Form 2450 R5.0: Post-Transplant Essential Data

**Center:**

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**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 0.95 hours per response when collected at 6 months post-transplant, 0.65 hours per response when collected at 1 and 2 years post-transplant, and 0.52 hours per response annually thereafter, 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@hsa.gov.

**Sequence Number:**

**Date Received:**

**CIBMTR Research ID:**

**CIBMTR Center Number:**

**Visit:**

- 100 day
- 6 months
- 1 year
- 2 years
- > 2 years, Specify:

---

**Survival**

Questions: 1 - 6

1. Date of actual contact with the recipient to determine medical status for this follow-up report: ___________ - ________
2. Specify the recipient's survival status at the date of last contact:
   - Alive - Answers to subsequent questions should reflect clinical status since the date of last report
   - Dead - Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death
3. Primary cause of death
4. Specify: ___________________

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5 Contributing cause of death (check all that apply)
- Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed
- Acute GVHD
- Chronic GVHD
- Graft rejection or failure
- Cytokine release syndrome
- Infection, organism not identified
- Bacterial infection
- Fungal infection
- Viral infection
- COVID-19 (SARS-CoV-2)
- Protozoal infection
- Other infection
- Idiopathic pneumonia syndrome (IPS)
- Pneumonitis due to Cytomegalovirus (CMV)
- Pneumonitis due to other virus
- Other pulmonary syndrome (excluding pulmonary hemorrhage)
- Diffuse alveolar damage (without hemorrhage)
- Acute respiratory distress syndrome (ARDS) (other than IPS)
- Liver failure (not VOD)
- Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS)
- Cardiac failure
- Pulmonary failure
- Central nervous system (CNS) failure
- Renal failure
- Gastrointestinal (GI) failure (not liver)
- Multiple organ failure
- Other organ failure
- New malignancy (post-HCT or post-cellular therapy)
- Prior malignancy (malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed)
- Pulmonary hemorrhage
- Diffuse alveolar hemorrhage (DAH)
- Intracranial hemorrhage
- Gastrointestinal hemorrhage
- Hemorrhagic cystitis
- Other hemorrhage
- Thromboembolic
- Disseminated intravascular coagulation (DIC)
- Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS))
- Other vascular
- Accidental death
- Suicide
- Other cause

6 Specify: __________________________

Subsequent Transplant

Questions: 7 - 13

7 Did the recipient receive a subsequent HCT since the date of last report?
- yes
- no
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8 Date of subsequent HCT: ___ ___ ___ - ___ ___ ___

9 What was the indication for subsequent HCT?
   - Graft failure/insufficient hematopoietic recovery - Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT
   - Persistent primary disease - Complete a Pre-TED Form 2400 for the subsequent HCT
   - Recurrent primary disease - Complete a Pre-TED Form 2400 for the subsequent HCT
   - Planned subsequent HCT, per protocol - Complete a Pre-TED Form 2400 for the subsequent HCT
   - New malignancy (including PTLD and EBV lymphoma) - Complete a Pre-TED Form 2400 for the subsequent HCT
   - Insufficient chimerism - Complete a Pre-TED Form 2400 for the subsequent HCT
   - Other - Complete a Pre-TED Form 2400 for the subsequent HCT

10 Specify other indication:

11 Source of HSCs (check all that apply)
   - Allogeneic, related
   - Allogeneic, unrelated
   - Autologous

12 Has the recipient received a cellular therapy since the date of last report? (e.g. CAR-T, DCI)
   - yes - Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000
   - no

13 Date of cellular therapy: ___ ___ ___ - ___ ___ ___

Initial ANC Recovery

14 Was there evidence of initial hematopoietic recovery?
   - Yes (ANC ≥ 500/mm³ achieved and sustained for 3 lab values)
   - No (ANC ≥ 500/mm³ was not achieved)
   - Not applicable (ANC never dropped below 500/mm³ at any time after the start of the preparative regimen)
   - Previously reported (Recipient's initial hematopoietic recovery was recorded on a previous report)

15 Date ANC ≥ 500/mm³ (first of 3 lab values): ___ ___ ___ - ___ ___ ___

16 Did late graft failure occur?
   - Yes  No

(Optional for Non-U.S. Centers)

17 Was an initial platelet count ≥ 20 × 10⁹/L achieved?
   - Yes
   - No
   - Not applicable - Platelet count never dropped below 20 × 10⁹/L
   - Previously reported - ≥ 20 × 10⁹/L was achieved and reported previously

18 Date platelets ≥ 20 × 10⁹/L: ___ ___ ___ - ___ ___ ___

Initial Platelet Recovery

Graft vs. Host Disease

Questions: 19 - 44

If an allogeneic donor was used for the recipient's HCT or cellular therapy, report all graft-versus-host disease occurring in this reporting period. If an allogeneic donor was not used, continue to Liver Toxicity Prophylaxis, question 45.

19 Did acute GVHD develop since the date of last report?
   - Yes  No  Unknown

20 Date of acute GVHD diagnosis: ___ ___ ___ - ___ ___ ___

21 Did acute GVHD persist since the date of last report?
   - Yes  No  Unknown

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<table>
<thead>
<tr>
<th>Sequence Number</th>
<th>CRID:</th>
</tr>
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<tbody>
<tr>
<td>CIBMTR Recipient ID</td>
<td>CIBMTR Center Number</td>
</tr>
<tr>
<td>Today's Date:</td>
<td>Infusion Date:</td>
</tr>
<tr>
<td>Month</td>
<td>Day</td>
</tr>
</tbody>
</table>

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<tr>
<td>Intervention for relapsed disease, persistent disease, or progressive disease</td>
</tr>
</tbody>
</table>

**List the stage for each organ at diagnosis of acute GVHD:**

### 22 Overall grade of acute GVHD at diagnosis

- I - Rash on ≤ 50% of skin, no liver or gut involvement
- II - Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500-1000 mL/day or persistent nausea or vomiting
- III - Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus
- IV - Generalized erythroderma with bullous formation, or bilirubin > 15 mg/dL
- Not applicable (acute GVHD present but grade is not applicable)

### 23 Skin

- Stage 0 - No rash, no rash attributable to acute GVHD
- Stage 1 - Maculopapular rash, < 25% of body surface
- Stage 2 - Maculopapular rash, 25-50% of body surface
- Stage 3 - Generalized erythroderma, > 50% of body surface
- Stage 4 - Generalized erythroderma with bullae formation and/or desquamation

### 24 Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)

- Stage 0 - No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)
- Stage 1 - Diarrhea 500-1000 mL/day (adult), or 10-19.9 mL/kg/day (pediatric)
- Stage 2 - Diarrhea 1001-1500 mL/day (adult), or 20-30 mL/kg/day (pediatric)
- Stage 3 - Diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)
- Stage 4 - Severe abdominal pain, with or without ileus, and/or grossly bloody stool

### 25 Upper intestinal tract

- Stage 0 - No persistent nausea or vomiting
- Stage 1 - Persistent nausea or vomiting

### 26 Liver

- Stage 0 - No liver acute GVHD/bilirubin < 2.0 mg/dL (<34 µmol/L)
- Stage 1 - Bilirubin 2.0-3.0 mg/dL (34-52 µmol/L)
- Stage 2 - Bilirubin 3.1-6.0 mg/dL (53-103 µmol/L)
- Stage 3 - Bilirubin 6.1-15.0 mg/dL (104-256 µmol/L)
- Stage 4 - Bilirubin > 15.0 mg/dL (>256 µmol/L)

### 27 Other site(s) involved with acute GVHD

- Yes
- No

### 28 Specify other site(s):

**Specify the maximum overall grade and organ staging of acute GVHD since the date of last report**

### 29 Maximum overall grade of acute GVHD

- I - Rash on ≤ 50% of skin, no liver or gut involvement
- II - Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500-1000 mL/day or persistent nausea or vomiting
- III - Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus
- IV - Generalized erythroderma with bullous formation, or bilirubin > 15 mg/dL
- Not applicable (acute GVHD present but cannot be graded)

### 30 Date maximum overall grade of acute GVHD: __ __ __ __ __ __ __ __

### 31 Skin

- Stage 0 - No rash, no rash attributable to acute GVHD
- Stage 1 - Maculopapular rash, < 25% of body surface
- Stage 2 - Maculopapular rash, 25-50% of body surface
- Stage 3 - Generalized erythroderma, >50% of body surface
- Stage 4 - Generalized erythroderma with bullae formation and/or desquamation

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32 Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)
   - Stage 0: No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)
   - Stage 1: Diarrhea 500-1000 mL/day (adult), or 10-19.9 mL/kg/day (pediatric)
   - Stage 2: Diarrhea 1001-1500 mL/day (adult), or 20-30 mL/kg/day (pediatric)
   - Stage 3: Diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)
   - Stage 4: Severe abdominal pain, with or without ileus, and/or grossly bloody stool

33 Upper intestinal tract
   - Stage 0: No persistent nausea or vomiting
   - Stage 1: Persistent nausea or vomiting

34 Liver
   - Stage 0: No liver acute GVHD/bilirubin < 2.0 mg/dL (>34 µmol/L)
   - Stage 1: Bilirubin 2.0-3.0 mg/dL (34-52 µmol/L)
   - Stage 2: Bilirubin 3.1-6.0 mg/dL (53-103 µmol/L)
   - Stage 3: Bilirubin 6.1-15.0 mg/dL (104-256 µmol/L)
   - Stage 4: Bilirubin >15.0 mg/dL (>256 µmol/L)

35 Other site(s) involved with acute GVHD
   - Yes
   - No

36 Specify other site(s):

37 Did chronic GVHD develop since the date of last report?
   - Yes
   - No
   - Unknown

38 Date of chronic GVHD diagnosis: __ __ __ __ __ __ __ __ Date estimated

39 Did chronic GVHD persist since the date of last report?
   - Yes
   - No
   - Unknown

40 Specify the maximum grade of chronic GVHD since the date of last report:
   - Mild
   - Moderate
   - Severe
   - Unknown

41 Specify if chronic GVHD was limited or extensive
   - Limited - localized skin involvement and/or liver dysfunction
   - Extensive - one or more of the following:
     - generalized skin involvement; or
     - liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or
     - involvement of eye: Schirmer's test < 5mm wetting; or
     - involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or
     - involvement of any other target organ

42 Date of maximum grade of chronic GVHD: __ __ __ __ __ __ __ __

43 Is the recipient still taking systemic steroids? (Do not report steroids for adrenal insufficiency, or steroid dose ≤ 10 mg/day for adults, < 0.1 mg/kg/day for children)
   - Yes
   - No
   - Not Applicable
   - Unknown

44 Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?
   - Yes
   - No
   - Not Applicable
   - Unknown

### Liver Toxicity Prophylaxis

**Questions: 45 - 47**

45 Was specific therapy used to prevent liver toxicity?
   - Yes
   - No
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46 Specify therapy (check all that apply)
- Defibrotide
- N-acetylcysteine
- Tissue plasminogen activator (TPA)
- Ursodiol
- Other

47 Specify other therapy: __________________________________________

Veno-occlusive disease (VOD) / Sinusoidal obstruction syndrome (SOS)
Questions: 48 - 49

48 Did veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) develop since the date of last report?
- Yes ☐ No ☐

49 Date of diagnosis: __ __ __ __ __ __ __ __ __

Infection
Questions: 50 - 51

50 Did the recipient develop COVID-19 (SARS-CoV-2) since the date of last report?
- Yes ☐ No ☐

51 Date of diagnosis: __ __ __ __ __ __ __ __ __

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder
Questions: 52 - 59

52 Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed? (include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)
- Yes ☐ No ☐

New Malignancy (1)
Questions: 53 - 59

53 Specify the new malignancy ____________________________

54 Specify other new malignancy: ____________________________

55 Is the tumor EBV positive?
- Yes ☐ No ☐

56 Date of diagnosis: __ __ __ __ __ __ __ __ __

57 Was documentation submitted to the CIBMTR? (e.g. pathology / autopsy report or other documentation)
- Yes ☐ No ☐

58 Was the new malignancy donor / cell product derived?
- Yes ☐ No ☐ Not done ☐

59 Was documentation submitted to the CIBMTR? (e.g. cell origin evaluation (VNTR, cytogenetics, FISH))
- Yes ☐ No ☐

Chimerism Studies (Cord Blood Units, Beta Thalassemia, and Sickle Cell Disease Only)
Questions: 60 - 79

This section relates to chimerism studies from allogeneic HCTs using cord blood units or for recipients whose primary disease is beta thalassemia or sickle cell disease. If this was an autologous HCT, or an allogeneic HCT using a bone marrow or PBSC product, or a different primary disease, continue to disease assessment.

60 Were chimerism studies performed since the date of last report?
- Yes ☐ No ☐
ERROR CORRECTION FORM

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61 Was documentation submitted to the CIBMTR? (e.g. chimerism laboratory reports)
   ☐ Yes ☐ No

62 Were chimerism studies assessed for more than one donor / multiple donors?
   ☐ Yes ☐ No

Chimerism Studies (Cord Blood Units and Beta Thalassemia) (1)

Questions: 63 - 78

64 NMDP cord blood unit ID: ________________________

65 Registry donor ID: _____________________________

66 Non-NMDP cord blood unit ID: ________________________

67 Global Registration Identifier for Donors (GRID) ________________________

68 Date of birth: (donor / infant) _______ - _______ - _______ OR - Age: (donor / infant) _______ ☐ Months ☐ years

69 Sex (donor / infant)
   ☐ male ☐ female

70 Date sample collected: _______ - _______ - _______

71 Method
   ☐ Karyotyping for XX/XY
   ☐ Fluorescent in situ hybridization (FISH) for XX/XX
   ☐ Restriction fragment-length polymorphisms (RFLP)
   ☐ VNTR or STR, micro or mini satellite (Also include AFLP)
   ☐ Other

72 Specify: ________________________

73 Cell source
   ☐ Bone marrow ☐ Peripheral blood

74 Cell type
   ☐ Unsorted / whole
   ☐ Red blood cells
   ☐ Hematopoietic progenitor cells (CD34+ cells)
   ☐ Total mononuclear cells (lymphs & monos)
   ☐ T-cells (includes CD3+, CD4+, and/or CD8+)
   ☐ B-cells (includes CD19+ or CD20+)
   ☐ Granulocytes (includes CD33+ myeloid cells)
   ☐ NK cells (CD56+)
   ☐ Other

75 Specify: ________________________

76 Total cells examined: ________________________

77 Number of donor cells: ________________________

78 Were donor cells detected?
   ☐ Yes ☐ No

79 Percent donor cells: ________________________%

Disease Assessment at the Time of Best Response to HCT

Questions: 80 - 102

80 Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)
   ☐ Continued complete remission (CCR) - For patients transplanted in CR
   ☐ Complete remission (CR)
   ☐ Not in complete remission
   ☐ Not evaluated

81 Specify disease status if not in complete remission
   ☐ Disease detected
   ☐ No disease detected but incomplete evaluation to establish CR

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**Post-HCT Therapy**

<table>
<thead>
<tr>
<th>Questions: 103 - 107</th>
</tr>
</thead>
</table>

Report therapy given since the date of last report to prevent relapse or progressive disease. This may include maintenance and consolidation therapy. Do not report any therapy given for relapsed, persistent, or progressive disease.

103 Was therapy given since the date of the last report for reasons other than relapse, persistent, or progressive disease? (Include any maintenance and consolidation therapy)

- [ ] yes
- [ ] no

104 Specify therapy (check all that apply)

- - Blinded randomized trial
- - Cellular therapy
- - Radiation
- - Systemic therapy
- - Other therapy
105 Specify systemic therapy (check all that apply)
- Alemtuzumab (Campath)
- Azacytidine (Vidaza)
- Blinatumomab
- Bortezomib (Velcade)
- Bosutinib
- Carfilzomib
- Chemotherapy
- Dasatinib (Sprycel)
- Decitabine (Dacogen)
- Gemtuzumab (Mylotarg, anti-CD33)
- Gilbertinib
- Ibrutinib
- Imatinib mesylate (Gleevec)
- Ixazomib
- Lenalidomide (Revlimid)
- Lestaurtinib
- Midostaurin
- Nilotinib (AMN107, Tasigna)
- Nivolumab
- Pembrolizumab
- Pomalidomide
- Quizzartinib
- Rituximab (Rituxan, MabThera)
- Sorafenib
- Sunitinib
- Thalidomide (Thalomid)
- Other systemic therapy

106 Specify other systemic therapy: ____________________________

107 Specify other therapy: ____________________________

Relapse or Progression Post-HCT

Questions: 108 - 118

Report if the recipient has experienced a clinical / hematologic relapse or progression post HCT. If the relapse or progression was detected in a previous reporting period indicate that and continue on. If the first clinical / hematologic relapse occurred since the date of last report, indicate the date it was first detected in this reporting period.

108 Did the recipient experience a clinical/hematologic relapse or progression post-HCT?
- Yes
- No

109 Was the date of the first clinical / hematologic relapse or progression previously reported?
- Yes
- No

110 Date first seen: __ __ __ __ __ __

Intervention for relapsed disease, persistent disease, or progressive disease

111 Was intervention given for relapsed, persistent or progressive disease since the date of last report?
- Yes
- No

112 Specify reason for which intervention was given
- Persistent disease
- Relapsed / progressive disease
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113 Specify the method(s) of disease detection for which intervention was given (check all that apply)
   - Clinical / hematologic
   - Cytogenetic
   - Disease specific molecular marker
   - Flow cytometry
   - Radiological (e.g. PET, MRI, CT)

114 Date intervention started: ____________

115 Specify therapy (check all that apply)
   - Blinded randomized trial
   - Cellular therapy
   - Radiation
   - Systemic therapy
   - Other therapy

116 Specify systemic therapy (check all that apply)
   - Alectuzumab (Campath)
   - Azacytidine (Vidaza)
   - Blinatumomab
   - Bortezomib (Velcade)
   - Bosutinib
   - Carfilzomib
   - Chemotherapy
   - Dasatinib (Sprycel)
   - Decitabine (Dacogen)
   - Gemtuzumab (Mylotarg, anti-CD33)
   - Gilteritinib
   - Ibrutinib
   - Imatinib mesylate (Gleevec)
   - Ixazomib
   - Lenalidomide (Revlimid)
   - Lestaurtinib
   - Midostaurin
   - Nilotinib (AMN107, Tasigna)
   - Nivolumab
   - Pembrolizumab
   - Pomalidomide
   - Quizartinib
   - Ruxitumab (Rituxan, MabTherap)
   - Sorafenib
   - Sunitinib
   - Thalidomide (Thalomid)
   - Other systemic therapy

117 Specify other systemic therapy: ______________________

118 Specify other therapy: ______________________

Current Disease Status

Questions: 119 - 122
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**Center:**

**CRID:**

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119 What is the current disease status?
- Complete remission (CR)
- Not in complete remission
- Not evaluated

120 Specify disease status if not in complete remission
- Disease detected
- No disease detected but incomplete evaluation to establish CR

121 Date of most recent disease assessment
- Known
- Unknown

122 Date of most recent disease assessment: ___ ___ - ___ ___ ___

**First Name:**

**Last Name:**

**E-mail address:**

**Date:** ___ ___ - ___ ___ ___