Recipient Baseline Data

Registry Use Only

Sequence Number:

Date Received: __ __ ___  -  __ __ -  __ ___

        YYYY    MM    DD

CIBMTR Center Number:  ___ ___ ___ ___ ___

CIBMTR Research ID:  ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Event date:  ___ ___ ___  —  ___ ___ —  ___ ___

        YYYY    MM    DD
For Transplant Centers that are members of the NMDP network, research blood samples should be collected before initiation of preparative regimen and sent to the NMDP Research Sample Repository. See Transplant Center Manual of Operations for instructions.

**Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)**

1. Does the recipient have a history of smoking or using chewing tobacco?
   - □ Yes – Go to question 2
   - □ No – Go to question 4
   - □ Unknown – Go to question 4

2. Select (check all that apply)
   - □ Chewing tobacco *(including naswar and paan)*
   - □ Cigarettes
   - □ Cigars / pipe
   - □ E-cigarettes
   - □ Marijuana

3. Has the recipient smoked cigarettes within the past year?
   - □ Yes
   - □ No
   - □ Unknown

**Organ Function Prior to the Preparative Regimen (Conditioning)**

Provide last laboratory values recorded for recipient’s organ function (testing done within 30 days prior to the start of the preparative regimen)

4. AST (SGOT)
   - □ Known – Go to question 5
   - □ Unknown – Go to question 7

5. ___ ___ ___ ● ___ ___ □ U/L
   - □ μkat/L
6. Upper limit of normal for your institution: ___ ___ ___ ● ___ ___

7. ALT (SGPT)
   □ Known – Go to question 8
   □ Unknown – Go to question 10

8. ___ ___ ___ ● ___ ___ □ U/L
   □ μkat/L

9. Upper limit of normal for your institution: ___ ___ ___ ● ___ ___

10. FEV1
    □ Known – Go to question 11
    □ Unknown – Go to question 12

11. ___ ___ ___ %

12. DLCO (corrected)
    □ Known – Go to question 13
    □ Unknown – Go to question 14

13. ___ ___ ___ %

14. Total serum bilirubin
    □ Known – Go to question 15
    □ Unknown – Go to question 17

15. ___ ___ ___ ● ___ □ mg/dL
   □ μmol/L

16. Upper limit of normal for your institution: ___ ___ ___ ● ___

17. LDH
    □ Known – Go to question 18
    □ Unknown – Go to question 20

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18. ____ ____ ____ ____ • ____     ☐ U/L
     ☐ µkat/L

19. Upper limit of normal for your institution: ____ ____ ____ ____ • ____ ____

20. Serum creatinine
   ☐ Known – Go to question 21
   ☐ Unknown – Go to question 23

21. ____ ____ ____ ____ • ____     ☐ mg/dL
     ☐ mmol/L
     ☐ µmol/L

22. Upper limit of normal for your institution: ____ ____ ____ ____ • ____ ____

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**Hematologic Findings Prior to the Preparative Regimen (Conditioning)**

**Provide last laboratory values recorded just prior to preparative regimen:**

23. Date CBC tested: ____ ____ ____ ____ — ____ ____ — ____ ____

   YYYY  MM  DD

24. WBC
   ☐ Known – Go to question 25
   ☐ Unknown – Go to question 26

25. ____ ____ ____ ____ ____ • ____     ☐ x 10^9/L (x 10^3/mm^3)
     ☐ x 10^6/L

26. Neutrophils
   ☐ Known – Go to question 27
   ☐ Unknown – Go to question 28

27. ____ ____ %

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28. Lymphocytes
   □ Known – Go to question 29
   □ Unknown – Go to question 30

   29. ___ ___ %

30. Hemoglobin
   □ Known – Go to question 31
   □ Unknown – Go to question 32

   31. ___ ___ ___ • ___ ___ □ g/dL
      □ g/L
      □ mmol/L

32. Hematocrit
   □ Known – Go to question 33
   □ Unknown – Go to question 34

   33. ___ ___ %

34. Were RBCs transfused ≤ 30 days before date of test?
   □ Yes
   □ No

Infection

35. Did the recipient have a history of clinically significant fungal infection (documented or suspected) in the 6 months prior to the start of the preparative regimen?
   □ Yes – Go to question 36
   □ No – Go to question 38

36. Organism
   □ 211 Aspergillus flavus
   □ 212 Aspergillus fumigatus
   □ 213 Aspergillus niger
☐ 215 Aspergillus terreus
☐ 214 Aspergillus ustus
☐ 210 Aspergillus, NOS
☐ 270 Blastomyces (dermatitidis)
☐ 201 Candida albicans
☐ 208 Candida non-albicans
☐ 222 Cryptococcus gattii
☐ 221 Cryptococcus neoformans
☐ 230 Fusarium (all species)
☐ 261 Histoplasma (capsulatum)
☐ 241 Mucorales (all species)
☐ 242 Rhizopus (all species)
☐ 272 Scedosporium (all species)
☐ 240 Zygomycetes, NOS
☐ 503 Suspected fungal infection

37. Date of diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY        MM        DD

Copy questions 36–37 and complete for each infection

Testing for evidence of prior viral exposure / infection

38. Prior viral exposure / infection (check all that apply)
   ☐ HTLV1 antibody
   ☐ Anti-EBV (Epstein-Barr virus antibody)
   ☐ Hepatitis B surface antibody
   ☐ Anti HBe (hepatitis B core antibody) – For hepatitis tests that have a reactive result, also complete HEP form 2047.
   ☐ HBsAg (hepatitis B surface antigen) – For hepatitis tests that have a reactive result, also complete HEP form 2047.
   ☐ Hepatitis B — NAAT – For hepatitis tests that have a reactive result, also complete HEP form 2047.
   ☐ Anti-HCV(hepatitis C antibody) – For hepatitis tests that have a reactive result, also complete HEP form 2047.
   ☐ Hepatitis C – NAAT– For hepatitis tests that have a reactive result, also complete HEP form 2047.
HIV antibody – For HIV tests that have a positive result, also complete HIV form 2048.
HIV - NAAT – For HIV tests that have a positive result, also complete HIV form 2048.
Toxoplasmosis antibody
Not done
Not applicable (all viral testing negative)

Pre-HCT Preparative Regimen (Conditioning)

39. Was a pre-HCT preparative regimen given?
   □ Yes – Go to question 40
   □ No – Go to question 86

40. Specify protocol intent (check only one)
   □ All agents given as outpatient
   □ Some, but not all, agents given as inpatient
   □ All agents given as inpatient

41. Was irradiation performed as part of the pre-HCT preparative regimen?
   □ Yes – Go to question 42
   □ No – Go to question 58

42. What was the radiation field?
   □ Total body – Go to question 54
   □ Total body by intensity modulated radiation therapy (IMRT) Go to question 43
   □ Total lymphoid or nodal regions Go to question 54
   □ Thoracoabdominal region Go to question 54

43. Average organ doses (complete only if organ has been contoured and planned as an avoidance organ)
   □ Known – Go to question 44
   □ Unknown – Go to question 54

44. Heart
   □ Known – Go to question 45
   □ Unknown – Go to question 46
45. Heart: __ __ __ __ . __ □ Gy
   □ cGy

46. Intestine (small and large combined)
   □ Known – Go to question 47
   □ Unknown – Go to question 48

47. Intestine (small and large combined): __ __ __ __ . __ □ Gy
   □ cGy

48. Kidneys (right and left combined)
   □ Known – Go to question 49
   □ Unknown – Go to question 50

49. Kidneys (right and left combined): __ __ __ __ . __ □ Gy
   □ cGy

50. Lung (right and left combined)
   □ Known – Go to question 51
   □ Unknown – Go to question 52

51. Lung (right and left combined): __ __ __ __ . __ □ Gy
   □ cGy

52. Thyroid
   □ Known – Go to question 53
   □ Unknown – Go to question 54

53. Thyroid: __ __ __ __ . __ □ Gy
   □ cGy

54. Total dose: (dose per fraction x total number of fractions) __ __ __ __ __ __ __ __ . __ □ Gy
   □ cGy

55. Date started: __ __ __ __ — __ __ — __ __
   YYYY MM DD
56. Was the radiation fractionated?
   □ Yes – Go to question 57
   □ No – Go to question 58

57. Total number of fractions: ___ ___

58. Was additional radiation given to other sites within 21 days of the HCT?
   □ Yes – Go to question 59
   □ No – Go to question 76

Specify radiation field:

59. CNS
   □ Yes – Go to question 60
   □ No – Go to question 62

60. Total dose: ___ ___ ___ ___ .___ □ Gy
    □ cGy

61. Date started: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY MM DD

62. Gonadal
   □ Yes – Go to question 63
   □ No – Go to question 65

63. Total dose: ___ ___ ___ ___ .___ □ Gy
    □ cGy

64. Date started: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY MM DD

65. Splenic
   □ Yes – Go to question 66
   □ No – Go to question 68
CIBMTR Center Number: ___ ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

66. Total dose: ___ ___ ___ ___. ___ □ Gy

□ cGy

67. Date started: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

68. Site of residual tumor

□ Yes – Go to question 69

□ No – Go to question 72

69. Total dose: ___ ___ ___ ___. ___ □ Gy

□ cGy

70. Date started: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

71. Specify site: ____________________________

72. Other site

□ Yes – Go to question 73

□ No – Go to question 76

73. Total dose: ___ ___ ___ ___. ___ □ Gy

□ cGy

74. Date started: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

75. Specify other site: ____________________________

Indicate the total dose given for the preparative regimen:

76. Drug

□ Bendamustine

□ Busulfan
- Carboplatin
- Carmustine (BCNU)
- CCNU (Lomustine)
- Clofarabine (Clolar)
- Cyclophosphamide (Cytoxan)
- Cytarabine (Ara-C)
- Etoposide (VP-16, VePesid)
- Fludarabine
- Gemcitabine
- Ibritumomab tiuxetan (Zevalin)
- Ifosfamide
- Melphalan (L-Pam)
- Methylprednisolone (Solu-Medrol)
- Pentostatin
- Propylene glycol-free melphalan (Evomela)
- Rituximab (Rituxan)
- Thiotepa
- Tositumomab (Bexxar)
- Treosulfan
- Other drug - go to question 77

77. Specify other drug: __________

78. Total dose: __ __ __ __ : ___ □ mg

79. Date started: ___ ___ ___ ___ – ___ ___ – ___ ___
   YYYY MM DD

80. Dosing weight: ___ __ : ___ □ pounds
   □ kilograms

81. Was the exposure of busulfan measured?
   □ Yes – Go to question 82
   □ No – Go to question 83
82. Overall exposure: __ __ __ __. __ □ AUC (mg x h/L)
    □ AUC (µmol x min/L)
    □ CSS (ng/mL)

83. Was the busulfan dose adjusted based on pharmacokinetics?
    □ Yes – Go to question 84
    □ No – Go to question 85

84. Specify how dose was modified
    □ Increased
    □ Decreased

85. Specify administration (busulfan only)
    □ Oral
    □ IV
    □ Both

Copy and complete questions 76-85 to report more than one drug

Additional Drugs Given in the Peri-transplant Period

86. ALG, ALS, ATG, ATS
    □ Yes – Go to question 87
    □ No – Go to question 94

87. Total dose: ___ ___ ___ ___ ___ mg

88. Absolute lymphocyte count (prior to first dose)
    □ Known – Go to question 89
    □ Unknown – Go to question 90

89. ___ ___ ___ ___ ___ □ x10⁹/L (x10⁹/mm³)

    □ x10⁶/L
90. Date first dose
   □ Known – Go to question 91
   □ Unknown – Go to question 92

91. Date first dose: __ __ __ __ - __ __ - ___ __
      YYYY MM DD

92. Date last dose
   □ Known – Go to question 93
   □ Unknown – Go to question 94

93. Date last dose: __ __ __ __ - __ __ - ___ ___
      YYYY MM DD

94. Alemtuzumab (Campath)
   □ Yes – Go to question 95
   □ No – Go to question 100

95. Total dose: __ __ __ __ . __ □ mg

96. Date first dose
   □ Known – Go to question 97
   □ Unknown – Go to question 98

97. Date first dose: __ __ __ __ - __ __ - __ __
      YYYY MM DD

98. Date last dose
   □ Known – Go to question 99
   □ Unknown – Go to question 100

99. Date last dose: __ __ __ __ - __ __ - __ __
      YYYY MM DD

100. Were clinically significant donor specific anti-HLA antibodies detected?
    □ Yes – Go to question 101
    □ No – Go to question 104
Not done – Go to question 104

101. Was the recipient on a desensitization protocol?
   - Yes – Go to question 102
   - No – Go to question 104

102. Method of desensitization (check all that apply)
   - Bortezomib (Velcade)
   - Daratumumab
   - IVIG
   - Mycophenolate mofetil (CellCept, Myfortic)
   - Plasmapheresis
   - Tacrolimus (Astagraf XL, Prograf, Protopic)
   - Other method – Go to question 103

103. Specify other method: ___________________________

Socioeconomic Information

104. Is the recipient an adult (18 years of age or older) or emancipated minor?
   - Yes – Go to question 105
   - No – Go to question 106

105. Specify the recipient’s marital status
   - Single, never married
   - Married or living with a partner
   - Separated
   - Divorced
   - Widowed
   - Unknown

106. Specify the category which best describes the recipient’s current occupation (If the recipient is not currently employed, check the box which best describes his/her last job)
107. Specify other occupation: ____________________________

108. What is the recipient’s most recent work status? (within the last year)

- Full time
- Part time, by choice and not due to illness
- Part time, due to illness
- Unemployed, by choice and not due to illness
- Unemployed, due to illness
- Medical disability
- Retired
- Unknown

109. What is the highest educational grade the recipient completed?

- No primary education / under school age: no schooling (U.S. equivalent: less than 1st grade education)
☐ Less than primary or elementary education: some formal schooling, but less than a complete primary or elementary education *(U.S. equivalent: more than 1st grade education, but less than 6th grade education)*

☐ Primary or elementary education: beginning at age 5–7 and continuing for about 4–6 years *(U.S. equivalent: starts with 1st grade and ends with 6th grade)*

☐ Lower secondary education: beginning at about age 11–12 and continuing for about 2–3 years *(U.S. equivalent: starts with 7th grade and typically ends with 9th grade)*

☐ Upper secondary education: beginning at about age 15–16 and continuing for about 3 years *(U.S. equivalent: starts with 10th grade and ends with 12th grade)*

☐ Post-secondary, non-tertiary education: programs lasting 6 months–2 years *(U.S. equivalent: vocational programs of study)*

☐ Tertiary education, Type A: programs that provide education that is largely theoretical, lasting 3–4 years *(U.S. equivalent: includes university programs that last 4 years and lead to the award of a bachelor’s degree, and university programs that lead to a master’s degree)*

☐ Tertiary education, Type B: programs that focus on practical, technical or occupational skills with a minimum duration of 2 years of full-time enrollment *(U.S. equivalent: programs typically offered at community colleges that lead to an associate’s degree)*

☐ Advanced research qualification: programs that lead to the award of an advanced post-graduate degree, such as a Ph.D. *(U.S. equivalent: programs devoted to advanced study and original research)*

☐ Unknown

110. Is the recipient currently in school, or was enrolled prior to illness?

☐ Yes

☐ No

☐ Unknown

111. Is the recipient covered by health insurance?

☐ Yes – **Go to question 112**

☐ No – **Go to question 115**

**Specify type of health insurance:**

112. Specify type of health insurance *(check all that apply)*

☐ Private health insurance

☐ National Health Insurance *(Government-sponsored, non-U.S.)*

☐ Medicare *(Government-sponsored, U.S., includes Medicare Advantage plans)*

☐ Medigap *(Must have Medicare coverage)*

☐ Medicaid *(Government-sponsored, U.S.)*
- Children's Health Insurance Program (CHIP)
- Military related health care (TRICARE (CHAMPUS) / VA health care / CHAMP-VA)
- Indian Health Service
- State-sponsored health plan
- Other government program – Go to question 113
- Other health insurance coverage – Go to question 114

113. Specify other government program: ____________________

114. Specify other health insurance: ________________________

115. Specify the recipient’s combined household gross annual income (Include earnings by all family members living in the household, before taxes.) (For U.S. residents only)

- Less than $20,000
- $20,000–$39,999
- $40,000–$59,999
- $60,000–$79,999
- $80,000–$99,999
- $100,000 and over
- Recipient declines to provide this information
- Unknown

116. Number of people living in the household: ___ ___

117. Number of people living in the household under the age of 18: ___ ___