

4. Record CBU typing (continued)

HLA-DRB1

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

1st: 1 / 2 / 3 / 4

5 / 6 / 7 / 8

2nd: 1 / 2 / 3 / 4

5 / 6 / 7 / 8

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

6. Record proposed starting date for conditioning therapy:

M D Y

Patient Status

7. Date of birth:

M D Y

8. Sex 1 G Male
2 G Female 9. Is the patient pregnant or breastfeeding? 1 Yes 2 No

10. Has the patient had a previous allogeneic stem cell transplant with cytoreductive preparative therapy?
1 G Yes
2 G No

11. Date of allogeneic stem cell transplant:

M D Y

12. Has the patient had a previous autologous stem cell transplant?
1 G Yes
2 G No

13. Date of autologous stem cell transplant:

M D Y

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

15. Date Informed Consent Form signed:

M D Y

Patient Clinical Status

16. Does the primary disease include active CNS leukemia involvement at the time of enrollment?
1 G Yes
2 G No

17. Does the cerebrospinal fluid contain > 5 WBC/ μ L? 1 Yes 2 No

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

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

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

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

22. Does the patient have myelofibrosis?

- 1 G Yes
- 2 G No



23. Record grade of myelofibrosis:

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

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

26. Does the patient have symptomatic cardiac disease?

- 1 G Yes
- 2 G No



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

OR

b. Record the shortening fraction at rest: %

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

29. Does the patient have any pulmonary disease symptoms?

- 1 G Yes
- 2 G No



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

OR

b. Record O₂ saturation on room air: %

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

		ULN for your institution	LLN for your institution
Serum Creatinine	<input type="text"/> <input type="text"/> ! <input type="text"/> mg/dL	<input type="text"/> <input type="text"/> ! <input type="text"/> mg/dL	<input type="text"/> <input type="text"/> ! <input type="text"/> mg/dL
SGOT	<input type="text"/> <input type="text"/> <input type="text"/> Units/L	<input type="text"/> <input type="text"/> <input type="text"/> Units/L	
Total Serum Bilirubin	<input type="text"/> <input type="text"/> ! <input type="text"/> mg/dL		

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

- 1 G Yes
- 2 G No



33. Record creatinine clearance mL/min/1.73m² **LLN for your institution**

34. Record GFR ! mL/min ! mL/min

Continue with Question #35

Continue with Question #35

35. What is the patient's primary disease?

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)?
 1 G Yes →
 2 G No

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

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

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

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

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

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

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

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2 Acute Lymphoblastic Leukemia

44. Is the patient in first complete remission (\leq 5% blasts in marrow)?
 1 G Yes →
 2 G No
 ↓

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

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

47. Record the WBC at presentation: / μ L

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

49. Has the patient been diagnosed with B-ALL?
 1 G Yes →
 2 G No
 ↓

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

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

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

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

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

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3 Chronic Myelogenous Leukemia

55. Record date of diagnosis:

M D Y

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

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

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

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

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4 Undifferentiated Leukemia
 5 Bi-phenotypic Leukemia

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

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

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6 Juvenile Myelomonocytic Leukemia

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

63. Record % marrow blasts: %

64. Record peripheral blood monocytes: / μ L

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

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

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

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

69. Record the WBC count at diagnosis: / μ L

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7 Myelo-dysplastic Syndrome

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

- 1 G Refractory Anemia
- 2 G Refractory Anemia with Ringed Sideroblasts
- 3 G Refractory Anemia with Excess Blasts
- 4 G Refractory Anemia with Excess Blasts in Transformation
- 5 G Chronic Myelomonocytic Leukemia
- 6 G 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? 1 Yes 2 No

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

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

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

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11 Acquired Severe Aplastic Anemia

75. Record granulocyte count: cells/ μ L

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

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

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

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12 Hurler's Syndrome

13 Adrenoleukodystrophy

14 Maroteaux-Lamy Syndrome

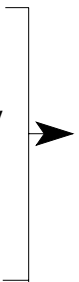
15 Globoid Cell Leukodystrophy

16 Metachromatic Leukodystrophy

17 Fucosidosis

18 Mannosidosis

19 Other Metabolic Disorder, Specify _____



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

b. If LESS THAN or EQUAL to 5 years of age 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? Yes 2 No

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20 Fanconi Anemia

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

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

- a. Severe pancytopenia 1 Yes 2 No
- b. Myelodysplastic syndrome with morphological evidence 1 Yes 2 No
- c. Leukemic transformation 1 Yes 2 No

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- 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: _____

82. Does the patient require cyto-reduction? 1 Yes 2 No
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- 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/mm³ lymphocytes plus monocytes? 1 Yes 2 No
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- 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? 1 Yes 2 No
Skip to Question #85 below

85. Indicate COBLT strata for this recipient:
- 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

