CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

100 Days Post-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

Today's Date: Month Day Year 2 0

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 ☐ multiple cord blood units infused ☐ other product, specify: _____

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. Date of actual contact with the recipient to determine the medical status for this follow-up report: 🕮 Month Day Year

2. Did this patient receive the scheduled HSCT? 2450: 2
   1 ☐ yes
   2 ☐ no →
   3. Reason:
      1 ☐ patient died between start of preparative regimen and HSCT
      2 ☐ HSCT was canceled, but patient is alive →
      4. Reason for cancellation: _____

5. Did the recipient receive a subsequent HSCT (bone marrow, mobilized peripheral blood stem cells, cord blood) prior to day 100 after the HSCT for which this form is being completed? 🕮 2450: key field
   1 ☐ yes → **Answers to subsequent questions should reflect clinical status immediately prior to the start of the preparative regimen for subsequent HSCT. Complete Subsequent HSCT questions 573–580.**
   2 ☐ no

6. Specify the recipient's survival status at the date of last contact: 2450: 26
   1 ☐ alive → **Answers to subsequent questions should reflect clinical status between HSCT and prior to or the day of actual contact for this follow-up evaluation (± 100 days post-HSCT).**
   2 ☐ dead → **Answers to subsequent questions should reflect clinical status between HSCT and immediately prior to death. Complete a Form 2900 – Recipient Death Data.**

7. Has the recipient received a donor cellular infusion (DCI)? 🕮 2450: 43
   1 ☐ yes → **Complete DCI Information questions 581–678.**
   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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Hematopoietic Reconstitution Post-HSCT

This section is similar to 2006: 2-10 but unsure of potential reuse. Need to ensure that curation is consistent

8. Did the *recipient* receive hematopoietic, lymphoid growth factors or cytokines after the start of the preparatory regimen?
   1 ☐ yes →
   2 ☐ no

Normalize 2100: 9-33

Specify agents and provide dates for the first course of each agent given in this reporting period:

9. G-CSF
   1 ☐ yes →
   2 ☐ no

   10. Date G-CSF therapy started: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
   11. Therapy code: ☐☐ (see below)
   12. Specify drug given:
       1 ☐ Neupogen
       2 ☐ Neulasta
       3 ☐ Lenograstim

13. GM-CSF
   1 ☐ yes →
   2 ☐ no

   14. Date GM-CSF therapy started: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
   15. Therapy code: ☐☐ (see below)

16. Erythropoietin
   1 ☐ yes →
   2 ☐ no

   17. Date therapy started: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
   18. Therapy code: ☐☐ (see below)
   19. Specify drug given:
       1 ☐ Epogen
       2 ☐ Aranesp (darbepoetin alfa)

20. KGF (palifermin, Kepivance) 📖 *(If used for GVHD prophylaxis, report at question 216.)*
   1 ☐ yes →
   2 ☐ no

   21. Date KGF therapy started: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
   22. Therapy code: 📖 ☐☐ (see below)

23. Velafermin *(If used for GVHD prophylaxis, report at question 216.)*
   1 ☐ yes →
   2 ☐ no

   24. Date velafermin therapy started: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
   25. Therapy code: 📖 ☐☐ (see below)

26. Blinded growth factor or cytokine trial
   1 ☐ yes →
   2 ☐ no

   27. Specify study agent: _____
   28. Date therapy started: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
   29. Therapy code: ☐☐ (see below)

30. Other agent
   1 ☐ yes →
   2 ☐ no

   31. Specify agent: _____
   32. Date other therapy started: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
   33. Therapy code: ☐☐ (see below)

Codes for Indication of Therapy

0 = Planned therapy per protocol (note: for mucositis prophylaxis, use code 10)
1 = Intervention for delay / decline in absolute neutrophil count (ANC)
2 = Intervention for delay / decline in platelets
3 = Intervention for delay / decline in both ANC and platelets
4 = Intervention for delay / decline in red blood cell counts
5 = Anti-leukemic or tumor agent to prevent relapse
6 = Anti-leukemic or tumor agent to treat relapse
10 = Planned therapy to prevent mucositis
90 = Other indication

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Granulopoiesis / Neutrophil Recovery

*** To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.**

34. Is (was) there evidence of hematopoietic recovery following the **initial** HSCT? *(check only one)* 2450: 8

1 ☐ Yes, ANC ≥ 500/mm^3 achieved and sustained for 3 lab values * with no subsequent decline →

35. Date ANC ≥ 500/mm^3 (first of 3 lab values): * 2450: 9 ☐☐ Month ☐☐ Day ☐☐☐☐ Year

2 ☐ Yes, ANC ≥ 500/mm^3 for 3 lab values * with subsequent decline in ANC to < 500/mm^3 for ≥ 3 days →

36. Date ANC ≥ 500/mm^3 (first of 3 lab values): * ☐☐ Month ☐☐ Day ☐☐☐☐ Year

37. Date of decline in ANC to < 500/mm^3 for ≥ 3 days (first of 3 days that the ANC declined): * ☐☐ Month ☐☐ Day ☐☐☐☐ Year

Actual CBC on first day of decline:

38. WBC: ☐☐☐☐☐☐ • ☐ 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L

Curate 2100: 38-43 using lab values decomposition template

39. Neutrophils: ☐☐ %

40. Did recipient recover and maintain ANC ≥ 500/mm^3 * following the decline? 📖

1 ☐ yes →
2 ☐ no

41. Date of ANC recovery: ☐☐ Month ☐☐ Day ☐☐☐☐ Year ☐ date unknown

CBC on first day of recovery:

42. WBC: ☐☐☐☐☐☐ • ☐ 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L

43. Neutrophils: ☐☐ %

3 ☐ No, ANC ≥ 500/mm^3 was not achieved * and there was **no evidence** of recurrent disease in the bone marrow

4 ☐ No, ANC ≥ 500/mm^3 was not achieved * and there was documented **persistent** disease in the bone marrow post-HSCT

5 ☐ ANC never dropped below 500/mm^3 at any time after the start of the preparative regimen

Megakaryopoiesis / Platelet Recovery

*** This section relates to initial platelet recovery. All dates should reflect no transfusions in the previous 7 days. To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.**

44. Was an initial platelet count ≥ 20 x 10^9/L achieved? 2450:12

1 ☐ yes →

45. Date platelets ≥ 20 x 10^9/L: * 2450: 13 ☐☐ Month ☐☐ Day ☐☐☐☐ Year 1 ☐ date estimated 2 ☐ date unknown

2 ☐ no → **Continue with question 48**

3 ☐ platelet count never dropped below 20 x 10^9/L

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46. Was an initial platelet count ≥ 50 x 10^9/L achieved?
1 ☐ yes →
2 ☐ no
3 ☐ platelet count never dropped below 50 x 10^9/L

47. Date platelets ≥ 50 x 10^9/L: * ☐☐ Month ☐☐ Day ☐☐☐☐ Year
1 ☐ date estimated
2 ☐ date unknown

Current Hematologic Findings

Curate 2100: 48-54 using lab values decomposition template

48. Date of most recent hematologic testing: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

49. WBC: ☐☐☐☐☐☐ • ☐
1 ☐ x 10^9/L (x 10^3/mm^3)
2 ☐ x 10^6/L
☐ not tested

50. Neutrophils: ☐☐ %
☐ not tested

51. Lymphocytes: ☐☐ %
☐ not tested

52. Hemoglobin: ☐☐☐☐ • ☐☐
1 ☐ g/dL
2 ☐ g/L
3 ☐ mmol/L
☐ not tested
☐ transfused RBC < 30 days from date of most current testing

53. Hematocrit: ☐☐ %
☐ not tested
☐ transfused RBC < 30 days from date of most current testing

54. Platelets: ☐☐☐☐☐☐☐
1 ☐ x 10^9/L (x 10^3/mm^3)
2 ☐ x 10^6/L
☐ not tested
☐ transfused platelets < 7 days from date of most current testing

Immune Reconstitution

Normalize 2100: 55-60 Curate using lab values decomposition template.

Specify the immunoglobulin values from the most recent testing:

	Value:		Month	Day	Year	
55. IgG:	☐☐☐☐☐ • ☐☐	1 ☐ mg/dL 2 ☐ g/dL 3 ☐ g/L	56. ☐☐	☐☐	☐☐☐☐	☐ not tested
57. IgM:	☐☐☐☐☐ • ☐☐	1 ☐ mg/dL 2 ☐ g/dL 3 ☐ g/L	58. ☐☐	☐☐	☐☐☐☐	☐ not tested
59. IgA:	☐☐☐☐☐ • ☐☐	1 ☐ mg/dL 2 ☐ g/dL 3 ☐ g/L	60. ☐☐	☐☐	☐☐☐☐	☐ not tested

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61. Did the recipient receive supplemental intravenous immunoglobulins (IVIG)?
1 ☐ yes →
2 ☐ no

62. Was therapy ongoing within one month of immunoglobulin testing?
1 ☐ yes
2 ☐ no

Indication(s) for use: Normalize 2100: 63-69

63. 1 ☐ yes 2 ☐ no prophylaxis for low IgG with no active infection (polyclonal IV gamma globulin / IVIG)
64. 1 ☐ yes 2 ☐ no prophylaxis for cytomegalovirus (CMV) infection (CMV / hyperimmune gamma globulin)
65. 1 ☐ yes 2 ☐ no treatment for CMV infection
66. 1 ☐ yes 2 ☐ no treatment for respiratory syncytial virus (RSV) infection
67. 1 ☐ yes 2 ☐ no treatment for infection with low IgG (not CMV or RSV)
68. 1 ☐ yes 2 ☐ no other indication → 69. Specify: _____

70. Were lymphocyte analyses performed? 📖
1 ☐ yes →
2 ☐ no

71. Date of most recent testing performed: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

Normalize 2100: 72-76 Curate using lab values decomposition template.

Specify units:

72. CD3 → ☐☐☐☐☐☐☐ 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L ☐ not tested
73. CD4 → ☐☐☐☐☐☐☐ 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L ☐ not tested
74. CD8 → ☐☐☐☐☐☐☐ 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L ☐ not tested
75. CD20 → ☐☐☐☐☐☐☐ 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L ☐ not tested
76. CD56 → ☐☐☐☐☐☐☐ 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L ☐ not tested

The next three sections relate to chimerisms and graft-versus-host disease from allogeneic HSCTs only. If this was an autologous HSCT, continue with the Infection section at question 358.

Chimerism Studies

77. *Allogeneic HSCTs only:* Were chimerism studies performed post-HSCT?
1 ☐ yes →
2 ☐ no → **Continue with question 201**

78. Are chimerism laboratory reports attached to this form? 2005: 5 (Generic CDE for laboratory report submission)
1 ☐ yes
2 ☐ no

79. Were infusions from more than one donor given? 2400:18
1 ☐ yes → **Continue with question 161**
2 ☐ no →

80. Specify donor gender: 2006: 266
1 ☐ male
2 ☐ female

Continue with question 81

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CIBMTR Center Number:

CIBMTR Recipient ID:

Chimerism Studies (Provide date(s), method(s) and other information for all chimerism studies performed prior to date of contact [question 1].)

Single Donor

	Date Month	Date Day	Date Year	Method (See valid list below)	Cell Type (See valid list below)	Total Cells Examined	Number of Donor Cells	Number of Host Cells	Percent Donor Cells Quant.	Percent Donor Cells *Non-Quant.	Percent Host Cells Quant.	Percent Host Cells *Non-Quant.
81.				82.	83.	84.	85.	86.	87.		88.	
89.				90.	91.	92.	93.	94.	95.		96.	
97.				98.	99.	100.	101.	102.	103.		104.	
105.				106.	107.	108.	109.	110.	111.		112.	
113.				114.	115.	116.	117.	118.	119.		120.	
121.				122.	123.	124.	125.	126.	127.		128.	
129.				130.	131.	132.	133.	134.	135.		136.	
137.				138.	139.	140.	141.	142.	143.		144.	
145.				146.	147.	148.	149.	150.	151.		152.	
153.				154.	155.	156.	157.	158.	159.		160.	

* If performed by non-quantitative method, indicate the presence of donor or host cells by (+).

Valid Method Codes

(Insert number in box above to indicate method used)

1 - Conventional (standard) cytogenetics
2 - Fluorescent in situ hybridization (FISH)
3 - Restriction fragment-length polymorphisms (RFLP)
4 - HLA typing
5 - VNTR or STR, micro or mini satellite
90 - Other, specify: _____

Valid Cell Types

(Insert number in box above to indicate cell type)

1 - Bone marrow (BM)
2 - Peripheral blood mononuclear cells (PBMC)
3 - T-cells
4 - B-cells
5 - Red blood cells
6 - Monocytes
7 - PMNs (neutrophils)
8 - Lymphocytes, not otherwise specified
9 - Myeloid cells, not otherwise specified
90 - Other, specify: _____

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CIBMTR Center Number:

CIBMTR Recipient ID:

Need to ensure that chimerism studies CDEs are curated consistently for single and multiple donors

Chimerism Studies (Provide date(s), method(s) and other information for all chimerism studies performed prior to date of contact [question 1].)

Multiple Donors

161. NMDP donor ID: ___ - ___ - ___ —or— 161. Donor date of birth: Month ___ Day ___ Year ___ 162. Donor gender: 1 ☐ male 2 ☐ female

NMDP cord blood unit ID:

	Date Month	Date Day	Date Year	Method [1]	Cell Type [2]	Total Cells Examined	Number of Donor Cells [3]	Number of Host Cells	Percent Donor Cells [3] Quant.	Percent Donor Cells [3] Non-Quant.[4]	Percent Host Cells Quant.	Percent Host Cells Non-Quant.[4]
163.				164.	165.	166.	167.	168.	169.		170.	

171. NMDP donor ID: ___ - ___ - ___ —or— 171. Donor date of birth: Month ___ Day ___ Year ___ 172. Donor gender: 1 ☐ male 2 ☐ female

NMDP cord blood unit ID:

	Date Month	Date Day	Date Year	Method [1]	Cell Type [2]	Total Cells Examined	Number of Donor Cells [3]	Number of Host Cells	Percent Donor Cells [3] Quant.	Percent Donor Cells [3] Non-Quant.[4]	Percent Host Cells Quant.	Percent Host Cells Non-Quant.[4]
173.				174.	175.	176.	177.	178.	179.		180.	

NMDP Donor ID 2004: key field
NMDP Cord Blood Unit: 2004: key field
Donor DOB 2004: key field
Donor gender: no reuse
Donor gender: no reuse because it needs to be distinct from 2100: 80

181. ___ - ___ - ___ —or— 181. Donor date of birth: Month ___ Day ___ Year ___ 182. Donor gender: 1 ☐ male 2 ☐ female

	Date Month	Date Day	Date Year	Method [1]	Cell Type [2]	Total Cells Examined	Number of Donor Cells [3]	Number of Host Cells	Percent Donor Cells [3] Quant.	Percent Donor Cells [3] Non-Quant.[4]	Percent Host Cells Quant.	Percent Host Cells Non-Quant.[4]
183.				184.	185.	186.	187.	188.	189.		190.	

191. NMDP donor ID: ___ - ___ - ___ —or— 191. Donor date of birth: Month ___ Day ___ Year ___ 192. Donor gender: 1 ☐ male 2 ☐ female

NMDP cord blood unit ID:

	Date Month	Date Day	Date Year	Method [1]	Cell Type [2]	Total Cells Examined	Number of Donor Cells [3]	Number of Host Cells	Percent Donor Cells [3] Quant.	Percent Donor Cells [3] Non-Quant.[4]	Percent Host Cells Quant.	Percent Host Cells Non-Quant.[4]
193.				194.	195.	196.	197.	198.	199.		200.	

[1] See previous page for valid list of Method codes.
[2] See previous page for valid list of Cell Type codes.
[3] Continue reporting donors who are no longer producing cells for the recipient as "0" for Number or Percent Donor Cells.
[4] If performed by non-quantitative method, indicate the presence of donor or host cells by "+".

Copy this page to report more than 4 tests.

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Engraftment Syndrome

201. Did engraftment syndrome occur?
1 ☐ yes →
2 ☐ no

202. Date of onset: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

Normalize section in red

Specify symptoms of engraftment syndrome:

203. 1 ☐ yes 2 ☐ no Capillary leak syndrome
204. 1 ☐ yes 2 ☐ no Fever
205. 1 ☐ yes 2 ☐ no Skin rash →

206. Specify amount of body surface affected: ☐☐☐ %

207. Was engraftment syndrome treated with corticosteroids?
1 ☐ yes
2 ☐ no

This section is very similar to 2400:141-158 which was not normalized. To facilitate reuse, this section is not labeled as proposed normalization.

Acute Graft vs. Host Disease (GVHD)

208. Was specific therapy used after the start of the preparative regimen to **prevent** acute GVHD or graft rejection *(note: do not include growth factors reported in question 8, or ex vivo T-cell depletion reported on the Product Insert),* or for autologous HSCT to induce acute GVHD?
1 ☐ yes →
2 ☐ no ↓

Allogeneic HSCTs continue with 238

Autologous HSCTs continue with 358

209. 1 ☐ yes 2 ☐ no ALS, ALG, ATS, ATG → 2400: 142

210. Specify source:
1 ☐ horse
2 ☐ rabbit
3 ☐ other → 211. Specify: _____

212. 1 ☐ yes 2 ☐ no Corticosteroids (systemic) 2400: 143
213. 1 ☐ yes 2 ☐ no Cyclosporine (CSA) (Sandimmune, Neoral) 2400: 144
214. 1 ☐ yes 2 ☐ no ECP (extra-corporeal photopheresis) 2400: 145
215. 1 ☐ yes 2 ☐ no FK 506 (Tacrolimus, Prograf) 2400: 146
216. 1 ☐ yes 2 ☐ no KGF (palifermin, Kepivance) 📖 →
(If used to prevent mucositis, report at question 20.)

217. Specify date started: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

218. 1 ☐ yes 2 ☐ no Velafermin →
(If used to prevent mucositis, report at question 23.)

219. Specify date started: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

220. 1 ☐ yes 2 ☐ no In vivo monoclonal antibody → 2400: 148 2400: 149

Specify:

221. 1 ☐ yes 2 ☐ no Anti CD 25 (Zenapax, Daclizumab, AntiTAC) ↓

222. Specify: _____

2400: 150 223. 1 ☐ yes 2 ☐ no Campath
2400: 151 224. 1 ☐ yes 2 ☐ no Etanercept (Enbrel)
2400: 152 225. 1 ☐ yes 2 ☐ no Infliximab (Remicade)

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2400: 153

226. 1 ☐ yes 2 ☐ no Other in vivo monoclonal antibody

2400: 154

227. Specify: _____

228. 1 ☐ yes 2 ☐ no In vivo immunotoxin → 229. Specify: _____

2400: 147 230. 1 ☐ yes 2 ☐ no Methotrexate (MTX) (Amethopterin)

2400: 155 231. 1 ☐ yes 2 ☐ no Mycophenolate mofetil (MMF) (CellCept)

2400: 156 232. 1 ☐ yes 2 ☐ no Sirolimus (Rapamycin, Rapamune)

233. 1 ☐ yes 2 ☐ no Ursodiol

234. 1 ☐ yes 2 ☐ no Blinded randomized trial 📖 → 235. Specify agent: _____

2400: 157 236. 1 ☐ yes 2 ☐ no Other agent → 237. Specify: _____ 2400: 158 _____

238. Did acute GVHD occur?

1 ☐ yes →

2 ☐ acute GVHD persists from prior HSCT / DCI

↓

Continue with 240

3 ☐ no

↓

Continue with 286

4 ☐ unknown

↓

Continue with 286

239. Date of acute GVHD diagnosis: ☐☐ Month ☐☐ Day ☐☐☐☐ Year ☐ Date is greater than 100 days; date is correct

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

1 ☐ yes →

2 ☐ no

Specify result(s):

Normalize 2100: 241-246

	positive	negative	inconclusive	not tested	
241.	1 ☐	2 ☐	3 ☐	4 ☐	gastrointestinal (GI)
242.	1 ☐	2 ☐	3 ☐	4 ☐	liver
243.	1 ☐	2 ☐	3 ☐	4 ☐	lung
244.	1 ☐	2 ☐	3 ☐	4 ☐	skin
245.	1 ☐	2 ☐	3 ☐	4 ☐	other site → 246. Specify other site: _____

247. Is a copy of the pathology report attached?

1 ☐ yes

2 ☐ no

2450: 25 (Generic CDE for pathology report submission)

248. Was the diagnosis based on clinical evidence?

1 ☐ yes

2 ☐ no

249. Maximum overall grade of acute GVHD: 2450: 15

1 ☐ I

2 ☐ II

3 ☐ III

4 ☐ IV

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250. Is acute GVHD still present at the date of contact for this report (question 1)?
- 1 ☐ yes
- 2 ☐ no
- 3 ☐ progressed to chronic GVHD
- 4 ☐ unknown

List the maximum severity of organ involvement:

251. 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

252. Lower intestinal tract: (use mL/day for adult recipients and mL/m^2/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^2/day
- 4 ☐ stage 1 – diarrhea > 500 but ≤ 1000 mL/day or 280-555 mL/m^2/day
- 5 ☐ stage 2 – diarrhea > 1000 but ≤ 1500 mL/day or 556-833 mL/m^2/day
- 6 ☐ stage 3 – diarrhea > 1500 mL/day or > 833 mL/m^2/day
- 7 ☐ stage 4 – severe abdominal pain, with or without ileus

253. Upper intestinal tract:
- 1 ☐ stage 0 – no persistent nausea or vomiting
- 2 ☐ stage 1 – persistent nausea or vomiting

254. 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)

255. Other clinical organ involvement?
- 1 ☐ yes →
- 2 ☐ no

Specify site:
256. 1 ☐ yes 2 ☐ no lung
257. 1 ☐ yes 2 ☐ no other →

258. Specify: _____

259. Was specific therapy used to **treat** acute GVHD?
- 1 ☐ yes →
- 2 ☐ no ↓

Continue with question 286

260. ALS, ALG, ATS, ATG
- 1 ☐ yes →
- 2 ☐ no

261. Specify source:
- 1 ☐ horse
- 2 ☐ rabbit
- 3 ☐ other →

262. Specify: _____

263. 1 ☐ yes 2 ☐ no Corticosteroids (systemic)
264. 1 ☐ yes 2 ☐ no Corticosteroids (topical)
265. 1 ☐ yes 2 ☐ no Cyclosporine (CSA) (Sandimmune, Neoral)
266. 1 ☐ yes 2 ☐ no ECP (extra-corporeal photopheresis)
267. 1 ☐ yes 2 ☐ no FK 506 (Tacrolimus, Prograf)

Curate 259-285 using a decomposition that is similar to 2100: 208-237

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268. In vivo monoclonal antibody
1 ☐ yes →
2 ☐ no

Specify:

269. Anti CD 25 (Zenapax, Daclizumab, AntiTAC)
1 ☐ yes → 270. Specify: _____
2 ☐ no

271. 1 ☐ yes 2 ☐ no Campath
272. 1 ☐ yes 2 ☐ no Etanercept (Enbrel)
273. 1 ☐ yes 2 ☐ no Infliximab (Remicade)

274. Other in vivo monoclonal antibody
1 ☐ yes → 275. Specify: _____
2 ☐ no

276. 1 ☐ yes 2 ☐ no In vivo immunotoxin → 277. Specify: _____

278. 1 ☐ yes 2 ☐ no Methotrexate (MTX) (Amethopterin)
279. 1 ☐ yes 2 ☐ no Mycophenolate mofetil (MMF) (CellCept)
280. 1 ☐ yes 2 ☐ no Sirolimus (Rapamycin, Rapamune)
281. 1 ☐ yes 2 ☐ no Ursodiol
282. 1 ☐ yes 2 ☐ no Blinded randomized trial → 283. Specify agent: _____

284. 1 ☐ yes 2 ☐ no Other agent → 285. Specify: _____

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Chronic Graft vs. Host Disease (GVHD)

286. Has the recipient developed clinical chronic GVHD?

1 ☐ yes →

2 ☐ chronic GVHD persists from prior HSCT / DCI

↓

Continue with 291

3 ☐ no

↓

Continue with 356

4 ☐ unknown

↓

Continue with 356

2450: 17 (Diagnosis Date)

287. Date of chronic GVHD diagnosis: ☐☐ Month ☐☐ Day ☐☐☐☐ Year ☐ Date is less than 100 days; date is correct

288. 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 GHVD flare (symptoms reactivated within 30 days of drug tapering or discontinuation)

289. Karnofsky / Lansky score at diagnosis of chronic GVHD: ☐☐☐
(refer to page 22 for scale)

290. Platelet count at diagnosis of chronic GVHD: ☐☐☐☐☐ 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L

291. Diagnosis was based on:
- 1 ☐ histologic evidence / biopsy proven
- 2 ☐ clinical evidence
- 3 ☐ both
- 4 ☐ unknown

292. Maximum grade of chronic GVHD: 2450: 16
- 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

293. 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

Normalize 2100: 294-323

Organ Involvement

Indicate if there was organ involvement with chronic GVHD from the list below:

	Organ / System	If yes, was involvement proven by biopsy?
294. 1 ☐ yes 2 ☐ no	Sclerosis of skin →	295. 1 ☐ yes 2 ☐ no
296. 1 ☐ yes 2 ☐ no	Other skin or hair involvement (rash, ulcers, pruritus or itching, dyspigmentation, alopecia, lichenoid skin changes, etc.) →	297. 1 ☐ yes 2 ☐ no
298. 1 ☐ yes 2 ☐ no	Eyes (xerophthalmia (dry eyes), abnormal Schirmer's test, abnormal slit lamp, corneal erosion / conjunctivitis, etc.) →	299. 1 ☐ yes 2 ☐ no
300. 1 ☐ yes 2 ☐ no	Mouth (lichenoid changes, mucositis / ulcers, erythema, etc.) →	301. 1 ☐ yes 2 ☐ no
302. 1 ☐ yes 2 ☐ no	Bronchiolitis obliterans 📖 →	303. 1 ☐ yes 2 ☐ no

Complete BO questions 444–452

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304. 1 ☐ yes 2 ☐ no Other lung involvement → 305. 1 ☐ yes 2 ☐ no
306. 1 ☐ yes 2 ☐ no Gastrointestinal tract (esophageal involvement, chronic nausea / vomiting, chronic diarrhea, malabsorption, abdominal pain / cramps, etc.) → 307. 1 ☐ yes 2 ☐ no
308. 1 ☐ yes 2 ☐ no Liver → 309. 1 ☐ yes 2 ☐ no
310. 1 ☐ yes 2 ☐ no Genitourinary tract (vaginitis / stricture, etc.) → 311. 1 ☐ yes 2 ☐ no
312. 1 ☐ yes 2 ☐ no Musculoskeletal (arthritis, contractures, myositis, myasthenia, etc.) → 313. 1 ☐ yes 2 ☐ no
314. 1 ☐ yes 2 ☐ no Thrombocytopenia (< 100 x 10^9/L)
315. 1 ☐ yes 2 ☐ no Eosinophilia
316. 1 ☐ yes 2 ☐ no Autoantibodies
317. 1 ☐ yes 2 ☐ no Other hematologic involvement
318. 1 ☐ yes 2 ☐ no Serositis → 319. 1 ☐ yes 2 ☐ no
320. 1 ☐ yes 2 ☐ no Weight loss
321. 1 ☐ yes 2 ☐ no Other organ involvement from chronic GVHD → 323. 1 ☐ yes 2 ☐ no
322. Specify site: _____

324. Was specific therapy used to **treat** chronic GVHD?
1 ☐ yes →
2 ☐ no

Curate 2100 324-354 using a decomposition that is similar to 2100: 208-237

Specify:
325. ALS, ALG, ATS, ATG
1 ☐ yes →
2 ☐ no

326. Specify source:
1 ☐ horse
2 ☐ rabbit
3 ☐ other → 327. Specify: _____

328. 1 ☐ yes 2 ☐ no Azathioprine
329. 1 ☐ yes 2 ☐ no Corticosteroids (systemic)
330. 1 ☐ yes 2 ☐ no Corticosteroids (topical)
331. 1 ☐ yes 2 ☐ no Cyclosporine (CSA) (Sandimmune, Neoral)
332. 1 ☐ yes 2 ☐ no ECP (extracorporeal photopheresis)
333. 1 ☐ yes 2 ☐ no Etretinate
334. 1 ☐ yes 2 ☐ no FK 506 (Tacrolimus, Prograf)
335. 1 ☐ yes 2 ☐ no Hydroxychloroquine (Plaquenil)
336. In vivo monoclonal antibody
1 ☐ yes →
2 ☐ no

Specify:
337. Anti CD 25 (Zenapax, Daclizumab, AntiTAC)
1 ☐ yes → 338. Specify: _____
2 ☐ no

339. 1 ☐ yes 2 ☐ no Campath
340. 1 ☐ yes 2 ☐ no Etanercept (Enbrel)
341. 1 ☐ yes 2 ☐ no Infliximab (Remicade)
342. Other in vivo monoclonal antibody
1 ☐ yes → 343. Specify: _____
2 ☐ no

344. 1 ☐ yes 2 ☐ no Lamprene (Clofazimine)
345. 1 ☐ yes 2 ☐ no Mycophenolate mofetil (MMF) (CellCept)
346. 1 ☐ yes 2 ☐ no Pentostatin
347. 1 ☐ yes 2 ☐ no PUVA (Psoralen and UVA)
348. 1 ☐ yes 2 ☐ no Sirolimus (Rapamycin, Rapamune)

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349. 1 ☐ yes 2 ☐ no Thalidomide
350. 1 ☐ yes 2 ☐ no Ursodiol
351. 1 ☐ yes 2 ☐ no Blinded randomized trial → 352. Specify agent: _____
353. 1 ☐ yes 2 ☐ no Other agent → 354. Specify: _____

355. Are symptoms of chronic GVHD still present on the date of actual contact (or present at the time of death)?
1 ☐ yes
2 ☐ no

356. Is the recipient still taking immunosuppressive agents (including PUVA) to treat or prevent GVHD? 📖
1 ☐ yes
2 ☐ no →
3 ☐ unknown

357. Date final treatment administered: ☐☐ Month ☐☐ Day ☐☐☐☐ Year ☐ date unknown

Infection

358. Did the recipient receive any of the following agents for infection prophylaxis after the start of the preparative regimen? *(Report prophylaxis immunoglobulins at questions 63–64.)* 📖
1 ☐ yes →
2 ☐ no
3 ☐ unknown

Normalize 2100: 359-387

Specify:

359. 1 ☐ yes 2 ☐ no Systemic antibacterial antibiotics
360. 1 ☐ yes 2 ☐ no Nonabsorbable oral antibiotics
361. 1 ☐ yes 2 ☐ no Amphotericin (Fungizone) **(non-lipid formulation)**
362. 1 ☐ yes 2 ☐ no Amphotericin (e.g. Abelcet, AmBisome, Amphotec) **(lipid formulation)**
363. 1 ☐ yes 2 ☐ no Caspofungin
364. 1 ☐ yes 2 ☐ no Fluconazole
365. 1 ☐ yes 2 ☐ no Itraconazole
366. 1 ☐ yes 2 ☐ no Micafungin
367. 1 ☐ yes 2 ☐ no Posaconazole
368. 1 ☐ yes 2 ☐ no Ravuconazole
369. 1 ☐ yes 2 ☐ no Voriconazole
370. 1 ☐ yes 2 ☐ no Other systemic antifungal agent → 371. Specify agent: _____
372. 1 ☐ yes 2 ☐ no Acyclovir
373. 1 ☐ yes 2 ☐ no Foscarnet
374. 1 ☐ yes 2 ☐ no Ganciclovir (DHPG)
375. 1 ☐ yes 2 ☐ no Valganciclovir (Valcyte)
376. 1 ☐ yes 2 ☐ no Valacyclovir
377. 1 ☐ yes 2 ☐ no Other antiviral agent → 378. Specify agent: _____
379. 1 ☐ yes 2 ☐ no Atovaquone (Mepron)
380. 1 ☐ yes 2 ☐ no Dapsone
381. 1 ☐ yes 2 ☐ no Pentamidine inhaled
382. 1 ☐ yes 2 ☐ no Pentamidine IV
383. 1 ☐ yes 2 ☐ no Trimethoprim/sulfamethoxazole (Bactrim/Septra)
384. 1 ☐ yes 2 ☐ no Other pneumocystis prophylaxis → 385. Specify agent: _____
386. 1 ☐ yes 2 ☐ no Other agent → 387. Specify agent: _____

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388. Did the recipient receive irradiated granulocyte infusions after the start of the preparative regimen to 60 days post-HSCT?

1 ☐ yes
2 ☐ no

2100: 398 is similar to 2000:163 except the time point is different.
Curate using a consistent decomposition

389. Did the recipient develop a clinically significant infection after the start of the preparative regimen? 📖

1 ☐ yes
2 ☐ no

FormsNet multiple. Cannot be normalized.

Report each infection organism, site and date of diagnosis. *(see page 16 for organism and site codes)*

	Organism ‡ § † ¤ (2000: 166)		Site * (2000: 168)	Date of Diagnosis (2000: 165) Month / Year
390.		391. If other, specify: _____	392.	393.
394.		395. If other, specify: _____	396.	397.
398.		399. If other, specify: _____	400.	401.
402.		403. If other, specify: _____	404.	405.
406.		407. If other, specify: _____	408.	409.
410.		411. If other, specify: _____	412.	413.
414.		415. If other, specify: _____	416.	417.

‡ The codes for "other organism, specify" (codes 198, 209, 219, 259, 329 and 409) should rarely be needed; check with your microbiology lab or HSCT physician before using them.

§ For fungal infections marked with a section symbol (codes 210, 211, 212, 213, 219, 230, 240, 241, 242 and 503), also complete a Fungal Infection insert (SUP-FNG).

† For hepatitis infections marked with a dagger symbol (codes 307 and 308), also complete a Hepatitis insert (SUP-HEP).

¤ For HIV infections marked with a currency symbol (code 309), also complete an HIV Infection insert (SUP-HIV).

* Do not report fever in the absence of infection. Report the most specific site of infection.

418. Did the recipient develop more than 7 infections post-HSCT?

1 ☐ yes
2 ☐ no

Copy this page to report more than 7 infections

419. Are extra pages attached?

1 ☐ yes
2 ☐ no

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Codes for Commonly Reported Organisms

Bacterial Infections

121 Acinetobacter
122 Actinomyces
123 Bacillus
124 Bacteroides (gracillis, uniformis, vulgaris, other species)
125 Bordetella pertussis (whooping cough)
126 Borrelia (Lyme disease)
127 Branhamella or Moraxella catarrhalis (other species)
128 Campylobacter (all species)
129 Capnocytophaga
171 Chlamydia pneumoniae
172 Other chlamydia, specify
113 Chlamydia, NOS
130 Citrobacter (freundii, other species)
131 Clostridium (all species except difficile)
132 Clostridium difficile
173 Corynebacterium jeikeium
133 Corynebacterium (all non-diptheria species)
101 Coxiella
134 Enterobacter
177 Enterococcus, vancomycin resistant (VRE)
135 Enterococcus (all species)
136 Escherichia (also E. coli)
137 Flavimonas oryzihabitans
138 Flavobacterium
139 Fusobacterium
144 Haemophilus (all species, including influenzae)
145 Helicobacter pylori
146 Klebsiella
147 Lactobacillus (bulgaricus, acidophilus, other species)
102 Legionella
103 Leptospira
148 Leptotrichia buccalis
149 Leuconostoc (all species)
104 Listeria
150 Methylobacterium
151 Micrococcus, NOS
112 Mycobacterium avium–intracellulare (MAC, MAI)
174 Mycobacterium species (cheloneae, fortuitum, haemophilum, kansasii, mucogenicum
110 Mycobacterium tuberculosis (tuberculosis, Koch bacillus)
175 Other mycobacterium, specify
176 Mycobacterium, NOS
105 Mycoplasma
152 Neisseria (gonorrhoea, meningitidis, other species)
106 Nocardia
153 Pasteurella multocida
154 Propionibacterium (acnes, avidum, granulosum, other species)
155 Proteus
156 Pseudomonas (all species except cepacia & maltophilia)
157 Pseudomonas or Burkholderia cepacia
158 Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia
159 Rhodococcus
107 Rickettsia
160 Salmonella (all species)
161 Serratia marcescens
162 Shigella
163 Staphylococcus, coagulase negative (not aureus)
164 Staphylococcus aureus
165 Staphylococcus, NOS
166 Stomatococcus mucilaginosis
167 Streptococcus (all species except Enterococcus)
178 Streptococcus pneumoniae
168 Treponema (syphilis)
169 Vibrio (all species)
197 Multiple bacteria at a single site, specify bacterial codes
198 Other bacteria, specify ‡
501 Suspected atypical bacterial infection
502 Suspected bacterial infection

Fungal Infections

200 Candida, NOS
201 Candida albicans
206 Candida guillermondi
202 Candida krusei
207 Candida lusitaniae
203 Candida parapsilosis
204 Candida tropicalis
205 Candida (Torulopsis) glabrata
209 Other Candida, specify ‡
210 Aspergillus, NOS §
211 Aspergillus flavus §
212 Aspergillus fumigatus §
213 Aspergillus niger §
219 Other Aspergillus, specify ‡ §
220 Cryptococcus species
230 Fusarium species §
261 Histoplasmosis
240 Zygomycetes, NOS §
241 Mucormycosis §
242 Rhizopus §
250 Yeast, NOS
259 Other fungus, specify ‡
260 Pneumocystis (PCP / PJP)
503 Suspected fungal infection §

§ For fungal species marked with a section symbol (§), also complete a Fungal Infection insert (SUP-FNG)

Viral Infections

301 Herpes simplex (HSV1, HSV2)
302 Varicella (herpes zoster, chicken pox)
303 Cytomegalovirus (CMV)
304 Adenovirus
305 Enterovirus (coxsackie, echo, polio)
306 Hepatitis A (HAV)
307 Hepatitis B (HBV, Australian antigen) †
308 Hepatitis C (HCV) †
309 HIV-1 (HTLV-III) ¤
310 Influenza, NOS
323 Influenza A
324 Influenza B
311 Measles (rubeola)
312 Mumps
313 Progressive multifocal leukoencephalopathy (PML)
314 Respiratory syncytial virus (RSV)
315 Rubella (German measles)
316 Parainfluenza
317 Human herpesvirus-6 (HHV-6)
318 Epstein-Barr virus (EBV)
319 Polyoma virus (BK virus, JC virus)
320 Rotavirus
321 Rhinovirus
322 Human papilloma virus (HPV)
329 Other virus, specify ‡
504 Suspected viral infection

† For hepatitis infections marked with a dagger symbol (†), also complete a Hepatitis insert (SUP-HEP)

¤ For HIV infections marked with a currency symbol (¤), also complete an HIV Infection insert (SUP-HIV)

Parasitic Infections

402 Toxoplasma
403 Giardia
404 Cryptosporidium
409 Other parasite, specify ‡
505 Suspected parasite infection

Other Infections

509 No organism identified

Codes for Common Sites of Infection

1 Blood / buffy coat
2 Disseminated – generalized, isolated at 3 or more distinct sites

Central Nervous System

4 Brain
5 Spinal cord
6 Meninges and CSF
3 Central nervous system, not specified

Gastrointestinal Tract

11 Lips
12 Tongue, oral cavity and oropharynx
13 Esophagus
14 Stomach
15 Gallbladder and biliary tree (not hepatitis), pancreas
16 Small intestine
17 Large intestine
18 Feces / stool
19 Peritoneum
20 Liver
10 Gastrointestinal tract, not specified

Respiratory Tract

31 Upper airway and nasopharynx
32 Laryngitis / larynx
33 Lower respiratory tract (lung)
34 Pleural cavity, pleural fluid
35 Sinuses
30 Respiratory tract, not otherwise specified

Genito-Urinary Tract

41 Kidneys, renal pelvis, ureters and bladder
42 Prostate
43 Testes
44 Fallopian tubes, uterus, cervix
45 Vagina
40 Genito-urinary tract, not specified

Skin

51 Genital area
52 Cellulitis
53 Herpes zoster
54 Rash, pustules or abscesses not typical of any of the above
50 Skin, not otherwise specified

Other

60 Central venous catheter, not specified
61 Catheter insertion or exit site
62 Catheter tip
70 Eyes
75 Ears
81 Joints
82 Bone marrow
83 Bone cortex (osteomyelitis)
84 Muscle (excluding cardiac)
85 Cardiac (endocardium, myocardium, pericardium)
86 Lymph nodes
87 Spleen

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Organ Function

Pulmonary Function

420. Did the recipient develop interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) after the start of the preparative reigmen to the date of last contact (question 1)?

Interstitial pneumonitis / idiopathic pneumonia syndrome is characterized on chest x-ray by hypoxia and diffuse interstitial infiltrates not caused by fluid overload.

(Report bacterial and fungal pneumonia in Infection section (questions 389–417).)

1 ☐ yes →
2 ☐ no

2100: 421-440 is a FormsNet multiple and cannot be normalized.

421. Date of diagnosis of IPn / IPS: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

422. Were diagnostic tests done (other than radiographic studies)?
1 ☐ yes →
2 ☐ no

Diagnosis was evaluated by:

423. 1 ☐ yes 2 ☐ no bronchoalveolar lavage (BAL)
424. 1 ☐ yes 2 ☐ no transbronchial biopsy
425. 1 ☐ yes 2 ☐ no open / thorascopic (VATS) lung biopsy
426. 1 ☐ yes 2 ☐ no autopsy
427. 1 ☐ yes 2 ☐ no other → 428. Specify: _____

429. Was an organism isolated?
1 ☐ yes →
2 ☐ no / idiopathic

Etiology:

430. 1 ☐ yes 2 ☐ no adenovirus
431. 1 ☐ yes 2 ☐ no cytomegalovirus (CMV)
432. 1 ☐ yes 2 ☐ no herpes simplex (HSV1, HSV2)
433. 1 ☐ yes 2 ☐ no human herpes virus type 6 (HHV6)
434. 1 ☐ yes 2 ☐ no parainfluenza
435. 1 ☐ yes 2 ☐ no respiratory syncytial virus (RSV)
436. 1 ☐ yes 2 ☐ no toxoplasma
437. 1 ☐ yes 2 ☐ no other virus → 438. Specify: _____

439. 1 ☐ yes 2 ☐ no other organism → 440. Specify: _____

441. Did the recipient experience two or more episodes of IPn / IPS after the start of the preparative regimen to the date of last contact (question 1)?
1 ☐ yes →
2 ☐ no

Copy and complete this page for each episode.

442. Are extra pages attached?
1 ☐ yes
2 ☐ no

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443. Did the recipient develop non-infectious pulmonary abnormalities (other than IPn / IPS / ARDS) after the start of the preparative regimen to the date of last contact (question 1)?

1 ☐ yes →
2 ☐ no

444. Did the recipient develop bronchiolitis obliterans after the start of the preparative regimen to the date of last contact (question 1)?

1 ☐ yes →
2 ☐ no

445. Date of diagnosis: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

446. Were diagnostic tests done?

1 ☐ yes →
2 ☐ no

Normalize 2100:447-452

Diagnosis was evaluated by:

447. 1 ☐ yes 2 ☐ no bronchoalveolar lavage (BAL)
448. 1 ☐ yes 2 ☐ no transbronchial biopsy
449. 1 ☐ yes 2 ☐ no open / thorascopic (VATS) lung biopsy
450. 1 ☐ yes 2 ☐ no autopsy
451. 1 ☐ yes 2 ☐ no other → 452. Specify: _____

453. Did the recipient develop pulmonary hemorrhage?

1 ☐ yes →
2 ☐ no

454. Date of diagnosis: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

455. Were diagnostic tests done?

1 ☐ yes →
2 ☐ no

Normalize 2100: 456-461
Use same VD as 2100:447-452
for the type CDE

Diagnosis was evaluated by:

456. 1 ☐ yes 2 ☐ no bronchoalveolar lavage (BAL)
457. 1 ☐ yes 2 ☐ no transbronchial biopsy
458. 1 ☐ yes 2 ☐ no open / thorascopic (VATS) lung biopsy
459. 1 ☐ yes 2 ☐ no autopsy
460. 1 ☐ yes 2 ☐ no other → 461. Specify: _____

462. Did the recipient develop cryptogenic organizing pneumonia (COP)?

1 ☐ yes →
2 ☐ no

463. Date of diagnosis: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

464. Were diagnostic tests done?

1 ☐ yes →
2 ☐ no

Normalize 2100: 456-461
Use same VD as 2100:447-452
for the type CDE

Diagnosis was evaluated by:

465. 1 ☐ yes 2 ☐ no bronchoalveolar lavage (BAL)
466. 1 ☐ yes 2 ☐ no transbronchial biopsy
467. 1 ☐ yes 2 ☐ no open / thorascopic (VATS) lung biopsy
468. 1 ☐ yes 2 ☐ no autopsy
469. 1 ☐ yes 2 ☐ no other → 470. Specify: _____

471. Did the recipient develop any other non-infectious pulmonary abnormalities?

1 ☐ yes →
2 ☐ no

472. Specify: _____

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473. Did the recipient receive endotracheal intubation or mechanical ventilation post-HSCT?
1 ☐ yes
2 ☐ no

Liver Function

474. Did the recipient develop non-infectious liver toxicity (excluding GVHD) after the start of the preparative regimen to the date of last contact (question 1)?
1 ☐ yes →
2 ☐ no

475. Date of diagnosis: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

Etiology:

476. 1 ☐ yes 2 ☐ no cirrhosis
477. 1 ☐ yes 2 ☐ no veno-occlusive disease (VOD) / sinusodial obstruction syndrome (SOS) →

478. Did the recipient receive treatment for VOD?
1 ☐ yes → 479. Specify: _____
2 ☐ no

480. Did VOD resolve by day 100?
1 ☐ yes
2 ☐ no

481. Maximum bilirubin in first 100 days: ☐☐☐

482. 1 ☐ yes 2 ☐ no other → 483. Specify: _____
484. 1 ☐ yes 2 ☐ no unknown

Normalize 2100: 485-496

Specify diagnosis of liver toxicity by clinical signs and symptoms / evaluation:

485. 1 ☐ yes 2 ☐ no ascites
486. 1 ☐ yes 2 ☐ no autopsy
487. 1 ☐ yes 2 ☐ no bilirubin > 2.0 mg
488. 1 ☐ yes 2 ☐ no biopsy
489. 1 ☐ yes 2 ☐ no elevated hepatic venous pressure gradient
490. 1 ☐ yes 2 ☐ no elevated liver enzymes (e.g., alkaline phosphatase, ALT, AST, LDH, GGT)
491. 1 ☐ yes 2 ☐ no hepatomegaly
492. 1 ☐ yes 2 ☐ no right upper quadrant pain or tenderness
493. 1 ☐ yes 2 ☐ no ultrasonography / doppler (abnormal portal vein flow)
494. 1 ☐ yes 2 ☐ no weight gain > 5%
495. 1 ☐ yes 2 ☐ no other → 496. Specify: _____

Other Organ Impairment / Disorder

497. Has the recipient developed any other clinically significant organ impairment or disorder after the start of preparative regimen to the date of last contact (question 1)?
1 ☐ yes →
2 ☐ no

Normalize 2100:498-528

Specify impairment / disorder: Date of diagnosis: Month Day Year

498. 1 ☐ yes 2 ☐ no avascular necrosis → 499. ☐☐ ☐☐ ☐☐☐☐
500. 1 ☐ yes 2 ☐ no cataracts → 501. ☐☐ ☐☐ ☐☐☐☐
502. 1 ☐ yes 2 ☐ no congestive heart failure (EF < 40%) → 503. ☐☐ ☐☐ ☐☐☐☐
504. 1 ☐ yes 2 ☐ no diabetes / hyperglycemia → 505. ☐☐ ☐☐ ☐☐☐☐

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Date of diagnosis: Month Day Year

506. 1 ☐ yes 2 ☐ no gonadal dysfunction / infertility requiring hormone replacement (testosterone or estrogen) → 507. ☐☐ ☐☐ ☐☐☐☐

508. 1 ☐ yes 2 ☐ no growth hormone deficiency / growth disturbance → 509. ☐☐ ☐☐ ☐☐☐☐

510. 1 ☐ yes 2 ☐ no hemorraghic cystitis / hematuria requiring medical intervention (catheterization of bladder, extra transfusions, urology consult) → 511. ☐☐ ☐☐ ☐☐☐☐

512. 1 ☐ yes 2 ☐ no hypothyroidism → 513. ☐☐ ☐☐ ☐☐☐☐

514. 1 ☐ yes 2 ☐ no myocardial infarction → 515. ☐☐ ☐☐ ☐☐☐☐

516. 1 ☐ yes 2 ☐ no pancreatitis → 517. ☐☐ ☐☐ ☐☐☐☐

518. 1 ☐ yes 2 ☐ no post-transplant microangiopathy-thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS), or similar syndrome → 519. ☐☐ ☐☐ ☐☐☐☐

520. Did the recipient receive plasmapheresis?
1 ☐ yes
2 ☐ no

521. 1 ☐ yes 2 ☐ no renal failure severe enough to warrant dialysis → 522. ☐☐ ☐☐ ☐☐☐☐

523. Did the recipient receive dialysis?
1 ☐ yes
2 ☐ no

524. 1 ☐ yes 2 ☐ no stroke / seizure → 525. ☐☐ ☐☐ ☐☐☐☐

526. 1 ☐ yes 2 ☐ no other → 527. ☐☐ ☐☐ ☐☐☐☐

528. Specify impairment / disorder: _____

New Malignancy

529. Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear that is different from the disease for which the HSCT was performed?
1 ☐ yes →
2 ☐ no

Normalize
2100:530--567

Specify which new disease(s) occurred:

Date of diagnosis: Month Day Year

530. 1 ☐ yes 2 ☐ no acute myeloid leukemia (AML / ANLL) → 531. ☐☐ ☐☐ ☐☐☐☐

532. 1 ☐ yes 2 ☐ no other leukemia, including ALL → 533. ☐☐ ☐☐ ☐☐☐☐

534. Specify leukemia: _____

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Date of diagnosis: Month Day Year

535. 1 ☐ yes 2 ☐ no breast cancer → 536. ☐☐ ☐☐ ☐☐☐☐

537. 1 ☐ yes 2 ☐ no central nervous system (CNS) malignancy (glioblastoma, astrocytoma) → 538. ☐☐ ☐☐ ☐☐☐☐

539. 1 ☐ yes 2 ☐ no clonal cytogenetic abnormality without leukemia or MDS → 540. ☐☐ ☐☐ ☐☐☐☐

541. 1 ☐ yes 2 ☐ no gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine) → 542. ☐☐ ☐☐ ☐☐☐☐

543. 1 ☐ yes 2 ☐ no genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix) → 544. ☐☐ ☐☐ ☐☐☐☐

545. 1 ☐ yes 2 ☐ no Hodgkin disease → 546. ☐☐ ☐☐ ☐☐☐☐

547. 1 ☐ yes 2 ☐ no lung cancer → 548. ☐☐ ☐☐ ☐☐☐☐

549. 1 ☐ yes 2 ☐ no lymphoma or lymphoproliferative disease → 550. ☐☐ ☐☐ ☐☐☐☐

551. Is the tumor EBV positive?
1 ☐ yes
2 ☐ no

552. 1 ☐ yes 2 ☐ no melanoma → 553. ☐☐ ☐☐ ☐☐☐☐

554. 1 ☐ yes 2 ☐ no other skin malignancy (basal cell, squamous) → 555. ☐☐ ☐☐ ☐☐☐☐

556. Specify skin malignancy: _____

557. 1 ☐ yes 2 ☐ no myelodysplasia (MDS) / myelo-proliferative (MPS) disorder → 558. ☐☐ ☐☐ ☐☐☐☐

559. 1 ☐ yes 2 ☐ no oropharyngeal cancer (tongue, buccal mucosa) → 560. ☐☐ ☐☐ ☐☐☐☐

561. 1 ☐ yes 2 ☐ no sarcoma → 562. ☐☐ ☐☐ ☐☐☐☐

563. 1 ☐ yes 2 ☐ no thyroid cancer → 564. ☐☐ ☐☐ ☐☐☐☐

565. 1 ☐ yes 2 ☐ no other new malignancy → 566. ☐☐ ☐☐ ☐☐☐☐

567. Specify other malignancy: _____

2100: 568 is similar to 2450:25
Use consistent decomposition

568. Is a pathology / autopsy report or other documentation attached?
1 ☐ yes → **Attach a copy of the report with all identifiers removed, except for birth date and ID numbers. Reference question 568 on the report.**
2 ☐ no

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Functional Status

569. Was the recipient discharged from the hospital after HSCT? 🕮

1 ☐ yes →
2 ☐ no
3 ☐ not applicable, therapy and HSC infusion given as outpatient

570. Date first discharged from hospital post-HSCT: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

571. Total number of inpatient days (day 0 to day 100) in first 100 days post-HSCT: 🕮 ☐☐☐

572. 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 the Subsequent HSCT section below.

If the recipient is 16 years of age or older, complete the Karnofsky Scale. If the recipient is younger than 16 years of age, complete the Lansky Scale.

Karnofsky Scale (recipient age ≥ 16 years)

Select the phrase in the Karnofsky Scale which best describes the activity status of the recipient:

Able to carry on normal activity; no special care is needed

1 ☐ 100 Normal; no complaints; no evidence of disease
2 ☐ 90 Able to carry on normal activity
3 ☐ 80 Normal activity with effort

Unable to work; able to live at home, cares for most personal needs; a varying amount of assistance is needed

4 ☐ 70 Cares for self; unable to carry on normal activity or to do active work
5 ☐ 60 Requires occasional assistance but is able to care for most needs
6 ☐ 50 Requires considerable assistance and frequent medical care

Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly

7 ☐ 40 Disabled; requires special care and assistance
8 ☐ 30 Severely disabled; hospitalization indicated, although death not imminent
9 ☐ 20 Very sick; hospitalization necessary
10 ☐ 10 Moribund; fatal process progressing rapidly

Lansky Scale (recipient age < 16 years)

Select the phrase in the Lansky Play-Performance Scale which best describes the activity status of the recipient:

Able to carry on normal activity; no special care is needed

1 ☐ 100 Fully active
2 ☐ 90 Minor restriction in physically strenuous play
3 ☐ 80 Restricted in strenuous play, tires more easily, otherwise active

Mild to moderate restriction

4 ☐ 70 Both greater restrictions of, and less time spent in, active play
5 ☐ 60 Ambulatory up to 50% of time, limited active play with assistance / supervision
6 ☐ 50 Considerable assistance required for any active play; fully able to engage in quiet play

Moderate to severe restriction

7 ☐ 40 Able to initiate quiet activities
8 ☐ 30 Needs considerable assistance for quiet activity
9 ☐ 20 Limited to very passive activity initiated by others (e.g., TV)
10 ☐ 10 Completely disabled, not even passive play

2100: 572 Curate using functional status decomposition template

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Subsequent HSCT

Complete this section if the recipient received a subsequent HSCT (question 5, answered "yes"). If no subsequent HSCTs were performed, continue with the DCI section at question 581.

573. Date of subsequent HSCT: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

574. Was the subsequent HSCT performed at a different institution?
- 1 ☐ yes →
- 2 ☐ no

575. Specify the institution that performed the subsequent HSCT:
Name: _____
City: _____
State / Country: _____

576. 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 → **Complete the section on New Malignancy (questions 529–568).**
- 8 ☐ stable, mixed chimerism
- 9 ☐ declining chimerism
- 10 ☐ other →

577. Specify: _____

578. Source of HSCs:
- 1 ☐ allogeneic, related →

Complete a new Form 2000 — Recipient Baseline Data.

579. Was the same donor used?
- 1 ☐ yes
- 2 ☐ no

- 2 ☐ allogeneic, unrelated →

Complete a new Form 2000 — Recipient Baseline Data.

580. 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

- 3 ☐ autologous → **Complete a new Form 2000 — Recipient Baseline Data.**

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2100: 581-678 is a FormsNet multiple. This section cannot be normalized.

Donor Cellular Infusion (DCI) Information

This section captures information on DCIs (question 7, 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 recieve any DCIs, continue with the signature lines at question 679.

581. Date the first DCI was given: ☐☐ Month ☐☐ Day ☐☐☐☐ Year 2450:75

582. Specify the number of cell infusions given within 10 weeks of the first DCI: ☐☐ 2450: 76

583. Was the DCI infusion performed at a different institution?
- 1 ☐ yes →
- 2 ☐ no

584. Specify the institution that performed the DCI:
Name: _____
City: _____
State / Country: _____

585. Indication for DCI:
- 1 ☐ planned as part of initial HSCT protocol 2450: 83 Verify that the permissible values are the same.
- 2 ☐ treatment for relapsed, persistent or progressive disease →
- 3 ☐ treatment for B cell lympho-proliferative disorder (PTLD, EBV lymphoma)
- 4 ☐ treatment for GVHD

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 580).

	positive	negative	not done / unknown			Month	Day	Year
586.	1 ☐	2 ☐	3 ☐	molecular	587. Date:	☐☐	☐☐	☐☐☐☐
588.	1 ☐	2 ☐	3 ☐	cytogenetic	589. Date:	☐☐	☐☐	☐☐☐☐
590.	1 ☐	2 ☐	3 ☐	clinical evidence / hematologic	591. Date:	☐☐	☐☐	☐☐☐☐

592. Was chemotherapy used to attempt to induce disease response prior to the first DCI?
- 1 ☐ yes →
- 2 ☐ no

593. Date of administration of final chemotherapy dose: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

- 5 ☐ viral infection →

594. Specify viral organism code: *(see page 16 for code list)* ☐☐☐

- 6 ☐ stable, mixed chimerism →
- 7 ☐ loss of / decreased donor T-cell chimerism →

595. Date documented: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
(document chimerism testing on page 6 or 7)

- 8 ☐ other →

596. Specify indication: _____

597. 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 599**

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

599. Specify the functional status of the recipient immediately prior to the first DCI: ☐☐☐
(see page 22 for Karnofsky / Lansky Scale descriptions)

Specify DCI source:

600. 1 ☐ yes 2 ☐ no collected at the time of PBSC mobilization and collection
601. 1 ☐ yes 2 ☐ no negative fraction of CD34 selected PBSC
602. 1 ☐ yes 2 ☐ no negative fraction of CD34 selected bone marrow
603. 1 ☐ yes 2 ☐ no apheresis at a different time than collection of PBSC used for allogeneic HSCT →
604. Date of apheresis: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

605. 1 ☐ yes 2 ☐ no isolated from a unit(s) of whole blood →
606. Specify number of units: ☐☐☐

607. Were the donor cells collected by leukapheresis?
1 ☐ yes →
2 ☐ no

608. Date of first leukapheresis: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
609. Date of last leukapheresis: ☐☐ Month ☐☐ Day ☐☐☐☐ Year
610. Number of leukaphereses: ☐☐

611. Did the donor receive treatment to enhance cell collection prior to donation?
1 ☐ yes →
2 ☐ no

Specify treatment(s) given:

612. Growth factors
1 ☐ yes →
2 ☐ no

Specify agent:
613. 1 ☐ yes 2 ☐ no G-CSF
614. 1 ☐ yes 2 ☐ no GM-CSF
615. 1 ☐ yes 2 ☐ no Other agent →
616. Specify agent: _____

617. Other treatment
1 ☐ yes →
2 ☐ no

618. Specify treatment: _____

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: 🕮		
619. CD3+ cells:	☐☐☐☐ . ☐☐	x 10	☐☐	☐ not tested	2006: 148
620. CD4+ cells:	☐☐☐☐ . ☐☐	x 10	☐☐	☐ not tested	2006: 149
621. CD8+ cells:	☐☐☐☐ . ☐☐	x 10	☐☐	☐ not tested	2006: 150
622. CD34+ cells:	☐☐☐☐ . ☐☐	x 10	☐☐	☐ not tested	2006: 147
623. NK cells:	☐☐☐☐ . ☐☐	x 10	☐☐	☐ not tested	
624. Nucleated cells:	☐☐☐☐ . ☐☐	x 10	☐☐	☐ not tested	2006: 144
625. Mesenchymal cells:	☐☐☐☐ . ☐☐	x 10	☐☐	☐ not tested	

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626. Were dendritic cells infused? 2450:79
1 ☐ yes
2 ☐ no

627. Were fibroblasts infused? 2450: 78
1 ☐ yes
2 ☐ no

628. Were any other cell types infused (not including cell types reported in questions 620–628)? 2450:81
1 ☐ yes →
2 ☐ no

629. Specify cell type(s): 2450: 82 _____

630. Were the cells cryopreserved prior to infusion? 2006: 32
1 ☐ yes →
2 ☐ no

631. Specify portion cryopreserved: 2006: 33
1 ☐ all cells
2 ☐ portion of cells

632. Were the cells manipulated prior to infusion?
1 ☐ yes →
2 ☐ no

2100: 632-677 is nearly identical to 2006: 44-91. 2006:44-91 has been normalized, and 2100-632-677 cannot be normalized because it is part of a FormsNet multiple. Should 2006:44-91 be de-normalized to facilitate reuse?

633. Specify portion manipulated:
1 ☐ all cells
2 ☐ portion of cells

Specify all methods used to manipulate the cells:

634. ABO incompatibility
1 ☐ yes →
2 ☐ no

Specify method:

635. 1 ☐ yes 2 ☐ no buffy coat preparation
636. 1 ☐ yes 2 ☐ no cell separator (i.e., COBE Spectra)
637. 1 ☐ yes 2 ☐ no density gradient separation (i.e., Ficoll)
638. 1 ☐ yes 2 ☐ no plasma removal
639. 1 ☐ yes 2 ☐ no sedimentation (i.e., hetastarch)
640. 1 ☐ yes 2 ☐ no other → 641. Specify: _____

642. 1 ☐ yes 2 ☐ no dextran-albumin wash
643. 1 ☐ yes 2 ☐ no ex-vivo expansion
644. 1 ☐ yes 2 ☐ no genetic manipulation (gene transfer / transduction)
645. 1 ☐ yes 2 ☐ no volume reduction

646. CD34+ selection 🕮
1 ☐ yes →
2 ☐ no

647. Specify manufacturer:
1 ☐ CliniMACS / CliniMax
2 ☐ Isolex
3 ☐ other, specify: _____

648. T-cell depletion
1 ☐ yes →
2 ☐ no

Specify method:

649. 1 ☐ yes 2 ☐ no antibody affinity column →
650. 1 ☐ yes 2 ☐ no antibody coated plates →
651. 1 ☐ yes 2 ☐ no antibody coated plates and soybean lectin →
652. 1 ☐ yes 2 ☐ no antibody + complement →
653. 1 ☐ yes 2 ☐ no antibody + toxin →
654. 1 ☐ yes 2 ☐ no immunomagnetic beads →

Report antibodies used for T-cell depletion at question 661.

655. 1 ☐ yes 2 ☐ no elutriation
656. 1 ☐ yes 2 ☐ no CD34 affinity column plus sheep red blood cell rosetting 🕮
657. 1 ☐ yes 2 ☐ no other → 658. Specify: _____

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659. other manipulation
1 ☐ yes → 660. Specify: _____
2 ☐ no

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

Specify antibodies:

662. 1 ☐ yes 2 ☐ no anti CD2
663. 1 ☐ yes 2 ☐ no anti CD4
664. 1 ☐ yes 2 ☐ no anti CD5
665. 1 ☐ yes 2 ☐ no anti CD6
666. 1 ☐ yes 2 ☐ no anti CD7
667. 1 ☐ yes 2 ☐ no anti CD8
668. 1 ☐ yes 2 ☐ no anti CD34
669. 1 ☐ yes 2 ☐ no anti TCR alpha / beta (T10-B9)
670. 1 ☐ yes 2 ☐ no OKT-3
671. 1 ☐ yes 2 ☐ no other CD3 → 672. Specify: _____

673. 1 ☐ yes 2 ☐ no anti CD52 →

Specify antibodies:

	yes	no	
674.	1 ☐	2 ☐	campath-NOS
675.	1 ☐	2 ☐	campath-1G
676.	1 ☐	2 ☐	campath-1H

677. 1 ☐ yes 2 ☐ no other antibody → 678. Specify: _____

679. Signed: _____
Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____

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