

Legend: 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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- 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

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

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

- | | | |
|---|---|--|
| <input type="checkbox"/> Acre | <input type="checkbox"/> Maranhão | <input type="checkbox"/> Rio de Janeiro |
| <input type="checkbox"/> Alagoas | <input type="checkbox"/> Mato Grosso | <input type="checkbox"/> Rio Grande do Norte |
| <input type="checkbox"/> Amapá | <input type="checkbox"/> Mato Grosso do Sul | <input type="checkbox"/> Rio Grande do Sul |
| <input type="checkbox"/> Amazonas | <input type="checkbox"/> Minas Gerais | <input type="checkbox"/> Rondônia |
| <input type="checkbox"/> Bahia | <input type="checkbox"/> Pará | <input type="checkbox"/> Roraima |
| <input type="checkbox"/> Ceará | <input type="checkbox"/> Paraíba | <input type="checkbox"/> Santa Catarina |
| <input type="checkbox"/> Distrito Federal | <input type="checkbox"/> Paraná | <input type="checkbox"/> São Paulo |
| <input type="checkbox"/> Espírito Santo | <input type="checkbox"/> Pernambuco | <input type="checkbox"/> Sergipe |
| <input type="checkbox"/> Goiás | <input type="checkbox"/> Piauí | <input type="checkbox"/> 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*) _____

- | | | |
|---|--|---|
| <input type="checkbox"/> Alabama | <input type="checkbox"/> Kentucky | <input type="checkbox"/> North Dakota |
| <input type="checkbox"/> Alaska | <input type="checkbox"/> Louisiana | <input type="checkbox"/> Ohio |
| <input type="checkbox"/> Arizona | <input type="checkbox"/> Maine | <input type="checkbox"/> Oklahoma |
| <input type="checkbox"/> Arkansas | <input type="checkbox"/> Maryland | <input type="checkbox"/> Oregon |
| <input type="checkbox"/> California | <input type="checkbox"/> Massachusetts | <input type="checkbox"/> Pennsylvania |
| <input type="checkbox"/> Colorado | <input type="checkbox"/> Michigan | <input type="checkbox"/> Rhode Island |
| <input type="checkbox"/> Connecticut | <input type="checkbox"/> Minnesota | <input type="checkbox"/> South Carolina |
| <input type="checkbox"/> Delaware | <input type="checkbox"/> Mississippi | <input type="checkbox"/> South Dakota |
| <input type="checkbox"/> District of Columbia | <input type="checkbox"/> Missouri | <input type="checkbox"/> Tennessee |
| <input type="checkbox"/> Florida | <input type="checkbox"/> Montana | <input type="checkbox"/> Texas |

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- | | | |
|-----------------------------------|---|--|
| <input type="checkbox"/> Georgia | <input type="checkbox"/> Nebraska | <input type="checkbox"/> Utah |
| <input type="checkbox"/> Hawaii | <input type="checkbox"/> Nevada | <input type="checkbox"/> Vermont |
| <input type="checkbox"/> Idaho | <input type="checkbox"/> New Hampshire | <input type="checkbox"/> Virginia |
| <input type="checkbox"/> Illinois | <input type="checkbox"/> New Jersey | <input type="checkbox"/> Washington |
| <input type="checkbox"/> Indiana | <input type="checkbox"/> New Mexico | <input type="checkbox"/> West Virginia |
| <input type="checkbox"/> Iowa | <input type="checkbox"/> New York | <input type="checkbox"/> Wisconsin |
| <input type="checkbox"/> Kansas | <input type="checkbox"/> North Carolina | <input type="checkbox"/> 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.**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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: _____

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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.**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

YYYY MM DD

35. Date of relapse: _____ - _____ - _____ - **Go to question 38.**
YYYY MM

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: _____ - _____ - _____
DD YYYY

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

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CIBMTR Research ID: _____

- 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. Registry 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.**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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

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- 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

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- 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 used for COVID-19 (SARS-CoV-2) infection?

- Yes
- No

90. Was a vaccine for COVID-19 (SARS-CoV-2) received?

- Yes – **Go to question 91.**
- No – **Go to question 95.**
- Unknown – **Go to question 95.**

Copy and complete questions 91.-94. to report all vaccine doses received.

91. Specify vaccine brand

- AstraZeneca – **Go to question 93.**
- Johnson & Johnson's / Janssen – **Go to question 93.**
- Moderna – **Go to question 93.**
- Novavax – **Go to question 93.**
- Pfizer-BioNTech – **Go to question 93.**

Other type – **Go to question 92.**

92. Specify other type: _____

93. Select dose(s) received

One dose (*without planned second dose*)

First dose (*with planned second dose*)

Second dose

Third dose

Booster dose

94. Date received: _____ Date estimated

YYYY MM DD

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

Yes

No

96. Is there a history of invasive fungal infection?

Yes

No

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

Known- **Go to question 98.**

Unknown- **Go to question 99.**

98. Glomerular filtration rate (GFR): ___ ___ mL/min/1.73²

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

Yes

No

100. 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 101.**

No- **Go to question 107.**

101. 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 $\leq 50\%$ 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 $1.5 \times$ upper limit of normal, or AST/ALT $>$ upper limit of normal to $2.5 \times$ 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 $> 1.5 \times$ upper limit of normal, or AST/ALT $> 2.5 \times$ 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 or 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 $\leq 65\%$ 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 μ mol/L; on dialysis during the 4 weeks prior to transplant; OR prior renal transplantation **-go to question 102.**
- Rheumatologic -Any history of a rheumatologic disease (e.g., systemic lupus erythematosus, 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 103.**

102. Was the recipient on dialysis immediately prior to start of preparative regimen?

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- Yes
- No
- Unknown

103. 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 104.**
- Other hematologic malignancy **-go to question 105.**
- Other solid tumor **-go to question 106.**

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

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

106. 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)

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

- Known – **Go to question 108.**
- Unknown – **Go to question 111.**

108. _____ ng/mL (µg/L)

CIBMTR Center Number: _____ CIBMTR Research ID: _____

119. Specify other organ: _____

120. Year of prior solid organ transplant: _____

YYYY

Copy and complete questions 118.-120. for each prior solid organ transplant

Pre-HCT Preparative Regimen (Conditioning)

121. Height at initiation of pre-HCT preparative regimen: _____ inches
 centimeters

122. Actual weight at initiation of pre-HCT preparative regimen: _____ . _____ pounds
 kilograms

123. Was a pre-HCT preparative regimen prescribed?

- Yes – **Go to question 124.**
- No – **Go to question 132**

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

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

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

- Yes – **Go to question 126.**
- No – **Go to question 131.**

126. What was the prescribed radiation field?

- Total body – **Go to question 127.**
- Total body by intensity-modulated radiation therapy (IMRT) – **Go to question 127.**
- Total lymphoid or nodal regions – **Go to question 127.**
- Thoracoabdominal region – **Go to question 127.**

127. Total prescribed dose: (*dose per fraction x total number of fractions*) _____ . _____ Gy
 cGy

128. Date started: _____ — _____ — _____
YYYY MM DD

CIBMTR Center Number: _____ CIBMTR Research ID: _____

129. Was the radiation fractionated?

- Yes – **Go to question 130.**
- No – **Go to question 131.**

130. Total number of fractions: _____

Indicate the total prescribed cumulative dose for the preparative regimen

131. Drug (*drop down list*)

- Bendamustine
- Busulfan
- Carboplatin
- Carmustine (BCNU)
- CCNU (Lomustine)
- Clofarabine (Clolar)
- Cyclophosphamide (Cytosan)
- 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 132.**

132. Specify other drug: _____

133. Total prescribed dose: _____ . _____
- mg/m²
 - mg/kg
 - AUC (mg x h/L)
 - AUC (μmol x min/L)

CIBMTR Center Number: _____ CIBMTR Research ID: _____

CSS (ng/mL)

134. Date started: _____
YYYY MM DD

135. Specify administration (*busulfan only*)

- Oral
- IV
- Both

Copy and complete question 131.-135. to report each drug given for the preparative regimen

Additional Drugs Given in the Peri-Transplant Period

136. ALG, ALS, ATG, ATS

- Yes – **Go to question 137.**
- No – **Go to question 140.**

137. Total prescribed dose: _____ mg/kg

138. Specify source

- ATGAM (horse) – **Go to question 140.**
- ATG – Fresenius (rabbit) – **Go to question 140.**
- Thymoglobulin (rabbit) – **Go to question 140.**
- Other – **Go to question 139.**

139. Specify other source: _____

140. Alemtuzumab (Campath)

- Yes – **Go to question 141.**
- No – **Go to question 142.**

141. Total prescribed dose: _____ . ____ mg/m²

mg/kg

mg

142. Defibrotide

- Yes
- No

CIBMTR Center Number: _____

CIBMTR Research ID: _____

143. KGF

Yes

No

144. Ursodiol

Yes

No

GVHD Prophylaxis

This section is to be completed for allogeneic HCTs only; autologous HCTs continue with question 148..

145. Was GVHD prophylaxis planned?

Yes - **Go to question 146.**

No - **Go to question 148.**

146. 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 (Cytosan)
- 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 147.**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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

Post-HCT Disease Therapy Planned as of Day 0

148. Is additional post-HCT therapy planned?

Yes - **Go to question 149.**

No - **Go to First Name**

Questions 149.-150. are optional for non-U.S. centers

149. 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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- Ponatinib
- Quizartinib
- Rituximab (Rituxan, MabThera)
- Sorafenib
- Sunitinib
- Thalidomide (Thalomid)
- Other therapy- **Go to question 150.**
- Unknown

150. Specify other therapy: _____

Prior Exposure: Potential Study Eligibility

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

151. 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