Form 2400 R8.0: 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: __ __ __ __ _ _ _ _ _
CIBMTR Center Number: ____________________________
EBMT Code (CIC): ____________________________

Recipient Identification

CIBMTR Research ID: (CRID) ____________________________
Event date: __ __ __ __ _ _ _ _ _

Recipient Information

Questions: 1 - 23

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

15 Date form was signed: __ __ __ __ / __ __ __

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Center: CRID:

16 Did the recipient submit a research sample to the NMDP/CIBMTR repository? (Related donors only)
   ☑ yes ☐ no

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 ☐ no

19 Study Sponsor
   __________________________

20 Specify other sponsor: __________________________

21 Study ID Number: __________________________

22 Subject ID: __________________________

23 Specify the ClinicalTrials.gov identification number: NCT __________________________

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 ☐ no

25 Specify subsequent HCT planned
   ☑ Autologous ☑ Allogeneic

26 Has the recipient ever had a prior HCT?
   ☑ Yes ☐ No

27 Specify the number of prior HCTs:
   __________________________

28 Were all prior HCTs reported to the CIBMTR?
   ☑ Yes ☐ No ☑ Unknown

Prior HCTs (1)

29 Date of the prior HCT: __________________________
   ☑ Date estimated

30 Was the prior HCT performed at a different institution?
   ☑ Yes ☐ No

   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
   ☑ Persistent primary disease
   ☑ Recurrent primary disease
   ☑ Planned subsequent HCT, per protocol
   ☑ New malignancy (including PTLD and EBV lymphoma)
   ☑ Insufficient chimerism
   ☑ Other

   34 Date of graft failure / rejection: __________________________

   35 Date of relapse: __________________________

   36 Date of secondary malignancy: __________________________

   37 Specify other reason: __________________________
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### Key Fields

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

- [ ] Yes
- [ ] No
- [ ] Unknown

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

- [ ] Yes
- [ ] No
- [ ] Unknown

### Prior Cellular Therapies (1)

#### Questions: 40 - 43

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
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<tbody>
<tr>
<td>40 Date of the prior cellular therapy:</td>
<td>_ _ _ _ _ _ _ _ _ _</td>
</tr>
<tr>
<td>41 Was the cellular therapy performed at a different institution?</td>
<td></td>
</tr>
</tbody>
</table>
- [ ] Yes
- [ ] No
| 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

#### Questions: 44 - 82

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>44 Multiple donors?</td>
<td></td>
</tr>
</tbody>
</table>
- [ ] Yes
- [ ] No
| 45 Specify number of donors: | 
| 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
| 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)
- [ ] HLA-identical sibling (may include non-monozygotic twin)
- [ ] HLA-matched other relative (does NOT include a haplo-identical donor)
- [ ] HLA-mismatched relative

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### 51 Specify the biological relationship of the donor to the recipient
- Mother
- Father
- Child
- Sibling
- Fraternal twin
- Maternal aunt
- Maternal uncle
- Maternal cousin
- Paternal aunt
- Paternal uncle
- Paternal cousin
- Grandparent
- Grandchild
- Other relative

### 52 Specify other biological relative: __________________________

### 53 Degree of mismatch (related donors only)
- HLA-mismatched 1 allele
- HLA-mismatched ≥ 2 alleles (does include haplo-identical donor)

### 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: ________________________________

### 58 Registry donor ID: *(not applicable for related donors)* ________________________________

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

### 60 Global Registration Identifier for Donors (GRD)

### 61 Is the CBU ID also the ISBT DIN number?
- Yes
- No
- Unknown

### 62 Specify the ISBT DIN number: ________________________________

### 63 Registry or UCB Bank ID: ________________________________

### 64 Specify other Registry or UCB Bank: ________________________________

### 65 Donor date of birth
- Known
- Unknown

### 66 Donor date of birth: ——— ——— ———

### 67 Donor age
- Known
- Unknown

### 68 Donor age: ________________________________
- Months *(use only if less than 1 year old)*
- Years

### 69 Donor sex
- male
- female

### 70 Specify blood type *(donor)* *(non-NMDP allogeneic donors only)*
- A
- B
- AB
- O

### 71 Specify Rh factor *(donor)* *(non-NMDP allogeneic donors only)*
- Positive
- Negative
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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)
- No (donor declined)
- Not approached
- Not applicable (center not participating)

74 Date form was signed: ___________ - _________

75 Did the donor submit a research sample to the NMDP/CIBMTR repository? (Related donors only)
- Yes
- No

76 Research sample donor ID: _______________________

77 Specify number of products infused from this donor: _______________________

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

Questions 79 - 80 are for autologous HCT recipients only.

79 What agents were used to mobilize the autologous recipient for this HCT? (check all that apply)
- G-CSF (filgrastim, Neupogen)
- Pegylated G-CSF (pegfilgrastim, Neulasta)
- Plerixafor (Mozobil)
- Combined with chemotherapy
- Anti-CD20 (rituximab, Rituxan)
- Other agent

80 Specify other agent: _______________________

81 Name of product (gene therapy recipients)
- Other name

82 Specify other name: _______________________

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

Questions: 83 - 86

83 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:

84 Karnofsky Scale (recipient age ≥ 16 years)

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

86 Recipient CMV-antibodies (IgG or Total)
- Reactive
- Non-reactive
- Indeterminate
- Not done

Comorbid Conditions
Questions: 87 - 115

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
- No

88 Did the patient require hospitalization for management of COVID-19 (SARS-CoV-2) infection?
- Yes
- No

89 Was mechanical ventilation used for COVID-19 (SARS-CoV-2) infection?
- Yes
- No
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Center: CRID:

90 Is there a history of mechanical ventilation? (excluding COVID-19 (SARS-CoV-2))
- Yes - No

91 Is there a history of invasive fungal infection?
- Yes - No

92 Glomerular filtration rate (GFR) before start of preparative regimen (pediatric only)
- Known - Unknown

93 Glomerular filtration rate (GFR): mL/min/1.73²

94 Does the recipient have known complex congenital heart disease? (corrected or uncorrected) (excluding simple ASD, VSD, or PDA repair) (pediatric only)
- Yes - No

95 Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)? (Source: Sorens, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. Blood, 121(15), 2854-2863.)
- Yes - No

96 Specify co-existing diseases or organ impairment (check all that apply)
- Arhythmia
- Cardiac
- Cerebrovascular disease
- Diabetes
- Heart valve disease
- Hepatic, mild
- Hepatic, moderate / severe
- Infection
- Inflammatory bowel disease
- Obesity
- Peptic ulcer
- Psychiatric disturbance
- Pulmonary, moderate
- Pulmonary, severe
- Renal, moderate / severe
- Rheumatologic
- Prior malignancy

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

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- **Month**
- **Day**
- **Year**

### Other organ (clinical trial sponsors that use CIBMTR forms to capture outcomes data)

- **Questions: 126 – 130**
- **Unknown**
- **(pediatric only)**
- **(check all that apply)**

### Other solid tumor (prior)

- **Specify other skin malignancy:**

### Questions: 116 - 130

- **Unknown**
- **(check all that apply)**
- **NCT**
- **(recipient age ≥ 1 year and < 16 years)**
- **Negative**
- **(For allogeneic HCTs only)**

### 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)

- **Serum ferritin (within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)**
- **Date sample collected:**
- **Upper limit of normal for your institution:**

### Questions: 102 - 106

- **(within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)**
- **g/dL**
- **g/L**

### Questions: 107 - 108

- **Platelets (within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)**
- **x 10^9/L (x 10^3/mm^3)**
- **x 10^6/L**

### Questions: 109

- **Were platelets transfused ≤ 7 days before date of test?**
- **Did the recipient have a prior solid organ transplant?**
- **Yes**
- **No**
- **Unknown**

### Questions: 112

- **Prior Solid Organ Transplant (1)**

### Questions: 113

- **Specify organ:**
- **Bowel**
- **Heart**
- **Kidney(s)**
- **Liver**
- **Lung(s)**
- **Pancreas**
- **Other organ**

### Questions: 114

- **Specify other organ:**

### Questions: 115

- **Year of prior solid organ transplant:**

### Questions: 116

- **Height at initiation of pre-HCT preparative regimen:**
- **inches**
- **centimeters**
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Center: CRID:

### Preparative Regimen (1)

117 Actual weight at initiation of pre-HCT preparative regimen: _______________ pounds ___________ kilograms

118 Was a pre-HCT preparative regimen prescribed?

- ☐ yes  ☐ no

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  ☐ no

121 What was the prescribed radiation field?

- ☐ Total body
- ☐ Total body by intensity-modulated radiation therapy (IMRT)
- ☐ Total lymphoid or nodal regions
- ☐ Thoracoabdominal region

122 Total prescribed dose: (dose per fraction x total number of fractions) __________________________

- ☐ Gy  ☐ cGy

123 Date started: __ __ __ __ __ __ __

124 Was the radiation fractionated?

- ☐ yes  ☐ no

125 Total number of fractions: __________________________

### Additional Drugs Given In The Peri-Transplant Period

131 ALG, ALS, ATG, ATS

- ☐ yes  ☐ no

132 Total prescribed dose: __________________________ mg/kg

133 Specify source

- ☐ ATGAM (horse)
- ☐ ATG - Fresenius (rabbit)
- ☐ Thymoglobulin (rabbit)
- ☐ Other

134 Specify other source:

135 Alemtuzumab (Campath)

- ☐ yes  ☐ no

136 Total prescribed dose: __________________________ mg/m2  mg/kg  mg

137 Defibrotide

- ☐ yes  ☐ no

138 KGF

- ☐ yes  ☐ no

139 Ursodiol

- ☐ yes  ☐ no

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**Error Correction Form**

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**GVHD Prophylaxis**

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

140 Was GVHD prophylaxis planned?  
- [ ] Yes  
- [ ] No

141 Specify drugs / intervention (check all that apply)

- [ ] Abatacept
- [ ] Anti CD 25 (Zenapax, Dadilizumab, 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)
- [ ] Ruxolitinib
- [ ] Sirolimus (Rapamycin, Rapamune)
- [ ] Tacrolimus (FK 506)
- [ ] Tocilizumab
- [ ] Other agent

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  
- [ ] No
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
- Gilcixil
- Ibrutinib
- Imanit 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

145 Specify other therapy: ________________________________

Prior Exposure: Potential Study Eligibility

Questions: 146 - 146

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 (Blinvyto)
- Gemtuzumab ozogamicin (Mylotarg)
- Inotuzumab ozogamicin (Besponsa)
- Adapten Tepidana®
- Mogamulizumab (Poteligo)
- None of the above