Form 2400 R7.0: Pre-Transplant Essential Data

Center: CRID:

Key Fields

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.

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

Center Identification

CIBMTR Center Number: _____

EBMT Code (CIC): _____

Recipient Identification

CIBMTR Research ID: (CRID) _____

Event date: __ __ __ __ - __ __- __ __

Recipient Information

Questions: 1 - 25

1 Date of birth: __ __ __ __ - __ __- __ __

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
- ☐ Black or African American
- ☐ Asian
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Not reported
- ☐ Unknown

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 _____

7 State of residence of recipient (for residents of Brazil) _____

8 Province or territory of residence of recipient (for residents of Canada) _____

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

10 NMDP Recipient ID (RID): _____

11 Zip or postal code for place of recipient's residence: (USA 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 Has the recipient signed an IRB / ethics committee (or similar body) approved consent form for submitting research data to the NMDP / CIBMTR?

- ○ Yes (recipient consented)
- ○ No (recipient declined)
- ○ Not approached

15 Did the recipient give permission to be directly contacted by CIBMTR for future research?

- ○ Yes (recipient provided permission)
- ○ No (recipient declined)

16 Date form was signed: __ __ __ __ - __ __- __ __

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)
- ○ No (recipient declined)
- ○ Not approached
- ○ Not applicable (center not participating)

18 Date form was signed: __ __ __ __ - __ __- __ __

19 Did the recipient submit a research sample to the NMDP/CIBMTR repository? **(Related donors only)**
○ yes ○ no

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 ○ no

Clinical Trials (1) **Questions: 22 - 25**

22 Study Sponsor _____
23 Specify other sponsor: _____
24 Study ID Number _____
25 Subject ID: _____

Hematopoietic Cellular Transplant (HCT) and Cellular Therapy

Questions: 26 - 45

26 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 ○ no

27 Specify subsequent HCT planned
○ Autologous ○ Allogeneic

28 Has the recipient ever had a prior HCT?
○ Yes ○ No

29 Specify the number of prior HCTs: _____
30 Were all prior HCTs reported to the CIBMTR?
○ Yes ○ No ○ Unknown

Prior HCTs (1) **Questions: 31 - 34**

31 Date of the prior HCT: __ __ __ __ - __ __- __ __ ☐ Date estimated
32 Was the prior HCT performed at a different institution?
○ Yes ○ No

Specify the institution that performed the last HCT:

33 Name: _____
City: _____
State: _____
Country: _____
34 What was the HPC source for the prior HCT? (check all that apply)
☐ Autologous
☐ Allogeneic, unrelated
☐ Allogeneic, related

35 Reason for current HCT
○ Graft failure / insufficient hematopoietic recovery
○ Persistent primary disease
○ Recurrent primary disease
○ Planned subsequent HCT, per protocol
○ New malignancy (including PTLD and EBV lymphoma)
○ Insufficient chimerism
○ Other

36 Date of graft failure / rejection: __ __ __ __ - __ __- __ __
37 Date of relapse: __ __ __ __ - __ __- __ __
38 Date of secondary malignancy: __ __ __ __ - __ __- __ __
39 Specify other reason: _____
40 Has the recipient ever had a prior cellular therapy? (do not include DLIs)
○ Yes ○ No ○ Unknown

41 Were all prior cellular therapies reported to the CIBMTR?
○ Yes ○ No ○ Unknown

Prior Cellular Therapies (1) **Questions: 42 - 45**

42 Date of the prior cellular therapy: __ __ __ __ - __ __- __ __
43 Was the cellular therapy performed at a different institution?
○ Yes ○ No

44 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

Questions: 46 - 83

46 Multiple donors?

○ yes ○ no

47 Specify number of donors: _____

Donor Information for this HCT (1)

Questions: 48 - 83

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

50 Specify other product: _____

51 Is the product genetically modified? **If autologous, go to question 80. If allogeneic related, go to question 52. If allogeneic unrelated, go to question 56.**

○ Yes ○ No

52 Specify the related donor type

- ○ Syngeneic (monozygotic twin)
- ○ HLA-identical sibling (may include non-monozygotic twin)
- ○ HLA-matched other relative (does NOT include a haplo-identical donor)
- ○ HLA-mismatched relative

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

54 Specify other biological relative: _____

55 Degree of mismatch (related donors only)

- ○ HLA-mismatched 1 allele
- ○ HLA-mismatched ≥ 2 alleles (does include haplo-identical donor)

56 Specify unrelated donor type

- ○ HLA matched unrelated
- ○ HLA mismatched unrelated

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

○ Yes ○ No

58 Was this donor used for any prior HCTs? (for this recipient)

○ yes ○ no

59 NMDP cord blood unit ID: _____

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

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

63 Global Registration Identifier for Donors (GRID) _____

64 Is the CBU ID also the ISBT DIN number?

○ Yes ○ No ○ Unknown

65 Specify the ISBT DIN number: _____

66 Registry or UCB Bank ID _____

67 Specify other Registry or UCB Bank: _____

68 Date of birth (donor / infant)

○ Known ○ Unknown

69 Date of birth: (donor / infant) __ __ __ __ - __ __- __ __

70 Age (donor / infant)

○ Known ○ Unknown

71 Age: (donor / infant) _____

○ Months (use only if less than 1 year old)

○ years

72 Sex (donor / infant)

○ male ○ female

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

○ A ○ B ○ AB ○ O

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

○ Positive ○ Negative

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

○ Reactive

○ Non-reactive

○ Indeterminate

○ Not done

○ Not applicable (cord blood unit)

76 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)

○ No (donor declined)

○ Not approached

○ Not applicable (center not participating)

77 Date form was signed: __ __ __ __ - __ __- __ __

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

○ yes ○ no

79 Research sample donor ID: _____

80 Specify number of products infused from this donor: _____

81 Specify the number of these products intended to achieve hematopoietic engraftment: _____

Questions 82 - 83 are for autologous HCT recipients only. If other than autologous skip to question 84.

82 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

83 Specify other agent: _____

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

Questions: 84 - 87

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

○ Karnofsky (recipient age ≥ 16 years)

○ Lansky (recipient age ≥ 1 year and < 16 years)

Performance score prior to the preparative regimen:

85 Karnofsky Scale (recipient age ≥ 16 years) _____

86 Lansky Scale (recipient age ≥ 1 year and < 16 years) _____

87 Recipient CMV-antibodies (IgG or Total)

○ Reactive ○ Non-reactive ○ Indeterminate ○ Not done

Comorbid Conditions

Questions: 88 - 116

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 ○ No

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

○ Yes ○ No

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 ○ Unknown

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 ○ No

97 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), congest 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 x upper limit of normal, or AST / ALT > upper limit of normal to 2.5 x 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 x upper limit of normal, or AST / ALT > 2.5 x 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 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 disea 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 f 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**
- ☐ 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**

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

○ Yes ○ No ○ Unknown

99 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)
- ☐ Other hematologic malignancy
- ☐ Other solid tumor

100 Specify other skin malignancy: (prior) _____

101 Specify other hematologic malignancy: (prior) _____

102 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.

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

○ Known ○ Unknown

104 _____ ng/mL (µg/L)

105 Date sample collected: __ __ __ __ - __ __- __ __

106 Upper limit of normal for your institution: _____

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

○ Known ○ Unknown

108 _____ ○ g/dL ○ g/L

109 Date sample collected: __ __ __ __ - __ __- __ __

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

○ Known ○ Unknown

111 _____ ○ x 10^9/L (x 10^3/mm^3)

○ x 10^6/L

112 Were platelets transfused ≤ 7 days before date of test?

○ Yes ○ No ○ Unknown

113 Did the recipient have a prior solid organ transplant?

○ Yes ○ No

Prior Solid Organ Transplant (1) — Questions: 114 - 116

114 Specify organ

○ Bowel ○ Heart ○ Kidney(s) ○ Liver ○ Lung(s) ○ Pancreas ○ Other organ

115 Specify other organ: _____

116 Year of prior solid organ transplant: _____

Pre-HCT Preparative Regimen (Conditioning) — Questions: 117 - 131

117 Height at initiation of pre-HCT preparative regimen: _____ ○ inches ○ centimeters

118 Actual weight at initiation of pre-HCT preparative regimen: _____ ○ pounds ○ kilograms

119 Was a pre-HCT preparative regimen prescribed?

○ yes ○ no

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

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

121 Was irradiation planned as part of the pre-HCT preparative regimen?
○ yes ○ no

122 What was the prescribed radiation field?
○ Total body
○ Total body by intensity-modulated radiation therapy (IMRT)
○ Total lymphoid or nodal regions
○ Thoracoabdominal region

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

124 Date started: __ __ __ __ - __ __- __ __

125 Was the radiation fractionated?
○ yes ○ no

126 Total number of fractions: _____

Preparative Regimen (1) — Questions: 127 - 131

Indicate the total prescribed cumulative dose for the preparative regimen:

127 Drug _____

128 Specify other drug: _____

129 Total prescribed dose: _____ ○ mg/m2 ○ mg/kg ○ AUC (mg x h/L) ○ AUC (µmol x min/L) ○ CSS (ng/mL)

130 Date started: __ __ __ __ - __ __- __ __

131 Specify administration (busulfan only)
○ Oral ○ IV ○ Both

Additional Drugs Given In the Peri-Transplant Period — Questions: 132 - 140

132 ALG, ALS, ATG, ATS
○ yes ○ no

133 Total prescribed dose: _____ mg/kg

134 Specify source
○ ATGAM (horse)
○ ATG - Fresenius (rabbit)
○ Thymoglobulin (rabbit)
○ Other

135 Specify other source: _____

136 Alemtuzumab (Campath)
○ yes ○ no

137 Total prescribed dose: _____ ○ mg/m2 ○ mg/kg ○ mg

138 Defibrotide
○ Yes ○ No

139 KGF
○ Yes ○ No

140 Ursodiol
○ Yes ○ No

GVHD Prophylaxis — Questions: 141 - 143

This section is to be completed for allogeneic HCTs only; autologous HCTs continue with question 144.

141 Was GVHD prophylaxis planned?
○ Yes ○ No

142 Specify drugs / intervention (check all that apply)

- ☐ Abatacept
- ☐ Anti CD 25 (Zenapax, Daclizumab, AntiTAC)
- ☐ Blinded randomized trial
- ☐ Bortezomib
- ☐ CD34 enriched (CD34+ selection)
- ☐ Corticosteriods (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)
- ☐ Ruxolitinib
- ☐ Sirolimus (Rapamycin, Rapamune)
- ☐ Tacrolimus (FK 506)
- ☐ Tocilizumab
- ☐ Other agent

143 Specify other agent: _____ (do not report ATG, campath)

Post-HCT Disease Therapy Planned as of Day 0

Questions: 144 - 146

144 Is additional post-HCT therapy planned?

○ yes ○ no

Questions 145 – 146 are optional for non-U.S. centers

145 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
- ☐ Imanitib 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
- ☐ Unknown

146 Specify other therapy: _____

Prior Exposure: Potential Study Eligibility

Questions: 147 - 147

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

147 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: __ __ __ __ - __ __- __ __