Pre-Transplant Essential Data

CIBMTR Use Only

Sequence Number:

Date Received:

OMB No: 0915-0310
Expiration Date: 10/31/2022

Center Identification

CIBMTR Center Number: ___ ___ ___ ___ ___

EBMT Code (CIC): ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Recipient Identification

CIBMTR Research ID (CRID): ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Event date: __ __ __ __ / __ __ / __ __

YYYY MM DD

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

Recipient Information

1. Date of birth: ___ ___ ___ ___ — ___ ___ — ___ ___
   YYYY MM DD

2. Sex
   - ☐ Male
   - ☐ Female

3. Ethnicity
   - ☐ Hispanic or Latino
   - ☐ Not Hispanic or Latino
   - ☐ Not applicable *(not a resident of the USA)*
   - ☐ Unknown

4. Race *(check all that apply)*
   - ☐ White – ***Go to question 5***
   - ☐ Black or African American– ***Go to question 5***
   - ☐ Asian– ***Go to question 5***
   - ☐ American Indian or Alaska Native– ***Go to question 5***
   - ☐ Native Hawaiian or Other Pacific Islander– ***Go to question 5***
   - ☐ Not reported – ***Go to question 6***
   - ☐ Unknown– ***Go to question 6***

5. Race detail *(check all that apply)*
   - ☐ Eastern European
   - ☐ Mediterranean
   - ☐ Middle Eastern
   - ☐ North Coast of Africa
   - ☐ North American
   - ☐ Northern European
   - ☐ Western European
   - ☐ White Caribbean
   - ☐ White South or Central American
   - ☐ Other White
   - ☐ African
   - ☐ African American

- ☐ Black Caribbean
- ☐ Black South or Central American
- ☐ Other Black
- ☐ Alaskan Native or Aleut
- ☐ North American Indian
- ☐ American Indian, South or Central America
- ☐ Caribbean Indian
- ☐ South Asian
- ☐ Filipino (Pilipino)
- ☐ Japanese
- ☐ Korean
- ☐ Chinese
- ☐ Vietnamese
- ☐ Other Southeast Asian
- ☐ Guamanian
- ☐ Hawaiian
- ☐ Samoan
- ☐ Other Pacific Islander
- ☐ Unknown

6. Country of primary residence

- ☐ Afghanistan
- ☐ Aland Islands
- ☐ Albania
- ☐ Algeria
- ☐ American Samoa
- ☐ Andorra
- ☐ Angola
- ☐ Anguilla
- ☐ Antarctica
- ☐ Antigua and Barbuda
- ☐ Argentina
- ☐ Armenia
- ☐ Aruba
- ☐ Australia
- ☐ Austria
- ☐ Ghana
- ☐ Gibraltar
- ☐ Greece
- ☐ Greenland
- ☐ Grenada
- ☐ Guadeloupe
- ☐ Guam
- ☐ Guatemala
- ☐ Guernsey
- ☐ Guinea
- ☐ Guinea-Bissau
- ☐ Guyana
- ☐ Haiti
- ☐ Heard Island and McDonald Islands
- ☐ Holy See
- ☐ Palau
- ☐ Palestine, State of
- ☐ Panama
- ☐ Papua New Guinea
- ☐ Paraguay
- ☐ Peru
- ☐ Philippines
- ☐ Pitcairn Islands
- ☐ Poland
- ☐ Portugal
- ☐ Puerto Rico
- ☐ Qatar
- ☐ Reunion
- ☐ Romania
- ☐ Russia

- ☐ Azerbaijan
- ☐ Bahamas
- ☐ Bahrain
- ☐ Bangladesh
- ☐ Barbados
- ☐ Belarus
- ☐ Belgium
- ☐ Belize
- ☐ Benin
- ☐ Bermuda
- ☐ Bhutan
- ☐ Bolivia
- ☐ Bonaire, Sint Eustatius and Saba
- ☐ Bosnia and Herzegovina
- ☐ Botswana
- ☐ Bouvet Island
- ☐ Brazil - G***o to question 7***
- ☐ British Indian Ocean Territory
- ☐ British Virgin Islands
- ☐ Brunei Darussalam
- ☐ Bulgaria
- ☐ Burkina Faso
- ☐ Burundi
- ☐ Cambodia
- ☐ Cameroon
- ☐ Canada - G***o to question 8***
- ☐ Cape Verde
- ☐ Cayman Islands
- ☐ Central African Republic
- ☐ Chad
- ☐ Chile
- ☐ China
- ☐ Christmas Island
- ☐ Cocos (Keeling) Islands
- ☐ Colombia
- ☐ Honduras
- ☐ Hong Kong
- ☐ Hungary
- ☐ Iceland
- ☐ India
- ☐ Indonesia
- ☐ Iran
- ☐ Iraq
- ☐ Ireland
- ☐ Isle of Man
- ☐ Israel
- ☐ Italy
- ☐ Jamaica
- ☐ Japan
- ☐ Jersey
- ☐ Jordan
- ☐ Kazakhstan
- ☐ Kenya
- ☐ Kiribati
- ☐ Kuwait
- ☐ Kyrgyzstan
- ☐ Laos
- ☐ Latvia
- ☐ Lebanon
- ☐ Lesotho
- ☐ Liberia
- ☐ Libya
- ☐ Liechtenstein
- ☐ Lithuania
- ☐ Luxembourg
- ☐ Macau
- ☐ Macedonia
- ☐ Madagascar
- ☐ Malawi
- ☐ Malaysia
- ☐ Maldives
- ☐ Rwanda
- ☐ Saint Barthelemy
- ☐ Saint Helena
- ☐ Saint Kitts and Nevis
- ☐ Saint Lucia
- ☐ Saint Martin, French
- ☐ Saint Pierre and Miquelon
- ☐ Saint Vincent and the Grenadines
- ☐ Samoa
- ☐ San Marino
- ☐ Sao Tome and Principe
- ☐ Saudi Arabia
- ☐ Senegal
- ☐ Serbia
- ☐ Seychelles
- ☐ Sierra Leone
- ☐ Singapore
- ☐ Sint Maarten, Dutch
- ☐ Slovak Republic
- ☐ Slovenia
- ☐ Solomon Islands
- ☐ Somalia
- ☐ South Africa
- ☐ South Georgia and the South Sandwich Islands
- ☐ South Korea
- ☐ South Sudan
- ☐ Spain
- ☐ Sri Lanka
- ☐ Sudan
- ☐ Suriname
- ☐ Svalbard and Jan Mayen
- ☐ Swaziland
- ☐ Sweden
- ☐ Switzerland
- ☐ Syria

- ☐ Comoros
- ☐ Congo, Democratic Republic of the
- ☐ Congo, Republic of the
- ☐ Cook Islands
- ☐ Costa Rica
- ☐ Cote d'Ivoire
- ☐ Croatia
- ☐ Cuba
- ☐ Curacao
- ☐ Cyprus
- ☐ Czech Republic
- ☐ Denmark
- ☐ Djibouti
- ☐ Dominica
- ☐ Dominican Republic
- ☐ Ecuador
- ☐ Egypt
- ☐ El Salvador
- ☐ Equatorial Guinea
- ☐ Eritrea
- ☐ Estonia
- ☐ Ethiopia
- ☐ Falkland Islands
- ☐ Faroe Islands
- ☐ Fiji
- ☐ Finland
- ☐ France
- ☐ French Guiana
- ☐ French Polynesia
- ☐ French Southern Territories
- ☐ Gabon
- ☐ Gambia
- ☐ Georgia
- ☐ Germany
- ☐ Mali
- ☐ Malta
- ☐ Marshall Islands
- ☐ Martinique
- ☐ Mauritania
- ☐ Mauritius
- ☐ Mayotte
- ☐ Mexico
- ☐ Micronesia
- ☐ Moldova
- ☐ Monaco
- ☐ Mongolia
- ☐ Montenegro
- ☐ Montserrat
- ☐ Morocco
- ☐ Mozambique
- ☐ Myanmar
- ☐ Namibia
- ☐ Nauru
- ☐ Nepal
- ☐ Netherlands
- ☐ Netherlands Antilles
- ☐ New Caledonia
- ☐ New Zealand
- ☐ Nicaragua
- ☐ Niger
- ☐ Nigeria
- ☐ Niue
- ☐ Norfolk Island
- ☐ North Korea
- ☐ Northern Mariana Islands
- ☐ Norway
- ☐ Oman
- ☐ Pakistan
- ☐ Taiwan
- ☐ Tajikistan
- ☐ Tanzania
- ☐ Thailand
- ☐ Timor-Leste
- ☐ Togo
- ☐ Tokelau
- ☐ Tonga
- ☐ Trinidad and Tobago
- ☐ Tunisia
- ☐ Turkey
- ☐ Turkmenistan
- ☐ Turks and Caicos Islands
- ☐ Tuvalu
- ☐ Uganda
- ☐ Ukraine
- ☐ United Arab Emirates
- ☐ United Kingdom (England, Wales, Scotland, Northern Ireland)
- ☐ United States - G***o to question 9***
- ☐ United States Minor Outlying Islands
- ☐ United States Virgin Islands
- ☐ Uruguay
- ☐ Uzbekistan
- ☐ Vanuatu
- ☐ Venezuela
- ☐ Vietnam
- ☐ Wallis and Futuna Islands
- ☐ Western Sahara
- ☐ Yemen
- ☐ Zambia
- ☐ Zimbabwe

7. State of residence of recipient *(for residents of Brazil)* _____ - ***Go to question 10***

- ☐ Acre
- ☐ Alagoas
- ☐ Amapá
- ☐ Amazonas
- ☐ Bahia
- ☐ Ceará
- ☐ Distrito Federal
- ☐ Espírito Santo
- ☐ Goiás
- ☐ Maranhão
- ☐ Mato Grosso
- ☐ Mato Grosso do Sul
- ☐ Minas Gerais
- ☐ Pará
- ☐ Paraíba
- ☐ Paraná
- ☐ Pernambuc
- ☐ Piauí
- ☐ Rio de Janeiro
- ☐ Rio Grande do Norte
- ☐ Rio Grande do Sul
- ☐ Rondônia
- ☐ Roraima
- ☐ Santa Catarina
- ☐ São Paulo
- ☐ Sergipe
- ☐ Tocantins

8. Province or territory of residence of recipient *(for residents of Canada)* _____- ***Go to question 10***

Provinces

- ☐ Alberta
- ☐ British Columbia
- ☐ Manitoba
- ☐ New Brunswick
- ☐ Newfoundland and Labrador
- ☐ Nova Scotia
- ☐ Ontario
- ☐ Prince Edward Island
- ☐ Quebec
- ☐ Saskatchewan

Territories

- ☐ Northwest Territories
- ☐ Nunavut
- ☐ Yukon

9. State of residence of recipient *(for residents of USA)* _____

- ☐ Alabama
- ☐ Alaska
- ☐ Arizona
- ☐ Arkansas
- ☐ California
- ☐ Colorado
- ☐ Connecticut
- ☐ Delaware
- ☐ District of Columbia
- ☐ Kentucky
- ☐ Louisiana
- ☐ Maine
- ☐ Maryland
- ☐ Massachusetts
- ☐ Michigan
- ☐ Minnesota
- ☐ Mississippi
- ☐ Missouri
- ☐ North Dakota
- ☐ Ohio
- ☐ Oklahoma
- ☐ Oregon
- ☐ Pennsylvania
- ☐ Rhode Island
- ☐ South Carolina
- ☐ South Dakota
- ☐ Tennessee

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

☐ Florida	☐ Montana	☐ Texas
☐ Georgia	☐ Nebraska	☐ Utah
☐ Hawaii	☐ Nevada	☐ Vermont
☐ Idaho	☐ New Hampshire	☐ Virginia
☐ Illinois	☐ New Jersey	☐ Washington
☐ Indiana	☐ New Mexico	☐ West Virginia
☐ Iowa	☐ New York	☐ Wisconsin
☐ Kansas	☐ North Carolina	☐ Wyoming

10. NMDP Recipient ID (RID): __ __ __ __ __ __ __

11. Zip or postal code for place of recipient's residence *(USA and Canada recipients only)*: ___ ___ ___ ___ ___ _____ ___ ___ ___

12. Specify blood type *(of recipient)* **(For allogeneic HCTs only)**

- ☐ A
- ☐ B
- ☐ AB
- ☐ O

13. Specify Rh factor *(of recipient)* **(For allogeneic HCTs only)**

- ☐ Positive
- ☐ Negative

14. Has the recipient signed an IRB / ethics committee (or similar body) approved consent form to donate research blood samples to the NMDP / CIBMTR? **(For allogeneic HCTs only)**

- ☐ Yes *(recipient consented)* – ***Go to question 15***
- ☐ No *(recipient declined)* - ***Go to question 18***
- ☐ Not approached - ***Go to question 18***
- ☐ Not applicable *(center not participating)* - ***Go to question 18***

15. Date form was signed: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

16. Did the recipient submit a research sample to the NMDP/CIBMTR repository? **(Related donors only)**

- ☐ Yes – ***Go to question 17***

☐ No – ***Go to question 18***

17. Research sample recipient ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

18. Is the recipient participating in a clinical trial? *(clinical trial sponsors that use CIBMTR forms to capture outcomes data)*

☐ Yes - ***Go to question 19***

☐ No – ***Go to question 24***

19. Study Sponsor

☐ BMT CTN ***– Go to question 21***

☐ RCI BMT ***– Go to question 21***

☐ PIDTC ***– Go to question 21***

☐ USIDNET ***– Go to question 22***

☐ COG ***– Go to question 22***

☐ Other sponsor ***– Go to question 20***

20. Specify other sponsor: _____ ***- Go to question 22***

21. Study ID Number: _____

22. Subject ID: _____

23. Specify the ClinicalTrials.gov identification number: NCT __ __ __ __ __ __ __ __

Copy questions 19-23 to report participation in more than one study.

Hematopoietic Cellular Transplant (HCT) and Cellular Therapy

24. Is a subsequent HCT planned as part of the overall treatment protocol? *(not as a reaction to post-HCT disease assessment)* **(For autologous HCTs only)**

☐ Yes – ***Go to question 25***

☐ No – ***Go to question 26***

25. Specify subsequent HCT planned

☐ Autologous

☐ Allogeneic

26. Has the recipient ever had a prior HCT?

☐ Yes – ***Go to question 27***

☐ No – ***Go to question 38***

27. Specify the number of prior HCTs: ___ ___

28. Were all prior HCTs reported to the CIBMTR?

- ☐ Yes – ***Go to question 33***
- ☐ No – ***Go to question 29***
- ☐ Unknown – ***Go to question 33***

Copy and complete questions 29- 32 to report all prior HCTs that have not yet been reported to the CIBMTR

29. Date of the prior HCT: ___ ___ ___ ___ — ___ ___ — ___ ___ ☐ Date estimated
YYYY MM DD

30. Was the prior HCT performed at a different institution?

- ☐ Yes – ***Go to question 31***
- ☐ No – ***Go to question 32***

Specify the institution that performed the last HCT

31. Name: _____

City:_____

State: _____

Country: _____

32. What was the HPC source for the prior HCT? *(check all that apply)*

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

33. Reason for current HCT

- ☐ Graft failure / insufficient hematopoietic recovery – ***Go to question 34***
- ☐ Persistent primary disease– ***Go to question 38***
- ☐ Recurrent primary disease– ***Go to question 35***
- ☐ Planned subsequent HCT, per protocol– ***Go to question 38***
- ☐ New malignancy *(including PTLD and EBV lymphoma)* – ***Go to question 36***
- ☐ Insufficient chimerism– ***Go to question 38***
- ☐ Other– ***Go to question 37***

34. Date of graft failure / rejection: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 38***

35. Date of relapse: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 38***
YYYY MM DD

36. Date of secondary malignancy: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 38***
YYYY MM DD

37. Specify other reason: _____ - ***Go to question 38***

38. Has the recipient ever had a prior cellular therapy? *(do not include DLIs)*

☐ Yes – ***Go to question 39***

☐ No – ***Go to question 44***

☐ Unknown– ***Go to question 44***

39. Were all prior cellular therapies reported to the CIBMTR?

☐ Yes – ***Go to question 44***

☐ No – ***Go to question 40***

☐ Unknown– ***Go to question 44***

Copy and complete questions 40-43 to report all prior cellular therapies that have not yet been reported to the CIBMTR

40. Date of the prior cellular therapy: __ __ __ __ -- __ __ -- __ __
YYYY MM DD

41. Was the cellular therapy performed at a different institution?

☐ Yes – ***Go to question 42***

☐ No – ***Go to question 43***

42. Name: _____
City: _____
State: _____
Country: _____

43. Specify the source(s) for the prior cellular therapy *(check all that apply)*

☐ Autologous

☐ Allogeneic, unrelated

☐ Allogeneic, related

Donor Information

44. Multiple donors?

- ☐ Yes – ***Go to question 45***
- ☐ No - ***Go to question 46***

45. Specify number of donors: ___ ___

To report more than one donor, copy questions 46-82 and complete for each donor.

46. Specify donor

- ☐ Autologous
- ☐ Allogeneic, related
- ☐ Allogeneic, unrelated

47. Specify product type *(check all that apply)*

- ☐ Bone marrow
- ☐ PBSC
- ☐ Single cord blood unit
- ☐ Other product– ***Go to question 48***

48. Specify other product: _____

49. Is the product genetically modified? ***If autologous, go to question 77. If allogeneic related, go to question 50. If allogeneic unrelated, go to question 54.***

- ☐ Yes
- ☐ No

50. Specify the related donor type

- ☐ Syngeneic *(monozygotic twin)* – ***Go to question 55***
- ☐ HLA-identical sibling *(may include non-monozygotic twin)* ***– Go to question 55***
- ☐ HLA-matched other relative *(does NOT include a haplo-identical donor)* - ***Go to question 51***
- ☐ HLA-mismatched relative– ***Go to question 51***

51. Specify the biological relationship of the donor to the recipient

- ☐ Mother
- ☐ Father
- ☐ Child
- ☐ Sibling

- ☐ Fraternal twin
- ☐ Maternal aunt
- ☐ Maternal uncle
- ☐ Maternal cousin
- ☐ Paternal aunt
- ☐ Paternal uncle
- ☐ Paternal cousin
- ☐ Grandparent
- ☐ Grandchild
- ☐ Other biological relative – ***Go to question 52***

52. Specify other biological relative: _____– ***Go to question 53***

53. Degree of mismatch *(related donors only)*
    - ☐ HLA-mismatched 1 allele– ***Go to question 55***
    - ☐ HLA-mismatched ≥2 alleles *(does include haplo-identical donor)* – ***Go to question 55***

54. Specify unrelated donor type
    - ☐ HLA matched unrelated
    - ☐ HLA mismatched unrelated

55. Did NMDP / Be the Match facilitate the procurement, collection, or transportation of the product?
    - ☐ Yes
    - ☐ No

56. Was this donor used for any prior HCTs? *(for this recipient)*
    - ☐ Yes
    - ☐ No

57. NMDP cord blood unit ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ – ***Go to question 72***

58. Non-NMDP unrelated donor ID: *(not applicable for related donors)*

    ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ - ***Go to question 63***

59. Non-NMDP cord blood unit ID: *(include related and autologous CBUs)*

    ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ - ***Go to question 61***

60. Global Registration Identifier for Donors (GRID): __

NMDP donor, go to question 72

Non-NMDP unrelated donor, go to question 63

61. Is the CBU ID also the ISBT DIN number?

- ☐ Yes – ***Go to question 63***
- ☐ No – ***Go to question 62***
- ☐ Unknown– ***Go to question 63***

62. Specify the ISBT DIN number: _____

63. Registry or UCB Bank ID: ___ ___ ___ ___ - ***If 'Other registry' go to 64, otherwise go to question 65***

64. Specify other Registry or UCB Bank: _____ - ***Go to question 65***

65. Donor date of birth

- ☐ Known – ***Go to question 66***
- ☐ Unknown – ***Go to question 67***

66. Donor date of birth: ___ ___ ___ ___ — ___ ___ — ___ ___ - ***Go to question 69***

YYYY MM DD

67. Donor age

- ☐ Known – ***Go to question 68***
- ☐ Unknown – ***Go to question 69***

68. Donor age: ___ ___ ☐ Months *(use only if less than 1 year old)* ☐ Years

69. Donor sex

- ☐ Male
- ☐ Female

70. Specify blood type *(donor)* **(non-NMDP allogeneic donors only)**

- ☐ A
- ☐ B
- ☐ AB
- ☐ O

71. Specify Rh factor *(donor)* **(non-NMDP allogeneic donors only)**

- ☐ Positive
- ☐ Negative

72. Donor CMV-antibodies *(IgG or Total)* **(Allogeneic HCTs only)**

- ☐ Reactive
- ☐ Non-reactive
- ☐ Indeterminate
- ☐ Not done
- ☐ Not applicable *(cord blood unit)*

73. Has the donor signed an IRB / ethics committee (or similar body) approved consent form to donate research blood samples to the NMDP / CIBMTR? **(Related donors only)**

- ☐ Yes *(donor consented)* – ***Go to question 74***
- ☐ No *(donor declined)* - ***Go to question 77***
- ☐ Not approached - ***Go to question 77***
- ☐ Not applicable *(center not participating)* - ***Go to question 77***

74. Date form was signed: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

75. Did the donor submit a research sample to the NMDP/CIBMTR repository? **(Related donors only)**

- ☐ Yes – ***Go to question 76***
- ☐ No – ***Go to question 77***

76. Research sample donor ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

77. Specify number of products infused from this donor: ___ ___

78. Specify the number of these products intended to achieve hematopoietic engraftment: ___ ___

Questions 79-80 are for autologous HCT recipients only.

79. What agents were used to mobilize the autologous recipient for this HCT? *(check all that apply)*

- ☐ G-CSF (filgrastim, Neupogen)
- ☐ Pegylated G-CSF (pegfilgrastim, Neulasta)
- ☐ Plerixafor (Mozobil)
- ☐ Combined with chemotherapy

☐ Anti-CD20 (rituximab, Rituxan)

☐ Other agent– ***Go to question 80***

80. Specify other agent: _____

81. Name of product: (gene therapy recipients)

☐ Other name

82. Specify other name: _____

To report more than one donor, copy questions 46-82 and complete for each donor.

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

83. What scale was used to determine the recipient's functional status?

☐ Karnofsky *(recipient age ≥ 16 years)* – ***Go to question 84***

☐ Lansky *(recipient age ≥ 1 year and < 16 years)* – ***Go to question 85***

Performance score prior to the preparative regimen:

84. Karnofsky Scale *(recipient age ≥ 16 years)*

☐ 100 Normal; no complaints; no evidence of disease - ***Go to question 86***

☐ 90 Able to carry on normal activity - ***Go to question 86***

☐ 80 Normal activity with effort - ***Go to question 86***

☐ 70 Cares for self; unable to carry on normal activity or to do active work - ***Go to question 86***

☐ 60 Requires occasional assistance but is able to care for most needs - ***Go to question 86***

☐ 50 Requires considerable assistance and frequent medical care - ***Go to question 86***

☐ 40 Disabled; requires special care and assistance - ***Go to question 86***

☐ 30 Severely disabled; hospitalization indicated, although death not imminent - ***Go to question 86***

☐ 20 Very sick; hospitalization necessary - ***Go to question 86***

☐ 10 Moribund; fatal process progressing rapidly - ***Go to question 86***

85. Lansky Scale (recipient age ≥ 1 year and < 16 years)

☐ 100 Fully active

☐ 90 Minor restriction in physically strenuous play

☐ 80 Restricted in strenuous play, tires more easily, otherwise active

☐ 70 Both greater restrictions of, and less time spent in, active play

- ☐ 60 Ambulatory up to 50% of time, limited active play with assistance / supervision
- ☐ 50 Considerable assistance required for any active play; fully able to engage in quiet play
- ☐ 40 Able to initiate quiet activities
- ☐ 30 Needs considerable assistance for quiet activity
- ☐ 20 Limited to very passive activity initiated by others (e.g., TV)
- ☐ 10 Completely disabled, not even passive play

86. Recipient CMV-antibodies (IgG or Total)

- ☐ Reactive
- ☐ Non-reactive
- ☐ Indeterminate
- ☐ Not done

Comorbid Conditions

87. Has the patient been infected with COVID-19 (SARS-CoV-2) based on a positive test result at any time prior to the start of the preparative regimen / infusion?

- ☐ Yes – ***Go to question 88***
- ☐ No – ***Go to question 90***

88. Did the patient require hospitalization for management of COVID-19 (SARS-CoV-2) infection?

- ☐ Yes – ***Go to question 89***
- ☐ No – ***Go to question 90***

89. Was mechanical ventilation given for COVID-19 (SARS-CoV-2) infection?

- ☐ Yes
- ☐ No

90. Is there a history of mechanical ventilation (excluding COVID-19 (SARS-CoV-2))?

- ☐ Yes
- ☐ No

91. Is there a history of invasive fungal infection?

- ☐ Yes
- ☐ No

92. Glomerular filtration rate (GFR) before start of preparative regimen **(pediatric only)**

- ☐ Known- ***Go to question 93***
- ☐ Unknown- ***Go to question 94***

93. Glomerular filtration rate (GFR): __ __ __ mL/min/1.73^2

94. Does the recipient have known complex congenital heart disease? *(corrected or uncorrected) (excluding simple ASD, VSD, or PDA repair)* ***(pediatric only)***

- ☐ Yes
- ☐ No

95. Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)? *(Source: Sorror, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. Blood, 121(15), 2854-2863.)*

- ☐ Yes- ***Go to question 96***
- ☐ No- ***Go to question 102***

96. Specify co-existing diseases or organ impairment *(check all that apply)*

- ☐ Arrhythmia - **Any history of atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias requiring treatment**
- ☐ Cardiac -**Any history of coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft), congestive heart failure, myocardial infarction, OR ejection fraction ≤ 50% on the most recent test**
- ☐ Cerebrovascular disease **-Any history of transient ischemic attack, subarachnoid hemorrhage or cerebral thrombosis, embolism, or hemorrhage**
- ☐ Diabetes **-Requiring treatment with insulin or oral hypoglycemic drugs in the last 4 weeks but not diet alone**
- ☐ Heart valve disease **-At least a moderate to severe degree of valve stenosis or insufficiency as determined by Echo; prosthetic mitral or aortic valve; or symptomatic mitral valve prolapse**
- ☐ Hepatic, mild **- Bilirubin > upper limit of normal to 1.5 × upper limit of normal, or AST/ALT > upper limit of normal to 2.5 × upper limit of normal at the time of transplant OR any history of hepatitis B or hepatitis C infection**
- ☐ Hepatic, moderate/severe **-Liver cirrhosis, bilirubin > 1.5 × upper limit of normal, or AST/ALT > 2.5 × upper limit of normal**
- ☐ Infection **-Includes a documented infection, fever of unknown origin, or pulmonary nodules suspicious for fungal pneumonia or a positive PPD test requiring prophylaxis against tuberculosis. Patients must have started antimicrobial treatment before Day 0 with continuation of antimicrobial treatment after Day 0**
- ☐ Inflammatory bowel disease **-Any history of Crohn's disease or ulcerative colitis requiring treatment**
- ☐ Obesity **-Patients older than 18 years with a body mass index (BMI) > 35 kg/m2 prior to the start of conditioning or a BMI of the 95th percentile of higher for patients aged 18 years or younger**
- ☐ Peptic ulcer **-Any history of peptic (gastric or duodenal) ulcer confirmed by endoscopy or radiologic diagnosis requiring treatment**
- ☐ Psychiatric disturbance **-Presence of any mood (e.g., depression), anxiety, or other psychiatric disorder (e.g. bipolar disorder or schizophrenia) requiring continuous treatment in the last 4 weeks**

- ☐ Pulmonary, moderate **-Corrected diffusion capacity of carbon monoxide and/or FEV1 of 66-80% or dyspnea on slight activity attributed to pulmonary disease at transplant**
- ☐ Pulmonary, severe **-Corrected diffusion capacity of carbon monoxide and/or FEV1 of ≤ 65% or dyspnea at rest attributed to pulmonary disease or the need for intermittent or continuous oxygen during the 4 weeks prior to transplant**
- ☐ Renal, moderate / severe **-Serum creatinine > 2 mg/dL or > 177 µmol/L; on dialysis during the 4 weeks prior to transplant; OR prior renal transplantation *-go to question 97***
- ☐ Rheumatologic **-Any history of a rheumatologic disease (e.g., systemic lupus erythematosis, rheumatoid arthritis, polymyositis, mixed connective tissue disease, or polymyalgia rheumatica, etc.) requiring treatment. (Do NOT include degenerative joint disease, osteoarthritis)**
- ☐ Prior malignancy**-Treated at any time point in the patient's past history, other than the primary disease for which this infusion is being performed *-go to question 98***

97. Was the recipient on dialysis immediately prior to start of preparative regimen?
    - ☐ Yes
    - ☐ No
    - ☐ Unknown

98. Specify prior malignancy *(check all that apply)*
    - ☐ Breast cancer
    - ☐ Central nervous system (CNS) malignancy *(e.g., glioblastoma, astrocytoma)*
    - ☐ Gastrointestinal malignancy *(e.g., colon, rectum, stomach, pancreas, intestine, esophageal)*
    - ☐ Genitourinary malignancy *(e.g., kidney, bladder, ovary, testicle, genitalia, uterus, cervix, prostate)*
    - ☐ Leukemia *(includes acute or chronic leukemia)*
    - ☐ Lung cancer
    - ☐ Lymphoma *(includes Hodgkin & non-Hodgkin lymphoma)*
    - ☐ MDS / MPN
    - ☐ Melanoma
    - ☐ Multiple myeloma / plasma cell disorder (PCD)
    - ☐ Oropharyngeal cancer *(e.g., tongue, buccal mucosa)*
    - ☐ Sarcoma
    - ☐ Thyroid cancer
    - ☐ Other skin malignancy *(basal cell, squamous)**- go to question 99***
    - ☐ Other hematologic malignancy ***-go to question 100***
    - ☐ Other solid tumor ***-go to question 101***

99. Specify other skin malignancy: *(prior)* _____

100. Specify other hematologic malignancy: *(prior)* _____

101. Specify other solid tumor: *(prior)* _____

Use results within 4 weeks prior to the start of the preparative regimen, report results from the test performed closest to the start date. Biomarkers according to the augmented HCT comorbidity index. (*Source: Biol Blood Marrow Transplant. 2015 Aug; 21(8): 1418–1424)*

102. Serum ferritin *(within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)*

☐ Known – ***Go to question 103***

☐ Unknown – ***Go to question 106***

103. ___ ___ ___ ___ ___ ng/mL (µg/L)

104. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

105. Upper limit of normal for your institution: ___ ___ ___ ___ ___

106. Serum albumin *(within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)*

☐ Known – ***Go to question 107***

☐ Unknown – ***Go to question 109***

107. ___ ___ • ___ ☐ g/dL
☐ g/L

108. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

109. Platelets *(within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)*

☐ Known – ***Go to question 110***

☐ Unknown – ***Go to question 112***

110. ___ ___ ___ ___ ___ ___ ___ ☐ x 10^9/L (x 10^3/mm^3)
☐ x 10^6/L

111. Were platelets transfused ≤ 7 days before date of test?

☐ Yes

☐ No

☐ Unknown

112. Did the recipient have a prior solid organ transplant?

- ☐ Yes- ***Go to question 113***
- ☐ No- ***Go to question 116***

113. Specify organ:

- ☐ Bowel
- ☐ Heart
- ☐ Kidney(s)
- ☐ Liver
- ☐ Lung(s)
- ☐ Pancreas
- ☐ Other organ- ***Go to question 114***

114. Specify other organ: _____

115. Year of prior solid organ transplant: ___ ___ ___ ___
YYYY

Copy and complete questions 113-115 for each prior solid organ transplant

Pre-HCT Preparative Regimen (Conditioning)

116. Height at initiation of pre-HCT preparative regimen: ___ ___ ___ ☐ inches ☐ centimeters

117. Actual weight at initiation of pre-HCT preparative regimen: ___ ___ ___ . ___ ☐ pounds ☐ kilograms

118. Was a pre-HCT preparative regimen prescribed?

- ☐ Yes – ***Go to question 119***
- ☐ No – ***Go to question 132***

119. Classify the recipient's prescribed preparative regimen **(Allogeneic HCTs only)**

- ☐ Myeloablative
- ☐ Non-myeloablative (NST)
- ☐ Reduced intensity (RIC)

120. Was irradiation planned as part of the pre-HCT preparative regimen?

- ☐ Yes – ***Go to question 121***
- ☐ No – ***Go to question 126***

121. What was the prescribed radiation field?

- ☐ Total body – ***Go to question 122***
- ☐ Total body by intensity-modulated radiation therapy (IMRT) – ***Go to question 122***
- ☐ Total lymphoid or nodal regions – ***Go to question 122***
- ☐ Thoracoabdominal region – ***Go to question 122***

122. Total prescribed dose: *(dose per fraction x total number of fractions)* ___ ___ ___ ___ . ___ ☐ Gy ☐ cGy

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

124. Was the radiation fractionated?

- ☐ Yes – ***Go to question 125***
- ☐ No – ***Go to question 126***

125. Total number of fractions: ___ ___

Indicate the total prescribed cumulative dose for the preparative regimen

126. Drug *(drop down list)*

- ☐ 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 127***

127. Specify other drug: _____

128. Total prescribed dose: __ __ __ __ __. __ ☐ mg/m^2
☐ mg/kg
☐ AUC (mg x h/L)
☐ AUC (µmol x min/L)
☐CSS (ng/mL)

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

130. Specify administration *(busulfan only)*
- ☐ Oral
- ☐ IV
- ☐ Both

Copy and complete question 126-130 to report each drug given for the preparative regimen

Additional Drugs Given in the Peri-Transplant Period

131. ALG, ALS, ATG, ATS
- ☐ Yes – ***Go to question 132***
- ☐ No – ***Go to question 135***

132. Total prescribed dose: ___ ___ ___ ___ ___ mg/kg

133. Specify source
- ☐ ATGAM (horse) – ***Go to question 135***
- ☐ ATG – Fresenius (rabbit) – ***Go to question 135***
- ☐ Thymoglobulin (rabbit) – ***Go to question 135***
- ☐ Other – ***Go to question 134***

134. Specify other source: _____

135. Alemtuzumab (Campath)

- ☐ Yes – ***Go to question 136***
- ☐ No – ***Go to question 137***

136. Total prescribed dose: __ __ __ __ . __ ☐ mg/m2

☐ mg/kg

☐mg

137. Defibrotide

- ☐ Yes
- ☐ No

138. KGF

- ☐ Yes
- ☐ No

139. Ursodiol

- ☐ Yes
- ☐ No

GVHD Prophylaxis

This section is to be completed for allogeneic HCTs only; autologous HCTs continue with question 143.

140. Was GVHD prophylaxis planned?

- ☐ Yes - ***Go to question 141***
- ☐ No - ***Go to question 143***

141. Specify drugs / intervention *(check all that apply)*

- ☐ Abatacept
- ☐ Anti CD 25 (Zenapax, Daclizumab, AntiTAC)
- ☐ Blinded randomized trial
- ☐ Bortezomib
- ☐ CD34 enriched (CD34+ selection)
- ☐ Corticosteroids (systemic)
- ☐ Cyclophosphamide (Cytoxan)

- ☐ Cyclosporine (CSA, Neoral, Sandimmune)
- ☐ Extra-corporeal photopheresis (ECP)
- ☐ Ex-vivo T-cell depletion
- ☐ Filgotinib
- ☐ Maraviroc
- ☐ Methotrexate (MTX) (Amethopterin)
- ☐ Mycophenolate mofetil (MMF) (CellCept)
- ☐ Ruxolotinib
- ☐ Sirolimus (Rapamycin, Rapamune)
- ☐ Tacrolimus (FK 506)
- ☐ Tocilizumab
- ☐ Other agent-***go to question 142***

142. Specify other agent: _____ *(do not report ATG, campath)*

Post-HCT Disease Therapy Planned as of Day 0

143. Is additional post-HCT therapy planned?

- ☐ Yes - ***Go to question 144***
- ☐ No - ***Go to First Name***

Questions 144-145 are optional for non-U.S. centers

144. Specify post-HCT therapy planned *(check all that apply)*

- ☐ Azacytidine (Vidaza)
- ☐ Blinatumomab
- ☐ Bortezomib (Velcade)
- ☐ Bosutinib
- ☐ Brentuximab
- ☐ Carfilzomib
- ☐ Cellular therapy *(e.g. DCI, DLI)*
- ☐ Crenolanib
- ☐ Daratumumab
- ☐ Dasatinib
- ☐ Decitabine
- ☐ Elotuzumab
- ☐ Enasidenib

- ☐ Gilteritinib
- ☐ Ibrutinib
- ☐ Imatinib mesylate (Gleevec, Glivec)
- ☐ Intrathecal therapy *(chemotherapy)*
- ☐ Ivosidenib
- ☐ Ixazomib
- ☐ Lenalidomide (Revlimid)
- ☐ Lestaurtinib
- ☐ Local radiotherapy
- ☐ Midostaurin
- ☐ Nilotinib
- ☐ Obinutuzumab
- ☐ Pacritinib
- ☐ Ponatinib
- ☐ Quizartinib
- ☐ Rituximab (Rituxan, MabThera)
- ☐ Sorafenib
- ☐ Sunitinib
- ☐ Thalidomide (Thalomid)
- ☐ Other therapy- ***Go to question 145***
- ☐ Unknown

145. Specify other therapy: _____

Prior Exposure: Potential Study Eligibility

Selecting any option(s) below may generate an additional supplemental form.

146. Specify if the recipient received any of the following *(at any time prior to HCT / infusion) (check all that apply)*

- ☐ Blinatumomab (Blincyto)
- ☐ Gemtuzumab ozogamicin (Mylotarg)
- ☐ Inotuzumab ozogamicin (Besponsa)
- ☐ Adienne Tepadina®
- ☐ Mogamulizumab (Poteligeo)
- ☐ None of the above

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

First Name: _____

Last Name: _____

E-mail address: _____

Date: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD