CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

LEGEND

REVISON

ADDITION

Pre-Transplant Essential Data

CIBMTR Use Only

Sequence Number:

Date Received:

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

Public Burden Statement: The purpose of the data collection is to fulfill the legislative mandate to establish and maintain a standardized database of allogeneic marrow and cord blood transplants performed in the United States or using a donor from the United States. The data collected also meets the C.W. Bill Young Cell Transplantation Program requirements to provide relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0310 and it is valid until 10/31/2022. This information collection is voluntary under The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2010, Public Law 111–264 (the Act) and the Stem Cell Therapeutic and Research Reauthorization Act of 2015, Public Law 114-104. Public reporting burden for this collection of information is estimated to average 0.68 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.

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
- ☐ 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
- ☐ Ghana
- ☐ Gibraltar
- ☐ Greece
- ☐ Greenland
- ☐ Grenada
- ☐ Guadeloupe
- ☐ Guam
- ☐ Guatemala
- ☐ Guernsey
- ☐ Guinea
- ☐ Guinea-Bissau
- ☐ Guyana
- ☐ Haiti
- ☐ Heard Island and McDonald Islands
- ☐ Holy See
- ☐ Honduras
- ☐ Hong Kong
- ☐ Hungary
- ☐ Iceland
- ☐ India
- ☐ Indonesia
- ☐ Iran
- ☐ Iraq
- ☐ Ireland
- ☐ Isle of Man
- ☐ Israel
- ☐ Italy
- ☐ Jamaica
- ☐ Japan
- ☐ Jersey
- ☐ Jordan
- ☐ Kazakhstan
- ☐ Kenya
- ☐ Kiribati
- ☐ Kuwait
- ☐ Palau
- ☐ Palestine, State of
- ☐ Panama
- ☐ Papua New Guinea
- ☐ Paraguay
- ☐ Peru
- ☐ Philippines
- ☐ Pitcairn Islands
- ☐ Poland
- ☐ Portugal
- ☐ Puerto Rico
- ☐ Qatar
- ☐ Reunion
- ☐ Romania
- ☐ Russia
- ☐ 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

- ☐ Bulgaria
- ☐ Burkina Faso
- ☐ Burundi
- ☐ Cambodia
- ☐ Cameroon
- ☐ Canada - ***Go to question 8.***
- ☐ Cape Verde
- ☐ Cayman Islands
- ☐ Central African Republic
- ☐ Chad
- ☐ Chile
- ☐ China
- ☐ Christmas Island
- ☐ Cocos (Keeling) Islands
- ☐ Colombia
- ☐ 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
- ☐ Kyrgyzstan
- ☐ Laos
- ☐ Latvia
- ☐ Lebanon
- ☐ Lesotho
- ☐ Liberia
- ☐ Libya
- ☐ Liechtenstein
- ☐ Lithuania
- ☐ Luxembourg
- ☐ Macau
- ☐ Macedonia
- ☐ Madagascar
- ☐ Malawi
- ☐ Malaysia
- ☐ Maldives
- ☐ Mali
- ☐ Malta
- ☐ Marshall Islands
- ☐ Martinique
- ☐ Mauritania
- ☐ Mauritius
- ☐ Mayotte
- ☐ Mexico
- ☐ Micronesia
- ☐ Moldova
- ☐ Monaco
- ☐ Mongolia
- ☐ Montenegro
- ☐ Montserrat
- ☐ Morocco
- ☐ Mozambique
- ☐ Myanmar
- ☐ Namibia
- ☐ Nauru
- ☐ Nepal
- ☐ 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
- ☐ 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 - ***Go to question 9.***
- ☐ United States Minor Outlying

- ☐ Ethiopia
- ☐ Falkland Islands
- ☐ Faroe Islands
- ☐ Fiji
- ☐ Finland
- ☐ France
- ☐ French Guiana
- ☐ French Polynesia
- ☐ French Southern Territories
- ☐ Gabon
- ☐ Gambia
- ☐ Georgia
- ☐ Germany
- ☐ Netherlands
- ☐ Netherlands Antilles
- ☐ New Caledonia
- ☐ New Zealand
- ☐ Nicaragua
- ☐ Niger
- ☐ Nigeria
- ☐ Niue
- ☐ Norfolk Island
- ☐ North Korea
- ☐ Northern Mariana Islands
- ☐ Norway
- ☐ Oman
- ☐ Pakistan
- ☐ 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
- ☐ Paraná
- ☐ Paraíba
- ☐ 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
- ☐ Quebec
- ☐ Manitoba
- ☐ New Brunswick
- ☐ Saskatchewan
- ☐ Newfoundland and Labrador
- ☐ Nova Scotia
- ☐ Ontario
- ☐ Prince Edward Island
- ☐ Quebec

Territories

- ☐ Northwest Territories
- ☐ Nunavut
- ☐ Yukon

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

- ☐ Alabama
- ☐ Kentucky
- ☐ North Dakota

- ☐ Alaska
- ☐ Arizona
- ☐ Arkansas
- ☐ California
- ☐ Colorado
- ☐ Connecticut
- ☐ Delaware
- ☐ District of Columbia
- ☐ Florida
- ☐ Georgia
- ☐ Hawaii
- ☐ Idaho
- ☐ Illinois
- ☐ Indiana
- ☐ Iowa
- ☐ Kansas
- ☐ Louisiana
- ☐ Maine
- ☐ Maryland
- ☐ Massachusetts
- ☐ Michigan
- ☐ Minnesota
- ☐ Mississippi
- ☐ Missouri
- ☐ Montana
- ☐ Nebraska
- ☐ Nevada
- ☐ New Hampshire
- ☐ New Jersey
- ☐ New Mexico
- ☐ New York
- ☐ North Carolina
- ☐ Ohio
- ☐ Oklahoma
- ☐ Oregon
- ☐ Pennsylvania
- ☐ Rhode Island
- ☐ South Carolina
- ☐ South Dakota
- ☐ Tennessee
- ☐ Texas
- ☐ Utah
- ☐ Vermont
- ☐ Virginia
- ☐ Washington
- ☐ West Virginia
- ☐ Wisconsin
- ☐ Wyoming

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

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

(last 4 digits optional)

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.

15.

16.

17. 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 18.***
- ☐ No *(recipient declined)* - ***Go to question 14.***
- ☐ Not approached - ***Go to question 14.***
- ☐ Not applicable *(center not participating)* - ***Go to question 14.***

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

YYYY MM DD

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

- ☐ Yes – ***Go to question 20.***
- ☐ No – ***Go to question 14.***

20. Research sample recipient ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

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

- ☐ Yes - ***Go to question 22.***
- ☐ No – ***Go to question 27.***

22. Study Sponsor

- ☐ BMT CTN ***– Go to question 24.***
- ☐ RCI BMT ***– Go to question 24.***
- ☐ PIDTC ***– Go to question 24.***
- ☐ USIDNET ***– Go to question 25.***
- ☐ COG ***– Go to question 25.***
- ☐ Other sponsor ***– Go to question 23.***

23. Specify other sponsor: _____ ***- Go to question 25.***

24. Study ID Number: _____

25. Subject ID: _____

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

Copy questions 22.-26. to report participation in more than one study.

Hematopoietic Cellular Transplant (HCT) and Cellular Therapy

27. 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 28.***

☐ No – ***Go to question 29.***

28. Specify subsequent HCT planned

☐ Autologous

☐ Allogeneic

29. Has the recipient ever had a prior HCT?

☐ Yes – ***Go to question 30.***

☐ No – ***Go to question 41.***

30. Specify the number of prior HCTs: ___ ___

31. Were all prior HCTs reported to the CIBMTR?

☐ Yes – ***Go to question 36.***

☐ No – ***Go to question 32.***

☐ Unknown – ***Go to question 32.***

Copy and complete questions 32.- 35. to report all prior HCTs that have not yet been reported to the CIBMTR

32. Date of the prior HCT: ___ ___ ___ ___ — ___ ___ — ___ ___ ☐ date estimated
YYYY MMDD

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

☐ Yes – ***Go to question 34.***

☐ No – ***Go to question 35.***

Specify the institution that performed the last HCT

34. Name: _____

City: _____

State: _____

Country: _____

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

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

36. Reason for current HCT

- ☐ Graft failure / insufficient hematopoietic recovery – ***Go to question 37.***
- ☐ Persistent primary disease– ***Go to question 41.***
- ☐ Recurrent primary disease– ***Go to question 38.***
- ☐ Planned subsequent HCT, per protocol– ***Go to question 41.***
- ☐ New malignancy *(including PTLD and EBV lymphoma)* – ***Go to question 39.***
- ☐ Insufficient chimerism– ***Go to question 41.***
- ☐ Other– ***Go to question 40.***

37. Date of graft failure / rejection: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 41.***
YYYY MM DD

38. Date of relapse: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 41.***
YYYY
DD

39. Date of secondary malignancy: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 41.***
YYYY MM DD

40. Specify other reason: _____ - ***Go to question 41.***

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

- ☐ Yes – ***Go to question 42.***
- ☐ No – ***Go to question 46.***
- ☐ Unknown– ***Go to question 46.***

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

☐ Yes – ***Go to question 46.***

☐ No – ***Go to question 43.***

☐ Unknown– ***Go to question 46.***

Copy and complete questions 43.-45. to report all prior cellular therapies that have not yet been reported to the CIBMTR.

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

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

☐ Yes – ***Go to question***

☐ No – ***Go to question 45.***

Name: _____

City: _____

State: _____

Country: _____

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

☐ Autologous

☐ Allogeneic, unrelated

☐ Allogeneic, related

Donor Information

46. Multiple donors?

☐ Yes – ***Go to question 47.***

☐ No - ***Go to question 48.***

47. Specify number of donors: ___ ___

To report more than one donor, copy questions 48.-81. and complete for each donor.

48. Specify donor

☐ Autologous

☐ Allogeneic, related

☐ Allogeneic, unrelated

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

- ☐ Bone marrow
- ☐ PBSC
- ☐ Single cord blood unit
- ☐ Other product– ***Go to question 50.***

50. Specify other product: _____

51. Is the product genetically modified?

- ☐ Yes
- ☐ No

If autologous, go to question 78..

If allogeneic related, go to question 52..

If allogeneic unrelated, go to question 55..

52. Specify the related donor type

- ☐ Syngeneic *(monozygotic twin)* – ***Go to question 56.***
- ☐ HLA-identical sibling *(may include non-monozygotic twin)* ***– Go to question 56.***
- ☐ HLA-matched other relative *(does NOT include a haplo-identical donor)* - ***Go to question*** 53.
- ☐ HLA-mismatched relative– ***Go to question 53.***

53. 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***

Specify other biological relative: _____– ***Go to question 54.***

54._____Degree of mismatch *(related donors only)*

☐ HLA-mismatched 1 allele– ***Go to question 56.***

☐ HLA-mismatched ≥2 alleles *(does include haplo-identical donor)* – ***Go to question 56.***

55. Specify unrelated donor type

☐ HLA matched unrelated

☐ HLA mismatched unrelated

56. Did NMDP / Be the Match facilitate the procurement, collection, or transportation of the product?

☐ Yes

☐ No

57. Was this donor used for any prior HCTs? *(for this recipient)*

☐ Yes

☐ No

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

60.

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

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

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

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

Global Registration Identifier for Donors (GRID):

__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

NMDP cord blood unit, go to question 73.

NMDP donor, go to question 73.

Non-NMDP unrelated donor, go to question 65.

Non-NMDP cord blood unit, go to question 63.

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

☐ Yes – ***Go to question 65.***

☐ No – ***Go to question 64.***

☐ Unknown– ***Go to question 65.***

64. Specify the ISBT DIN number: _____

65. Registry or UCB Bank ID: ___ ___ ___ ___ - ***If 'Other registry' go to 66., otherwise go to question 67.***

66. Specify other Registry or UCB Bank: _____ - ***Go to question 67.***

67. Donor date of birth

☐ Known – ***Go to question 68.***

☐ Unknown – ***Go to question 69.***

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

YYYY MM DD

69. Donor age

☐ Known – ***Go to question 70.***

☐ Unknown – ***Go to question***

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

☐ Years

Donor sex

☐ Male

☐ Female

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

☐ A

☐ B

☐ AB

☐ O

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

☐ Positive

☐ Negative

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

☐ Reactive

☐ Non-reactive

☐ Indeterminate

☐ Not done

☐ Not applicable *(cord blood unit)*

74. 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 75.***
- ☐ No *(donor declined)* - ***Go to question 78.***
- ☐ Not approached - ***Go to question 78.***
- ☐ Not applicable *(center not participating)* - ***Go to question 78.***

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

YYYY MM DD

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

- ☐ Yes – ***Go to question 77.***
- ☐ No – ***Go to question 78.***

77. Research sample donor ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

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

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

Questions 80.-81. are for autologous HCT recipients only. If other than autologous skip to question 84..

80. 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 81.***

81. Specify other agent: _____

82. Name of product: (gene therapy recipients)

- ☐ Other name

83. Specify other name: _____

To report more than one donor, copy questions 48.**-83. and complete for each donor.**

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

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

- ☐ Karnofsky *(recipient age ≥ 16 years)* – ***Go to question 85.***
- ☐ Lansky *(recipient age ≥ 1 year and < 16 years)* – ***Go to question 86.***

Performance score prior to the preparative regimen:

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

- ☐ 100 Normal; no complaints; no evidence of disease - ***Go to question 87.***
- ☐ 90 Able to carry on normal activity - ***Go to question 87.***
- ☐ 80 Normal activity with effort - ***Go to question 87.***
- ☐ 70 Cares for self; unable to carry on normal activity or to do active work - ***Go to question 87.***
- ☐ 60 Requires occasional assistance but is able to care for most needs - ***Go to question 87.***
- ☐ 50 Requires considerable assistance and frequent medical care - ***Go to question 87.***
- ☐ 40 Disabled; requires special care and assistance - ***Go to question 87.***
- ☐ 30 Severely disabled; hospitalization indicated, although death not imminent - ***Go to question 87.***
- ☐ 20 Very sick; hospitalization necessary - ***Go to question 87.***
- ☐ 10 Moribund; fatal process progressing rapidly - ***Go to question 87.***

86. 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

87. Recipient CMV-antibodies (IgG or Total)

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

Comorbid Conditions

88. 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 89.***
- ☐ No – ***Go to question 91.***

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

- ☐ Yes – ***Go to question 90.***
- ☐ No – ***Go to question 91.***

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

- ☐ Yes
- ☐ No

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

- ☐ Yes
- ☐ No

92. Is there a history of invasive fungal infection?

- ☐ Yes
- ☐ No

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

- ☐ Known- ***Go to question 94.***
- ☐ Unknown- ***Go to question 95.***

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

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

- ☐ Yes
- ☐ No

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

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, prior ***-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

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 MMDD

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
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

First Name: _____

Last Name: _____

E-mail address: _____

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

YYYY MM DD