

# Form 2000 R5.0: 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   $\mu$ kat/L

6 Upper limit of normal for your institution: \_\_\_\_\_

7 ALT (SGPT)

Known  Unknown

8 \_\_\_\_\_  U/L   $\mu$ 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   $\mu$ mol/L

16 Upper limit of normal for your institution: \_\_\_\_\_

17 LDH

Known  Unknown

18 \_\_\_\_\_  U/L   $\mu$ kat/L

19 Upper limit of normal for your institution: \_\_\_\_\_

20 Serum creatinine

Known  Unknown

21 \_\_\_\_\_  mg/dL  mmol/L   $\mu$ 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 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/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: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

## 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

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**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

**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: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

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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: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

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

101 Was the recipient on a desensitization protocol?

Yes  No

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## 102 Method of desensitization (check all that apply)

- Bortezomib (Velcade)
- Daratumumab
- MG
- 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: \_\_\_\_\_

### 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

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109 What is the highest educational grade the recipient completed?

- No primary education / under school age : no schooling (U.S. equivalent: less than 1<sup>st</sup> 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 1<sup>st</sup> grade education, but less than 6<sup>th</sup> grade education)
- Primary or elementary education : beginning at age 5–7 and continuing for about 4–6 years (U.S. equivalent: starts with 1<sup>st</sup> grade and ends with 6<sup>th</sup> grade)
- Lower secondary education : beginning at about age 11–12 and continuing for about 2–3 years (U.S. equivalent: starts with 7<sup>th</sup> grade and typically ends with 9<sup>th</sup> grade)
- Upper secondary education : beginning at about age 15–16 and continuing for about 3 years (U.S. equivalent: starts with 10<sup>th</sup> grade and ends with 12<sup>th</sup> 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  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: \_\_\_\_ - \_\_\_\_ - \_\_\_\_