



# Yearly Follow-Up for Greater Than Two Years Post-HSCT Data

## Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

Today's Date:  /  /  20

Month                  Day                  Year

Date of HSCT for which this form is being completed:  /  /

Month                  Day                  Year

HSCT type:  autologous     allogeneic, unrelated     allogeneic, related     syngeneic (identical twin)

Product type:  marrow     PBSC     cord blood     other product, specify: \_\_\_\_\_  
 multiple cord blood units infused

Follow-up visit (years after transplant):

**Information should come from an actual examination by the Transplant Center physician, or the local physician who is following the recipient post-HSCT. Questions followed by the symbol indicate additional information necessary to complete the question is referenced in the forms instruction manual; A indicates an appendix.**

## Vital Status

1. Is the data reported on this form based on contact with the physician?

- 1  yes
- 2  no

2. Date of actual contact with recipient to determine medical status for this follow-up report:  /  /

Month                  Day                  Year

3. Did the recipient receive a subsequent HSCT (bone marrow, mobilized peripheral blood stem cells, cord blood) since the date of contact from the last report?

- 1  yes → **Answers to subsequent questions should reflect clinical status immediately prior to start of the preparative regimen for subsequent HSCT. Complete Subsequent HSCT questions 213–220.**
- 2  no

4. Specify the recipient's survival status at the date of actual contact:

- 1  alive → **Answers to subsequent questions should reflect clinical status between last day of contact reported on prior follow-up form and the day of actual contact for this follow-up form (question 2).**
- 2  dead → **Answers to subsequent questions should reflect clinical status between last day of contact reported on prior follow-up form and immediately prior to death. Complete a Form 2900 — Recipient Death Data.**

5. Has the recipient received a donor cellular infusion (DCI) since the date of contact from the last report?

- 1  yes → **Complete DCI Information questions 221–319.**
- 2  no

**Mail a copy of this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the Transplant Center.**

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### Functional Status

6. Specify the functional status of the recipient on the date of last actual contact (table below). If the recipient has died, skip this question and continue with question 7.

| Karnofsky Scale (recipient age ≥ 16 years)   | Lansky Scale (recipient age < 16 years)  |
|--|--|
| Select the phrase in the Karnofsky Scale which best describes the activity status of the recipient:<br><b>Able to carry on normal activity; no special care is needed</b><br>1 <input type="checkbox"/> 100 Normal; no complaints; no evidence of disease<br>2 <input type="checkbox"/> 90 Able to carry on normal activity<br>3 <input type="checkbox"/> 80 Normal activity with effort<br><b>Unable to work; able to live at home, cares for most personal needs; a varying amount of assistance is needed</b><br>4 <input type="checkbox"/> 70 Cares for self; unable to carry on normal activity or to do active work<br>5 <input type="checkbox"/> 60 Requires occasional assistance but is able to care for most needs<br>6 <input type="checkbox"/> 50 Requires considerable assistance and frequent medical care<br><b>Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly</b><br>7 <input type="checkbox"/> 40 Disabled; requires special care and assistance<br>8 <input type="checkbox"/> 30 Severely disabled; hospitalization indicated, although death not imminent<br>9 <input type="checkbox"/> 20 Very sick; hospitalization necessary<br>10 <input type="checkbox"/> 10 Moribund; fatal process progressing rapidly | Select the phrase in the Lansky Play-Performance Scale which best describes the activity status of the recipient:<br><b>Able to carry on normal activity; no special care is needed</b><br>1 <input type="checkbox"/> 100 Fully active<br>2 <input type="checkbox"/> 90 Minor restriction in physically strenuous play<br>3 <input type="checkbox"/> 80 Restricted in strenuous play, tires more easily, otherwise active<br><b>Mild to moderate restriction</b><br>4 <input type="checkbox"/> 70 Both greater restrictions of, and less time spent in, active play<br>5 <input type="checkbox"/> 60 Ambulatory up to 50% of time, limited active play with assistance / supervision<br>6 <input type="checkbox"/> 50 Considerable assistance required for any active play; fully able to engage in quiet play<br><b>Moderate to severe restriction</b><br>7 <input type="checkbox"/> 40 Able to initiate quiet activities<br>8 <input type="checkbox"/> 30 Needs considerable assistance for quiet activity<br>9 <input type="checkbox"/> 20 Limited to very passive activity initiated by others (e.g., TV)<br>10 <input type="checkbox"/> 10 Completely disabled, not even passive play |

7. Specify the category which best describes the recipient's current occupation:

(If the recipient is not currently employed, check the box which best describes his/her last job.)

- 1  professional, technical, or related occupation (e.g., teacher/professor, nurse/physician, lawyer, engineer)
- 2  manager, administrator, or proprietor (e.g., sales manager, real estate agent, postmaster)
- 3  clerical or related occupation (e.g., secretary, clerk, mail carrier)
- 4  sales occupation (e.g., sales associate, demonstrator, agent, broker)
- 5  service occupation (e.g., police officer, cook, hairdresser)
- 6  skilled craft or related occupation (e.g., carpenter, repair technician, telephone line worker)
- 7  equipment / vehicle operator or related occupation (e.g., driver, railroad brakeman, sewer worker)
- 8  laborer (e.g., helper, longshoreman, warehouse worker)
- 9  farmer (e.g., owner, manager, operator, tenant)
- 10  member of the military
- 11  homemaker
- 12  student
- 13  under school age → **Continue with question 11**
- 14  not previously employed
- 15  unknown
- 16  other →

9. What is the recipient's current or most recent work status during this reporting period?

- 1  full time
- 2  part time
- 3  unemployed
- 4  medical disability
- 5  retired →
- 6  unknown

10. Specify retirement status:
- 1  with a source of income
  - 2  no source of income

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The next two sections relate to graft-vs.-host disease from allogeneic HSCTs only. If this was an autologous HSCT, continue with the New Malignancies section at question 131.

### Acute Graft vs. Host Disease (GVHD)

11. Did acute GVHD develop or persist (or a flare-up that was more severe) since the date of the last report?

1  yes

2  no

Continue with 59

3  unknown

Continue with 59

12. Date of acute GVHD diagnosis:        
Month Day Year

Date was previously reported

13. Was the diagnosis based on evidence from a biopsy (histology)?

1  yes

2  no

Specify result(s):

positive negative incon- not  
clusive tested

14. 1  2  3  4  gastrointestinal (GI)

15. 1  2  3  4  liver

16. 1  2  3  4  lung

17. 1  2  3  4  skin

18. 1  2  3  4  other site

19. Specify other site:

20. Is a copy of the pathology report attached?

1  yes

2  no

21. Was the diagnosis based on clinical evidence?

1  yes

2  no

22. Maximum overall grade of acute GVHD:

1  I

2  II

3  III

4  IV

23. Is acute GVHD still present at the date of contact for this report (question 2)?

1  yes

2  no

3  progressed to chronic GVHD

4  unknown

List the maximum severity of organ involvement:

24. Skin:

1  no skin acute GVHD / rash not attributable to acute GVHD

2  stage 0 – no rash

3  stage 1 – maculopapular rash, < 25% of body surface

4  stage 2 – maculopapular rash, 25–50% of body surface

5  stage 3 – generalized erythroderma

6  stage 4 – generalized erythroderma with bullae formation and desquamation

25. Lower intestinal tract: (use mL/day for adult recipients and mL/m<sup>2</sup>/day for pediatric recipients) 

1  no gut acute GVHD / diarrhea not attributable to acute GVHD

2  stage 0 – no diarrhea

3  stage 0 – diarrhea ≤ 500 mL/day or < 280 mL/m<sup>2</sup>/day

4  stage 1 – diarrhea > 500 but ≤ 1000 mL/day or 280-555 mL/m<sup>2</sup>/day

5  stage 2 – diarrhea > 1000 but ≤ 1500 mL/day or 556-833 mL/m<sup>2</sup>/day

6  stage 3 – diarrhea > 1500 mL/day or > 833 mL/m<sup>2</sup>/day

7  stage 4 – severe abdominal pain, with or without ileus

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## 26. Upper intestinal tract:

- 1  stage 0 – no persistent nausea or vomiting  
 2  stage 1 – persistent nausea or vomiting

## 27. Liver:

- 1  no liver acute GVHD / bilirubin level not attributable to acute GVHD  
 2  stage 0 – bilirubin < 2.0 mg/dL (< 34 µmol/L)  
 3  stage 1 – bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)  
 4  stage 2 – bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)  
 5  stage 3 – bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)  
 6  stage 4 – bilirubin > 15.0 mg/dL (> 256 µmol/L)

## 28. Other clinical organ involvement?

- 1  yes  
 2  no

Specify site:

29. 1  yes 2  no lung30. 1  yes 2  no other

31. Specify:

## 32. Was specific therapy used to treat acute GVHD since the date of the last report?

- 1  yes  
 2  no

**Continue with  
question 59**

## 33. ALS, ALG, ATS, ATG

- 1  yes  
 2  no

34. Specify source:

- 1  horse  
 2  rabbit  
 3  other

35. Specify:

36. 1  yes 2  no Corticosteroids (systemic)  
 37. 1  yes 2  no Corticosteroids (topical)  
 38. 1  yes 2  no Cyclosporine (CSA) (Sandimmune, Neoral)  
 39. 1  yes 2  no ECP (extra-corporeal photopheresis)  
 40. 1  yes 2  no FK 506 (Tacrolimus, Prograf)

## 41. In vivo monoclonal antibody

- 1  yes  
 2  no

Specify:

42. Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

- 1  yes  
 2  no

43. Specify:

44. 1  yes 2  no Campath  
 45. 1  yes 2  no Etanercept (Enbrel)  
 46. 1  yes 2  no Infliximab (Remicade)

47. Other in vivo monoclonal antibody

- 1  yes  
 2  no

48. Specify:

49. 1  yes 2  no In vivo immunotoxin

50. Specify:

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|  |   |
|--|---|
| 51. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Methotrexate (MTX) (Amethopterin)       |
| 52. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Mycophenolate mofetil (MMF) (CellCept)  |
| 53. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Sirolimus (Rapamycin, Rapamune)         |
| 54. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Ursodiol                                |
| 55. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Blinded randomized trial →              |
|  | <input type="text"/> 56. Specify agent: |
| 57. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Other agent →                           |
|  | <input type="text"/> 58. Specify:       |

### Chronic Graft vs. Host Disease (GVHD)

59. Did chronic GVHD develop or persist (or a flare-up that was more severe) since the date of the last report?

1  yes →

2  no

**Continue with 129**

3  no symptoms, but recipient is receiving treatment

**Continue with 97**

4  unknown

**Continue with 129**

60. Date of chronic GVHD diagnosis:        Date was previously reported

Month Day Year

**Continue with 65**

61. Onset of chronic GVHD was:

- 1  progressive (acute GVHD progressed directly to chronic GVHD)
- 2  interrupted (acute GVHD resolved, then chronic GVHD developed)
- 3  de novo (acute GVHD never developed)
- 4  chronic GVHD flare (symptoms reactivated within 30 days of drug tapering or discontinuation)

62. Karnofsky / Lansky score at diagnosis of chronic GVHD:     
(See page 2 for scale descriptions.)

63. Platelet count at diagnosis of chronic GVHD:       1  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
2  x 10<sup>6</sup>/L

64. Diagnosis was based on:

- 1  histologic evidence / biopsy proven
- 2  clinical evidence
- 3  both
- 4  unknown

65. Maximum grade of chronic GVHD:

- 1  limited – localized skin involvement and/or hepatic dysfunction due to chronic GVHD
- 2  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 with < 5 mm wetting; or
  - involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or
  - involvement of any other target organ

66. Overall severity of chronic GVHD:

- 1  mild – signs and symptoms of chronic GVHD do not interfere substantially with function and do not progress once appropriately treated with local therapy or standard systemic therapy (corticosteroids and/or cyclosporine or FK 506)
- 2  moderate – signs and symptoms of chronic GVHD interfere somewhat with function despite appropriate therapy or are progressive through first line systemic therapy (corticosteroids and/or cyclosporine or FK 506)
- 3  severe – signs and symptoms of chronic GVHD limit function substantially despite appropriate therapy or are progressive through second line therapy

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**Organ Involvement**

Indicate if there was organ involvement with chronic GVHD:

- |     |  | Organ / System   | If yes, was involvement proven by biopsy?                        |
|-----|--|--|--|
| 67. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Sclerosis of skin →  | 68. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 69. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Other skin or hair involvement (rash, ulcers, pruritus or itching, dyspigmentation, alopecia, pruritus pruritus changes, etc.) →             | 70. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 71. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Eyes (xerophthalmia (dry eyes), abnormal Schirmer's test, abnormal slit lamp, corneal erosion / conjunctivitis, etc.) →                      | 72. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 73. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Mouth (lichenoid changes, mucositis / ulcers, erythema, etc.) →  | 74. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 75. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Bronchiolitis obliterans →   | 76. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 77. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Other lung involvement →   | 78. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 79. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Gastrointestinal tract (esophageal involvement, chronic nausea / vomiting, chronic diarrhea, malabsorption, abdominal pain / cramps, etc.) → | 80. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 81. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Liver →  | 82. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 83. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Genitourinary tract (vaginitis / stricture, etc.) →  | 84. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 85. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Musculoskeletal (arthritis, contractures, myositis, myasthenia, etc.) →  | 86. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 87. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Thrombocytopenia (< 100 x 10 <sup>9</sup> /L)  |  |
| 88. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Eosinophilia   |  |
| 89. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Autoantibodies   |  |
| 90. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Other hematologic involvement  |  |
| 91. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Serositis →  | 92. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
| 93. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Weight loss  |  |
| 94. | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no | Other organ involvement from chronic GVHD →  | 96. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no |
|     |  | 95. Specify site: _____  |  |

97. Was specific therapy used to treat chronic GVHD?

- 1  yes →  
2  no

Specify:

98. ALS, ALG, ATS, ATG

- 1  yes →  
2  no

99. Specify source:

- 1  horse  
2  rabbit  
3  other →

100. Specify:  
\_\_\_\_\_

101. 1  yes 2  no Azathioprine  
102. 1  yes 2  no Corticosteroids (systemic)  
103. 1  yes 2  no Corticosteroids (topical)  
104. 1  yes 2  no Cyclosporine (CSA) (Sandimmune, Neoral)  
105. 1  yes 2  no ECP (extracorporeal photopheresis)  
106. 1  yes 2  no Etretinate  
107. 1  yes 2  no FK 506 (Tacrolimus, Prograf)  
108. 1  yes 2  no Hydroxychloroquine (Plaquenil)

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109. In vivo monoclonal antibody

1  yes →  
2  no

Specify:

110. Anti CD 25 (Zenapax, Daclizumab, AntiTAC)  
1  yes → 111. Specify:   
2  no

112. 1  yes 2  no Campath  
113. 1  yes 2  no Etanercept (Enbrel)  
114. 1  yes 2  no Infliximab (Remicade)  
115. Other in vivo monoclonal antibody  
1  yes → 116. Specify:   
2  no

117. 1  yes 2  no Lamprene (Clofazimine)  
118. 1  yes 2  no Mycophenolate mofetil (MMF) (CellCept)  
119. 1  yes 2  no Pentostatin  
120. 1  yes 2  no PUVA (Psoralen and UVA)  
121. 1  yes 2  no Sirolimus (Rapamycin, Rapamune)  
122. 1  yes 2  no Thalidomide  
123. 1  yes 2  no Ursodiol  
124. 1  yes 2  no Blinded randomized trial → 125. Specify agent:   
126. 1  yes 2  no Other agent → 127. Specify:

128. Are symptoms of chronic GVHD still present on the date of actual contact (or present at the time of death)?

- 1  yes
- 2  no

129. Is recipient still taking immunosuppressive agents (including PUVA) to treat or prevent GVHD? 

- 1  yes →
- 2  no
- 3  unknown

130. Date final treatment administered:

Month                      Day                      Year

date unknown  
 date was previously reported

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### New Malignancies

131. Did a new malignancy, lymphoproliferative or myeloproliferative disorder develop since the date of the last report that is different from the disease for which the HSCT was performed?

- 1  yes
- 2  no

| Specify which new disease(s) occurred: |  | Date of diagnosis:   |                      |                      |
|--|--|--|----------------------|----------------------|
|  |  | Month  | Day                  | Year                 |
| 132.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no acute myeloid leukemia (AML / ANLL) →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 134.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no other leukemia, including ALL →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
|  |  | 135. <input type="text"/>  |                      |                      |
|  |  | 136. Specify: _____  |                      |                      |
| 137.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no breast cancer →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 139.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no central nervous system (CNS) malignancy (glioblastoma, astrocytoma) →                   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 141.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no clonal cytogenetic abnormality without leukemia or MDS →                                | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 142.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine) →             | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 143.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine) →             | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 144.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no genitourinary malignancy (kidney, bladder, ovary, testicle genitalia, uterus, cervix) → | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 145.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no genitourinary malignancy (kidney, bladder, ovary, testicle genitalia, uterus, cervix) → | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 146.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no Hodgkin disease →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 147.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no Hodgkin disease →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 148.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no lung cancer →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 149.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no lung cancer →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 150.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no lymphoma or lymphoproliferative disease →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 151.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no lymphoma or lymphoproliferative disease →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
|  |  | 152. <input type="text"/>  |                      |                      |
|  |  | 153. Is the tumor EBV positive?<br>1 <input type="checkbox"/> yes<br>2 <input type="checkbox"/> no   |                      |                      |
| 154.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no melanoma →  | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 155.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no melanoma →  | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 156.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no other skin malignancy (basal cell, squamous) →  | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 157.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no other skin malignancy (basal cell, squamous) →  | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
|  |  | 158. Specify: _____  |                      |                      |
| 159.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no myelodysplasia (MDS) / myeloproliferative (MPS) disorder →                              | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 160.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no myelodysplasia (MDS) / myeloproliferative (MPS) disorder →                              | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 161.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no oropharyngeal cancer (tongue, buccal mucosa) →  | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 162.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no oropharyngeal cancer (tongue, buccal mucosa) →  | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 163.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no sarcoma →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 164.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no sarcoma →   | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 165.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no thyroid cancer →  | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 166.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no thyroid cancer →  | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
| 167.                                   | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no other new malignancy →  | <input type="text"/>   | <input type="text"/> | <input type="text"/> |
|  |  | 168. <input type="text"/>  |                      |                      |
|  |  | 169. Specify: _____  |                      |                      |
| 170.                                   | Is a pathology / autopsy report or other documentation attached?<br>1 <input type="checkbox"/> yes →<br>2 <input type="checkbox"/> no                | <b>Attach a copy of the report with all identifiers removed, except for birth date and ID numbers. Reference question 170 on the report.</b> |                      |                      |

CIBMTR Center Number:

CIBMTR Recipient ID:

### Other Organ Impairment / Disorder

171. Has the recipient developed any other clinically significant organ impairment or disorder since the date of the last report?

- 1  yes
- 2  no

| Specify impairment / disorder: |  | Date of diagnosis:   |                      |                      |
|--------------------------------|--|----------------------|----------------------|----------------------|
|                                |  | Month                | Day                  | Year                 |
| 172.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no avascular necrosis  | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 174.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no bronchiolitis obliterans (BO)   | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 176.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no cataracts   | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 178.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no congestive heart failure (EF < 40%)   | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 180.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no cryptogenic organizing pneumonia (COP)  | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 182.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no diabetes / hyperglycemia  | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 184.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no gonadal dysfunction / infertility requiring hormone replacement (testosterone or estrogen)  | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 186.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no growth hormone deficiency / growth disturbance  | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 188.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no hemorrhagic cystitis / hematuria requiring medical intervention (catheterization of bladder, extra transfusions, urology consult) | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 190.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no hypothyroidism  | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 192.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no interstitial pneumonitis (IPn) / ARDS   | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 194.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no myocardial infarction   | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 196.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no non-infectious liver toxicity   | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 198.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no pancreatitis  | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 200.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no post-transplant microangiopathy-thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS), or similar syndrome   | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 201.                           | <input type="text"/>   |                      |                      |                      |
| 202.                           | Did the recipient receive plasmapheresis?<br>1 <input type="checkbox"/> yes<br>2 <input type="checkbox"/> no   |                      |                      |                      |
| 203.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no pulmonary hemorrhage  | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 205.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no renal failure severe enough to warrant dialysis   | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 206.                           | <input type="text"/>   |                      |                      |                      |
| 207.                           | Did the recipient receive dialysis?<br>1 <input type="checkbox"/> yes<br>2 <input type="checkbox"/> no   |                      |                      |                      |
| 208.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no stroke / seizure  | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 209.                           | <input type="text"/>   |                      |                      |                      |
| 210.                           | 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no other   | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 211.                           | <input type="text"/>   |                      |                      |                      |
| 212.                           | Specify impairment / disorder:<br><input type="text"/>   |                      |                      |                      |

CIBMTR Center Number:

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## Subsequent HSCT

**Complete this section if the recipient received a subsequent HSCT (question 3, answered “yes”). If the recipient received only DCIs with no subsequent HSCTs, continue with question 221. If no subsequent HSCTs or DCIs were performed, continue with the signature lines at question 320.**

213. Date of subsequent HSCT:        
Month Day Year

214. Was the subsequent HSCT performed at a different institution?

- 1  yes  
2  no

215. Specify the institution that performed the subsequent HSCT:

Name: \_\_\_\_\_  
City: \_\_\_\_\_  
State / Country: \_\_\_\_\_

216. What was the indication for subsequent HSCT?

**Subsequent autologous HSCTs performed for engraftment reasons (options 1–3) do not require separate report forms to be completed. All other subsequent HSCTs will require a separate follow-up report form completed for each infusion.**

- 1  no hematopoietic recovery  
2  partial hematopoietic recovery  
3  graft failure / rejection after achieving initial hematopoietic recovery  
4  persistent primary disease  
5  recurrent primary disease  
6  planned second HSCT, per protocol  
7  new malignancy  
8  stable, mixed chimerism  
9  declining chimerism  
10  other

**Complete the section on New Malignancies (questions 131–170).**

217. Specify: \_\_\_\_\_

218. Source of HSCs:

- 1  allogeneic, related  
2  allogeneic, unrelated  
3  autologous

**Complete a new Form 2000 — Recipient Baseline Data.**

219. Was the same donor used?

- 1  yes  
2  no

**Complete a new Form 2000 — Recipient Baseline Data.**

220. Specify:

- 1  fresh, original NMDP donor bone marrow  
2  fresh, original non-NMDP donor bone marrow  
3  fresh, second NMDP donor bone marrow  
4  fresh, second non-NMDP donor bone marrow  
5  fresh, original NMDP donor mobilized peripheral blood stem cells  
6  fresh, original non-NMDP donor mobilized peripheral blood stem cells  
7  fresh, second NMDP donor mobilized peripheral blood stem cells  
8  fresh, second non-NMDP donor mobilized peripheral blood stem cells  
9  NMDP cord blood  
10  non-NMDP cord blood  
11  cryopreserved original donor bone marrow  
12  cryopreserved original donor mobilized peripheral blood stem cells

**Complete a new Form 2000 — Recipient Baseline Data.**

CIBMTR Center Number:

CIBMTR Recipient ID:

### Donor Cellular Infusion (DCI) Information

This section captures information on DCIs (question 5, answered “yes”) from any donor source (unstimulated peripheral blood mononuclear cells, T cells, NK cells, other cells). Complete this DCI section for all infusions given in a 10 week period. If more than 10 weeks have elapsed between DCIs, copy and complete this section for each 10 week period. If the recipient did not receive any DCIs, continue with the signature lines at question 320.

221. Date the first DCI was given:        
Month Day Year

222. Specify the total number of cell infusions given within 10 weeks of the first DCI:

223. Was the DCI infusion performed at a different institution?

- 1  yes
- 2  no

224. Specify the institution that performed the DCI:  
Name: \_\_\_\_\_  
City: \_\_\_\_\_  
State / Country: \_\_\_\_\_

225. Indication for DCI:

- 1  planned as part of initial HSCT protocol
- 2  treatment for relapsed, persistent or progressive disease

- 3  treatment for B cell lymphoproliferative disorder (PTLD, EBV lymphoma)

- 4  treatment for GVHD

- 5  viral infection

- 6  stable, mixed chimerism

- 7  loss of / decreased donor T-cell chimerism

- 8  other

Specify the method(s) of disease detection below. For each method used, if the result was positive report the first date the disease was detected; if the result was negative report the last date the method was used prior to DCI (question 221).

|      | positive                   | negative                   | not done / unknown         |                                 | Month      | Day                  | Year                 |                      |                      |
|------|----------------------------|----------------------------|----------------------------|---------------------------------|------------|----------------------|----------------------|----------------------|----------------------|
| 226. | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | molecular                       | 227. Date: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 228. | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | cytogenetic                     | 229. Date: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 230. | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | clinical evidence / hematologic | 231. Date: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

232. Was chemotherapy used to attempt to induce disease response prior to the first DCI?

- 1  yes
- 2  no

233. Date of administration of final chemotherapy dose:        
Month Day Year

234. Specify viral organism code: (see manual for code list)

235. Date documented:        
Month Day Year

236. Specify indication: \_\_\_\_\_

237. What was the recipient's disease status immediately prior to the first DCI?

- 1  first complete remission post-HSCT (no hematologic evidence of disease)
- 2  therapy-induced complete remission after persistent disease or relapse post-HSCT
- 3  relapse or progression
- 4  persistent disease
- 5  not evaluated post-HSCT → **Continue with question 239**

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238. Date disease status was established prior to the first DCI:     
Month Day Year

239. Specify the functional status of the recipient immediately prior to the first DCI:  
(See page 2 for Karnofsky / Lansky Scale descriptions.)

Specify DCI source:

240. 1  yes 2  no collected at the time of PBSC mobilization and collection

241. 1  yes 2  no negative fraction of CD34 selected PBSC

242. 1  yes 2  no negative fraction of CD34 selected bone marrow

243. 1  yes 2  no apheresis at a different time than collection of PBSC used for allogeneic HSCT →

244. Date of apheresis:     
Month Day Year

245. 1  yes 2  no isolated from a unit(s) of whole blood →

246. Specify number of units:

247. Were the donor cells collected by leukapheresis?

1  yes →  
2  no

248. Date of first leukapheresis:     
Month Day Year

249. Date of last leukapheresis:     
Month Day Year

250. Number of leukaphereses:

251. Did the donor receive treatment to enhance cell collection prior to donation?

1  yes →  
2  no

Specify treatment(s) given:

252. Growth factors

1  yes →  
2  no

Specify agent:

253. 1  yes 2  no G-CSF

254. 1  yes 2  no GM-CSF

255. 1  yes 2  no Other agent →

256. Specify:

257. Other treatment

1  yes →  
2  no

258. Specify:

For each DCI given, report the total number of cells infused. If the cells were cryopreserved, report the totals after processing, but before cryopreservation. Copy this page to report more than one infusion.

|                         | Total cells:  |      | Specify exponent:                         |                                     |
|-------------------------|---|------|---|-------------------------------------|
| 259. CD3+ cells:        | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> | x 10 | <input type="text"/> <input type="text"/> | <input type="checkbox"/> not tested |
| 260. CD4+ cells:        | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> | x 10 | <input type="text"/> <input type="text"/> | <input type="checkbox"/> not tested |
| 261. CD8+ cells:        | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> | x 10 | <input type="text"/> <input type="text"/> | <input type="checkbox"/> not tested |
| 262. CD34+ cells:       | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> | x 10 | <input type="text"/> <input type="text"/> | <input type="checkbox"/> not tested |
| 263. NK cells:          | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> | x 10 | <input type="text"/> <input type="text"/> | <input type="checkbox"/> not tested |
| 264. Nucleated cells:   | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> | x 10 | <input type="text"/> <input type="text"/> | <input type="checkbox"/> not tested |
| 265. Mesenchymal cells: | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> | x 10 | <input type="text"/> <input type="text"/> | <input type="checkbox"/> not tested |

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266. Were dendritic cells infused?

- 1  yes
- 2  no

267. Were fibroblasts infused?

- 1  yes
- 2  no

268. Were any other cell types infused (not including cell types reported in questions 259–265)?

- 1  yes
- 2  no

269. Specify cell type(s):

270. Were the cells cryopreserved prior to infusion?

- 1  yes
- 2  no

271. Specify portion cryopreserved:  
1  all cells  
2  portion of cells

272. Were the cells manipulated prior to infusion?

- 1  yes
- 2  no

273. Specify portion manipulated:  
1  all cells  
2  portion of cells

Specify all methods used to manipulate the cells:

274. ABO incompatibility

- 1  yes
- 2  no

Specify method:  
275. 1  yes 2  no buffy coat preparation  
276. 1  yes 2  no cell separator (i.e., COBE Spectra)  
277. 1  yes 2  no density gradient separation (i.e., Ficoll)  
278. 1  yes 2  no plasma removal  
279. 1  yes 2  no sedimentation (i.e., hetastarch) 281. Specify:   
280. 1  yes 2  no other

- 282. 1  yes 2  no dextran-albumin wash
- 283. 1  yes 2  no ex-vivo expansion
- 284. 1  yes 2  no genetic manipulation (gene transfer / transduction)
- 285. 1  yes 2  no volume reduction

286. CD34+ selection

- 1  yes
- 2  no

287. Specify manufacturer:  
1  CliniMACS / CliniMax  
2  Isolex  
3  other  288. Specify:

289. T-cell depletion

- 1  yes
- 2  no

Specify method:  
290. 1  yes 2  no antibody affinity column   
291. 1  yes 2  no antibody coated plates   
292. 1  yes 2  no antibody coated plates and soybean lectin   
293. 1  yes 2  no antibody + complement   
294. 1  yes 2  no antibody + toxin   
295. 1  yes 2  no immunomagnetic beads   
296. 1  yes 2  no elutriation  
297. 1  yes 2  no CD34 affinity column plus sheep red blood cell rosetting   
298. 1  yes 2  no other  299. Specify:

**Report antibodies used for T-cell depletion at question 302.**

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300. other manipulation  
1  yes →  
2  no

301. Specify:

302. Were antibodies used during graft manipulation?  
1  yes →  
2  no

Specify antibodies:

303. 1  yes 2  no anti CD2  
304. 1  yes 2  no anti CD4  
305. 1  yes 2  no anti CD5  
306. 1  yes 2  no anti CD6  
307. 1  yes 2  no anti CD7  
308. 1  yes 2  no anti CD8  
309. 1  yes 2  no anti CD34  
310. 1  yes 2  no anti TCR alpha / beta (T10-B9)  
311. 1  yes 2  no OKT-3  
312. 1  yes 2  no other CD3 → 313. Specify:

314. 1  yes 2  no anti CD52 →

Specify antibodies:  
yes no  
315. 1  2  campath-NOS  
316. 1  2  campath-1G  
317. 1  2  campath-1H

318. 1  yes 2  no other antibody → 319. Specify:

320. Signed: \_\_\_\_\_  
*Person completing form*

Please print name: \_\_\_\_\_

Phone: ( \_\_\_\_\_ ) \_\_\_\_\_

Fax: ( \_\_\_\_\_ ) \_\_\_\_\_

E-mail address: \_\_\_\_\_