CIBMTR®
A RESEARCH COLLABORATION BETWEEN THE MEDICAL COLLEGE OF WISCONSIN AND NMDP

Recipient Baseline Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number: ___ ___ ___ ___ ___

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

Event date: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

CIBMTR Center Number: ___ ___ ___ ___ _____ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

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***

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: ___ ___ ___ • ___ ___

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. ___ ___ %

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***

Copy and complete questions 36 – 37 to report each infection.

36. Organism

☐ Aspergillus flavus

☐ Aspergillus fumigatus

☐ Aspergillus niger

☐ Aspergillus terreus

☐ Aspergillus ustus

☐ Aspergillus, NOS

☐ Blastomyces (all species, including dermatitidis)

☐ Candida albicans

☐ Candida auris

☐ Candida parapsilosis

- ☐ Candida non-albicans (excluding C. parapsilosis and C. auris)
- ☐ Coccidioides (all species)
- ☐ Cryptococcus gattii
- ☐ Cryptococcus neoformans
- ☐ Fusarium (all species)
- ☐ Histoplasma (all species, including capsulatum)
- ☐ Lomentospora prolificans
- ☐ Mucorales (all species including Rhizopus, Mucor, Rhizomucor, Absidia, Lichtheimia, Cunninghamella species)
- ☐ Pneumocystis (PCP / PJP)
- ☐ Scedosporium (all species)
- ☐ Suspected fungal infection

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

Copy and complete questions 36 – 37 to report each infection.

Testing for evidence of prior viral exposure / infection.

38. Prior viral exposure / infection *(check all that apply)*

- ☐ Anti-EBV (Epstein-Barr virus IgG and / or EBNA antibody)
- ☐ Anti HBc (hepatitis B core antibody) – **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**
- ☐ 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**
- ☐ HbsAb (hepatitis B surface antibody)
- ☐ 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**
- ☐ HTLV1 antibody
- ☐ Toxoplasma IgG (Toxoplasma antibody)
- ☐ Not done
- ☐ Not applicable (all baseline serology / NAATs 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***

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: _____

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

Indicate the total dose given for the preparative regimen:

76. Drug
☐ Bendamustine -***Go to question 78***
☐ Busulfan -***Go to question 78***
☐ Carboplatin -***Go to question 78***
☐ Carmustine (BCNU) -***Go to question 78***
☐ CCNU (Lomustine) -***Go to question 78***
☐ Clofarabine (Clolar) -***Go to question 78***
☐ Cyclophosphamide (Cytoxan) -***Go to question 78***
☐ Cytarabine (Ara-C) -***Go to question 78***
☐ Etoposide (VP-16, VePesid) -***Go to question 78***
☐ Fludarabine -***Go to question 78***
☐ Gemcitabine -***Go to question 78***

- ☐ Ibritumomab tiuxetan (Zevalin) -***Go to question 78***
- ☐ Ifosfamide -***Go to question 78***
- ☐ Melphalan (L-Pam) -***Go to question 78***
- ☐ Methylprednisolone (Solu-Medrol) -***Go to question 78***
- ☐ Pentostatin -***Go to question 78***
- ☐ Propylene glycol-free melphalan (Evomela) -***Go to question 78***
- ☐ Rituximab (Rituxan) -***Go to question 78***
- ☐ Thiotepa -***Go to question 78***
- ☐ Tositumomab (Bexxar) -***Go to question 78***
- ☐ Treosulfan -***Go to question 78***
- ☐ 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. __ __ __ __ __ __ __ ☐ x10^9/L (x10^3/mm^3)
☐ x10^6/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) – ***Go to question 104***

☐ Daratumumab – ***Go to question 104***

☐ IVIG – ***Go to question 104***

☐ Mycophenolate mofetil (CellCept, Myfortic) – ***Go to question 104***

☐ Plasmapheresis – ***Go to question 104***

☐ Rituximab (Rituxan) – ***Go to question 104***

☐ Tacrolimus (Astagraft XL, Prograf, Protopic) – ***Go to question 104***

☐ Other method– ***Go to question 103***

103. Specify other method: _____

Socioeconomic Information

104. 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)*

- ☐ Professional, technical, or related occupation *(e.g., teacher / professor, nurse / physician, lawyer, engineer)* – ***Go to question 106***
- ☐ Manager, administrator, or proprietor *(e.g., sales manager, real estate agent, postmaster)* – ***Go to question 106***
- ☐ Clerical or related occupation *(e.g., secretary, clerk, mail carrier)* – ***Go to question 106***
- ☐ Sales occupation *(e.g., sales associate, demonstrator, agent, broker)* – ***Go to question 106***
- ☐ Service occupation *(e.g., police officer, cook, hairdresser)* – ***Go to question 106***
- ☐ Skilled craft or related occupation *(e.g., carpenter, repair technician, telephone line worker)* – ***Go to question 106***
- ☐ Equipment / vehicle operator or related occupation *(e.g., driver, railroad brakeman, sewer worker)* – ***Go to question 106***
- ☐ Laborer *(e.g., helper, longshoreman, warehouse worker)* – ***Go to question 106***
- ☐ Farmer *(e.g., owner, manager, operator, tenant)* – ***Go to question 106***
- ☐ Member of the military – ***Go to question 106***
- ☐ Homemaker – ***Go to question 106***
- ☐ Student – ***Go to question 106***
- ☐ Under school age – ***Go to question 107***
- ☐ Not previously employed – ***Go to question 106***
- ☐ Unknown – ***Go to question 106***
- ☐ Other – ***Go to question 105***

105. Specify other occupation:_____

106. 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

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

- ☐ Yes
- ☐ No
- ☐ Unknown