ID] / RAND_ID

COBLT Recipient ID: ☐☐☐ ☐☐☐☐

MCC Use Only
Date Recd.:

COBLT Name Code: ☐☐☐

Center Code: TTCODE ☐☐☐

ASSESSPD

Assessment Period: Post-CBT 1 ☐1 Mo. 2 ☐2 Mo. 3 ☐3 Mo. 4 ☐6 Mo. 5 ☐9 Mo.
6 ☐12 Mo. 7 ☐18 Mo. 8 ☐24 Mo. 9 ☐36 Mo. 10 ☐48 Mo.

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1. Record date of sample collection ..... COLLDT ☐☐ ☐☐ ☐☐
M D Y

2. Record date sample(s) shipped ..... SHIPDT ☐☐ ☐☐ ☐☐
M D Y

3. Record date of most recent tetanus immunization ..... TETANDT ☐☐ ☐☐ ☐☐
M D Y

4. **If 1st assessment**, record patient results for the following tests pre-transplant:

Herpes Simplex I HERPSIMP	1 ☐ Positive	2 ☐ Negative	3 ☐ Not Done Pre-Transplant
Varicella Zoster VARICZOS	1 ☐ Positive	2 ☐ Negative	3 ☐ Not Done Pre-Transplant
CMV CMV	1 ☐ Positive	2 ☐ Negative	3 ☐ Not Done Pre-Transplant

SAMPLES SHOULD BE SHIPPED OVERNIGHT TO:

Robertson Parkman, M.D.
Children's Hospital, Los Angeles
4650 Sunset Boulevard, Mail Stop #62
Los Angeles, CA 90027

Comments: _____

_____ Signature

_____ Date

☐☐☐☐☐ Study ID