

Form 2000 R6.0: Recipient Baseline Data

Center: _____

CRID: _____

Key Fields

Sequence Number: _____

Date Received: ____-____-____

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: ____-____-____

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

Questions: 1 - 3

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.

1 Does the recipient have a history of smoking or using chewing tobacco?

Yes No Unknown

2 Select (check all that apply)

Chewing tobacco

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)

Questions: 4 - 22

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 Unknown

5 _____ U/L μ kat/L

6 Upper limit of normal for your institution: _____

7 ALT (SGPT)

Known Unknown

8 _____ U/L μ kat/L

9 Upper limit of normal for your institution: _____

10 FEV1

Known Unknown

11 _____ %

12 DLCO (corrected)

Known Unknown

13 _____ %

14 Total serum bilirubin

Known Unknown

15 _____ mg/dL μ mol/L

16 Upper limit of normal for your institution: _____

17 LDH

Known Unknown

18 _____ U/L μ kat/L

19 Upper limit of normal for your institution: _____

20 Serum creatinine

Known Unknown

21 _____ mg/dL mmol/L μ mol/L

22 Upper limit of normal for your institution: _____

Hematologic Findings Prior to the Preparative Regimen (Conditioning)

Questions: 23 - 34

Provide last laboratory values recorded just prior to preparative regimen:

23 Date CBC tested: ____-____-____

24 WBC

Known Unknown

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25 _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

26 Neutrophils
 Known Unknown

27 _____ %

28 Lymphocytes
 Known Unknown

29 _____ %

30 Hemoglobin
 Known Unknown

31 _____ g/dL g/L mmol/L

32 Hematocrit
 Known Unknown

33 _____ %

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

Infection

Questions: 35 - 38

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 no

Fungal Infection (1)

Questions: 36 - 37

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: ____ - ____ - ____

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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 HBc (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)

Questions: 39 - 85

39 Was a pre-HCT preparative regimen given?

- yes no

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 no

42 What was the radiation field?

- Total body
 Total body by intensity-modulated radiation therapy (IMRT)
 Total lymphoid or nodal regions
 Thoracoabdominal region

43 Average organ doses (complete only if organ has been contoured and planned as an avoidance organ)

- Known Unknown

44 Heart

- Known Unknown

45 Heart: _____ Gy cGy

46 Intestine (small and large combined)

- Known Unknown

47 Intestine: (small and large combined) _____ Gy cGy

48 Kidneys (right and left combined)

- Known Unknown

49 Kidneys: (right and left combined) _____ Gy cGy

50 Lung (right and left combined)

- Known Unknown

51 Lung: (right and left combined) _____ Gy cGy

52 Thyroid

- Known Unknown

53 Thyroid: _____ Gy cGy

54 Total dose: (dose per fraction x total number of fractions) _____ Gy cGy

55 Date started: ____ - ____ - ____

56 Was the radiation fractionated?

- yes no

57 Total number of fractions: _____

58 Was additional radiation given to other sites within 21 days of the HCT?

- yes no

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Specify radiation field:

59 CNS

yes no

60 Total dose: _____ Gy cGy

61 Date started: _____ - _____ - _____

62 Gonadal

yes no

63 Total dose: _____ Gy cGy

64 Date started: _____ - _____ - _____

65 Splenic

yes no

66 Total dose: _____ Gy cGy

67 Date started: _____ - _____ - _____

68 Site of residual tumor

yes no

69 Total dose: _____ Gy cGy

70 Date started: _____ - _____ - _____

71 Specify site: _____

72 Other site

yes no

73 Total dose: _____ Gy cGy

74 Date started: _____ - _____ - _____

75 Specify other site: _____

Preparative Regimen Drugs (1)

Questions: 76 - 85

Indicate the total dose given for the preparative regimen:

76 Drug _____

77 Specify other drug: _____

78 Total dose: _____ mg

79 Date started: _____ - _____ - _____

80 Dosing weight: _____ pounds kilograms

81 Was the exposure of busulfan measured?

Yes No

82 Overall exposure _____ AUC (mg x h/L) AUC ($\mu\text{mol} \times \text{min/L}$) CSS (ng/mL)

83 Was the busulfan dose adjusted based on the pharmacokinetics?

yes no

84 Specify how dose was modified

Increased Decreased

85 Specify administration (*busulfan only*)

Oral IV Both

Additional Drugs Given in the Peri-transplant Period

Questions: 86 - 103

86 ALG, ALS, ATG, ATS

yes no

87 Total dose: _____ mg

88 Absolute lymphocyte count (*prior to first dose*)

Known Unknown

89 _____ $\times 10^9/\text{L}$ ($\times 10^3/\text{mm}^3$)

$\times 10^6/\text{L}$

90 Date first dose:

Known Unknown

91 Date first dose: _____ - _____ - _____

92 Date last dose:

Known Unknown

93 Date last dose: _____ - _____ - _____

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94 Alemtuzumab (Campath)

yes no

95 Total dose: _____ mg

96 Date first dose:

Known Unknown

97 Date first dose: ____ - ____ - ____

98 Date last dose:

Known Unknown

99 Date last dose: ____ - ____ - ____

100 Were clinically significant donor specific anti-HLA antibodies detected?

Yes No Not done

101 Was the recipient on a desensitization protocol?

Yes No

102 Method of desensitization (check all that apply)

- Bortezomib (Velcade)
- Daratumumab
- IMG
- Mycophenolate mofetil (CellCept, Myfortic)
- Plasmapheresis
- Rituximab (Rituxan)
- Tacrolimus (Astagraft XL, Prograf, Protopic)
- Other method

103 Specify other method: _____

Socioeconomic Information

Questions: 104 - 117

104 Is the recipient an adult (18 years of age or older) or emancipated minor?

yes no

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.)

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

107 Specify other occupation: _____

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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 : 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 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 education 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 : programs that lead to the award of an advanced post-graduate degree, such as a Ph.D. (U.S. equivalent: programs devoted to advanced qualification 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 no

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
- Other health insurance coverage

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: _____

First Name: _____

Last Name: _____

E-mail address: _____

Date: ____ - ____ - ____