

Hematopoietic Cellular Transplant (HCT) Infusion

OMB No: 0915-0310 Expiration Date: 08/31/2025

Registry Use Only Sequence Number: Date Received: CIBMTR Center Number: CIBMTR Research ID: Current Date:	Public Burden Statement: The purpose of this data collection system is to provide technical assistance and share expertise with health care organizations, health care providers and health care networks interested in implementing telehealth technology. The resource centers serve as focal points for advancing the effective use of telehealth technologies in their respective communities and regions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection of information is estimated to average 0.69 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.
HCT type (check only one)	
Autologous	
Allogeneic, unrelated	
☐ Allogeneic, related	
Product type (check only one)	
□ Bone marrow	
D PBSC	
☐ Single cord blood unit	
□ Other product	
Specify:	
NMDP Product	
□ Yes	
□ No	
Product Identifiers:	
NMDP cord blood unit ID:	

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NMDP donor ID:
Registry donor ID:
Non-NMDP cord blood unit ID:
Global Registration Identifier for Donors (GRID):
ISBT DIN:
Registry or UCB Bank ID:
Donor DOB:
YYYY MM DD
Donor age: Donoths (use only if less than 1 year old)
□ Years
Donor sex: 🔲 Male 🗆 Female

If more than one type of HCT product is infused, each product type must be analyzed and reported separately.

A series of collections should be considered a single product when they are all from the same donor and use the same collection method and technique (and mobilization, if applicable), even if the collections are performed on different days.

Pre-Collection Therapy

- 1. Did the donor receive growth and mobilizing factors, prior to any stem cell harvest, to enhance the product collection for this HCT? Allogeneic donors only
 - □ Yes Go to auestion 2
 - □ No Go to question 4
 - 2. Specify growth and mobilizing factor(s) (check all that apply)
 - G-CSF (filgrastim, Neupogen) Go to question 4
 - Pegylated G-CSF (pegfilgrastim, Neulasta) Go to question 4
 - □ Motixafortide (Aphexda) Go to question 4
 - Plerixafor (Mozobil) Go to question 4
 - □ Other growth or mobilizing factor(s) **Go to guestion 3**

3. Specify other growth or mobilizing factor(s): ______ - Go to question 4

Product Collection

- Date of first collection for this mobilization: 4. MM DD
- Were anticoagulants or other agents added to the product between collection and infusion? 5. □ Yes – Go to question 6
 - □ No Go to question 8
 - 6. Specify anticoagulant(s) or other agents (check all that apply) □ Acid citrate dextrose (ACD, ACD-A)
 - □ Citrate phosphate dextrose (CPD, CPD-A)
 - □ Ethylenediaminetetraacetic acid (EDTA)
 - □ Heparin
 - □ Other agent *Go to question* 7
 - Specify other agent: 7.

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Product Transport and Receipt

- 8. Was this product collected off-site and shipped to your facility?
 □ Yes Go to question 9
 - □ No Go to question 22

 - 10. Time of receipt of product (24-hour clock): _____ Hour Hour ☐ standard time ☐ daylight savings time
 - Specify the shipping environment of the product(s)
 □ Room temperature *Go to question 13*
 - Cooled (refrigerator temperature, not frozen, refrigerated gel packs) **Go to question 13**
 - □ Frozen (cryopreserved) Go to question 13
 - □ Other shipping environment Go to question 12

12. Specify other shipping environment:

- 13. Was there any indication that the environment within the shipper was outside the expected temperature range for this product at any time during shipment?
 - □ Yes
 - 🗆 No
- 14. Were the secondary containers (e.g., insulated shipping containers and unit cassette) intact when they arrived at your center?
 - □ Yes
 - 🗆 No
- 15. Was the cord blood unit stored at your center prior to thawing? (Cord blood units only)
 □ Yes Go to question 16
 - □ No Go to question 19
 - Specify the storage method used for the cord blood unit
 □ Electric freezer
 - Liquid nitrogen
 - □ Vapor phase
 - 17. Temperature during storage
 - □ < -150° C

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□ ≥ -150° C to < -135° C	
□ ≥ -135° C to < -80° C	
□ ≥ -80° C	
18. Date storage started:	
Report the total number of cells (not cells per unit by the cord blood bank).	vilogram) prior to cryopreservation: (Information provided for the
19. Total nucleated cells:	• x 10 (Includes nucleated red and nucleated
20. CD34+ cells (Cord blood units onl □ Done – Go to question 21	у)
□ Not done – <i>Go to question</i> 22	
21. Total number of CD34+ cells: _	•x 10
Product Processing / Manipulation	
22. Was the product thawed from a cryoprese ☐ Yes – <i>Go to question 23</i>	rved state prior to infusion?
□ No – Go to question 32	
23. Was the entire product thawed?□ Yes – Go to question 26	
□ No – Go to question 24	
24. Specify the percent of the product th □ 80%	nat was thawed (Cord blood units only)
□ 20%	
Other percent– Go to que	estion 25

- 25. Specify other percent: ____%
- 26. Date thawing process initiated: ______YYYY ____ ___ ___MM ____DD

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	27.	Tim	ne at initiation of thaw (24-hour clock):Hour Hour Minute	 ☐ standard time ☐ daylight savings time
	28.	Tim	ne of thaw completion (24-hour clock):Hour Hour Minute	☐ standard time ☐ daylight savings time
	29.	Wh □	nat method was used to thaw the product? Water bath – Go to question 31	
			Electric warmer – Go to question 31	
			Other method – Go to question 30	
		30.	Specify other method:	
	31.	Did □	d any incidents or product complaints occur while preparin Yes	g or thawing the product?
			No	
32.	Was □	s the p Yes –	product processed prior to infusion? – Go to question 33	
		No –	Go to question 34	
	33.	Spe □	ecify processing (check all that apply) Buffy coat enriched (buffy coat preparation)	
			Diluted	
			Plasma reduced	
			RBC reduced	
			Washed	
34.	Was D	s the p Yes –	product manipulated prior to infusion? – Go to question 35	
		No –	Go to question 41	
	35.	Spe □	ecify manipulations performed (<i>check all that apply)</i> Ex-vivo expansion – Go to question 41	
			Genetic manipulation (gene transfer / transduction) – Ge	to question 41
			CD34 enriched (CD34+ selection) - Go to question 41	
			Ex-vivo T-cell depletion – Go to question 36	
			Other manipulation – <i>Go to question 40</i>	

36. Specify antibodies used *(check all that apply)* □ Anti CD3

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- □ Anti CD4
- □ Anti CD8
- □ Anti CD19
- Anti CD45RA
- \Box α/β Antibody
- □ Anti CD52
- □ Other antibody– *Go to question* 37

37. Specify other antibody:

38. Specify T-cell depletion method

- Antibody affinity column
- □ Immunomagnetic beads
- □ Other method *Go to question 39*
- 39. Specify other method: _____
- 40. Specify other cell manipulation: _____

Product Analysis (All Products)

- 41. Specify the timepoint in the product preparation phase that the product was analyzed □ Product arrival (cord blood only)
 - □ At infusion (final quantity infused)

43. Total volume of product plus additives: ____ ___ ___ ___ • ____h

In this section, report the total number of cells (not cells per kilogram) and do not correct for viability.

- 44. Total nucleated cells (TNC) (Includes nucleated red and nucleated white cells)
 □ Done Go to question 45
 - □ Not done *Go to question 50*
 - 45. Total nucleated cells: ____ ___ x 10 ____

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- 46. Viability of TNC
 - Done Go to question 47
 - □ Not done Go to question 50
 - □ Unknown Go to question 50
 - 47. Viability of TNC: _____%
 - 48. Method of testing TNC viability Flow cytometry based (includes 7-AAD, AOPI, and AOEB)
 - Trypan blue
 - Other method Go to question 49
 - 49. Specify other method:

50. Nucleated white blood cells

- Done Go to question 51
- □ Not done Go to question 52
- Total number of nucleated white blood cells: ____ ___ * 10 ____ x 10 ____ 51.

52. Mononuclear cells

- □ Done Go to question 53
- □ Not done Go to question 54
- Total number of mononuclear cells: ____ ___ ____ * 10 ____ x 10 ____ 53.

54. Nucleated red blood cells

- Done Go to question 55
- □ Not done Go to question 56
- Total number of nucleated red blood cells: _____ ____ ____ x 10 ____ 55.

56. CD34+ cells

- Done Go to question 57
- □ Not done *Go to question 62*
- Total number of CD34+ cells: ______ ____ 57. x 10 ____
- 58. Viability of CD34+ cells
 - Done Go to question 59
 - □ Not done Go to question 62

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62.

68.

	Unk	nown – Go to question 62
59.	Viat	bility of CD34+ cells: %
60.	Met □	hod of testing CD34+ cell viability Flow cytometry based (7-AAD, AOPI, and AOEB)
		Trypan blue
		Other method – <i>Go to question 61</i>
	61.	Specify other method:
CD3+ ce □ Done	lls e – Go	o to question 63
Not a	done -	- Go to question 68
63. To	tal nu	mber of CD3+ cells: • • x 10
64. Via □	ability Don	of CD3+ cells e – Go to question 65
	Not	done – Go to question 68
	Unk	nown – Go to question 68
65.	Viat	bility of CD3+ cells: %
66.	Met □	hod of testing CD3+ cell viability Flow cytometry based (7-AAD, AOPI, and AOEB)
		Trypan blue
		Other method – <i>Go to question</i> 67
	67.	Specify other method:
CD3+CD □ Done	4+ ce e – Go	lls o to question 69
□ Not o	done -	- Go to question 74
69. To	tal nu	mber of CD3+CD4+ cells: • \$ x 10
70. Via □	ability Don	of CD3+CD4+ cells e – <i>Go to question 71</i>
	Not	done – Go to question 74

Unknown – *Go to question 74* CIBMTR Form 2006 R6 (page 9 of 22). Form Released 23 Sep 2022. Last Updated 19 Apr 2024. Copyright [©] 2024 NMDP and The Medical College of Wisconsin, Inc. All rights reserved.

- 71. Viability of CD3+CD4+ cells: _____%
- 72. Method of testing CD3+CD4+ cell viability □ Flow cytometry based (7-AAD, AOPI, and AOEB)
 - □ Trypan blue
 - □ Other method *Go to question* 73
 - 73. Specify other method: _____

74. CD3+CD8+ cells

- Done Go to question 75
- □ Not done *Go to question 80*
- 75. Total number of CD3+CD8+ cells: ____ ___ ___ x 10 ____

76. Viability of CD3+CD8+ cells

- Done Go to question 77
- □ Not done Go to question 80
- □ Unknown *Go to question 80*
- 77. Viability of CD3+CD8+ cells: _____%

78. Method of testing CD3+CD8+ cell viability □ Flow cytometry based (7-AAD, AOPI, and AOEB)

- □ Trypan blue
- □ Other method Go to question 79
- 79. Specify other method: _____
- 80. Were the colony-forming units (CFU) assessed after thawing? (Cord blood units only) □ Yes – Go to question 81
 - □ No Go to question 86
 - 81. Was there growth?
 - □ Yes
 - □ No
 - 82. Indicate which assessments were carried out (check all that apply)
 - □ Total CFU-GM *Go to question 83*
 - □ Total CFU-GEMM Go to question 84
 - □ Total BFU-E *Go to question 85*

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- 83. Total CFU-GM: ____ ___ x 10 ____
- 84. Total CFU-GEMM: _____ ___ x 10 ____
- 85. Total BFU-E: ____ ___ x 10 ____
- 86. Were any positive cultures (for bacterial or fungal infections) obtained from the product at the transplant center? *(complete for all cell products)*
 - □ Yes Go to question 87
 - □ No Go to question 92
 - D Pending Go to question 92
 - □ Unknown– Go to question 92

Specify organism code(s):

- 87. ____ ____
- 88. ____ ____
- 89. ____ ____
- 90. ____ ____
 - 91. Specify organism: _____

Codes for Commonly Reported Organisms Bacterial Infections

- □ 121 Acinetobacter (all species)
- □ 125 Bordetella pertussis (whooping cough)
- □ 128 Campylobacter (all species)
- □ 129 Capnocytophaga (all species)
- □ 171 Chlamydia (pneumoniae)
- □ 130 Citrobacter (freundii, other species)
- □ 131 Clostridium (all species except difficile)
- □ 132 Clostridium difficile
- □ 173 Corynebacterium jeikeium
- □ 134 Enterobacter (all species)
- □ 135 Enterococcus (all species)
- □ 177 Enterococcus, vancomycin resistant (VRE)

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- □ 136 Escherichia (also E. coli)
- □ 139 Fusobacterium (all species)
- □ 187 Haemophilus influenzae
- □ 188 Haemophilus non-influenzae
- □ 146 Klebsiella (all species)
- □ 147 Lactobacillus (bulgaricus, acidophilus, other species)
- □ 189 Legionella pneumophila
- □ 190 Legionella non-pneumophila
- □ 103 Leptospira (all species)
- □ 148 Leptotrichia buccalis
- □ 149 Leuconostoc (all species)
- □ 104 Listeria monocytogenes
- □ 151 Micrococcus, NOS
- □ 118 Mycobacterium abscessus
- □ 112 Mycobacterium avium intracellulare (MAC, MAI)
- 108 Mycobacterium cheloneae
- □ 109 Mycobacterium fortuitum
- □ 114 Mycobacterium haemophilum
- □ 115 Mycobacterium kansasii
- □ 116 Mycobacterium marinum
- □ 117 Mycobacterium mucogenicum
- □ 110 Mycobacterium tuberculosis (tuberculosis, Koch bacillus)
- □ 105 Mycoplasma (all species)
- □ 183 Neisseria gonorrhoeae
- □ 184 Neisseria meningitidis
- □ 106 Nocardia (all species)
- □ 153 Pasteurella multocida
- □ 155 Proteus (all species)
- 157 Pseudomonas or Burkholderia cepacia
- 185 Pseudomonas aeruginosa
- □ 186 Pseudomonas non-aeruginosa
- □ 159 Rhodococcus (all species)
- □ 107 Rickettsia (all species)
- □ 160 Salmonella (all species)
- □ 161 Serratia marcescens

- □ 162 Shigella (all species)
- □ 180 Staphylococcus aureus (Methicillin Resistant)
- □ 179 Staphylococcus aureus (Methicillin Sensitive)
- 158 Stenotrophomonas maltophilia
- □ 166 Stomatococcus mucilaginosis
- □ 181 Streptococcus, alpha-hemolytic
- □ 182 Streptococcus, Group B
- □ 178 Streptococcus pneumoniae
- □ 168 Treponema (syphilis)
- □ 169 Vibrio (all species)

Fungal Infections

- □ 210 Aspergillus, NOS
- □ 211 Aspergillus flavus
- □ 212 Aspergillus fumigatus
- □ 213 Aspergillus niger
- □ 215 Aspergillus terreus
- □ 214 Aspergillus ustus
- □ 270 Blastomyces (dermatitidis)
- □ 201 Candida albicans
- □ 208 Candida non-albicans
- 271 Coccidioides (all species)
- 222 Cryptococcus gattii
- □ 221 Cryptococcus neoformans
- □ 230 Fusarium (all species)
- □ 261 Histoplasma (capsulatum)
- □ 241 Mucorales (all species)
- □ 260 Pneumocystis (PCP / PJP)
- 242 Rhizopus (all species)
- □ 272 Scedosporium (all species)
- □ 240 Zygomycetes, NOS
- □ 503 Suspected fungal infection
- □ 777 Other organism

Copy questions 41-91 to report multiple instances of Product Analysis

CIBM	TR Center Number: CIBMTR Recipient ID:
Prod	uct Infusion
92.	Date of this product infusion:
93.	Was the entire volume of received product infused?
	□ No – Go to question 94
	 94. Specify what happened to the reserved portion □ Discarded – <i>Go to question 96</i>
	Cryopreserved for future use – Go to question 96
	□ Other fate – <i>Go to question 95</i>
	95. Specify other fate:
96.	Time product infusion initiated (24-hour clock): <u>Hour</u> : Standard time daylight savings time
97.	Date infusion stopped:
98.	Time product infusion completed (24-hour clock): Hour Hour daylight savings time
99.	Specify the route of product infusion I Intravenous – <i>Go to question 101</i>
	□ Intramedullary (Intraosseous) – Go to question 101
	Other route of infusion – Go to question 100

100. Specify other route of infusion: _____

The following questions are applicable to cord blood units only. Non-NMDP allogeneic products continue with question 142. Autologous and NMDP products continue with the signature lines.

- 101. Were there any adverse events or incidents associated with the stem cell infusion?
 - □ Yes Go to question 102
 - □ No *Go to question* 142

Specify the following adverse event(s):

- 102. Brachycardia
 - □ Yes Go to question 103
 - □ No Go to question 104
 - 103. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 104. Chest tightness / pain
 - □ Yes Go to question 105
 - □ No Go to question 106
 - 105. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 106. Chills at time of infusion
 - □ Yes Go to question 107
 - □ No Go to question 108
 - 107. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 108. Fever $\leq 103^{\circ}$ F within 24 hours of infusion
 - □ Yes Go to question 109
 - □ No Go to question 110
 - 109. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 110. Fever > 103° F within 24 hours of infusion
 - □ Yes Go to question 111
 - □ No Go to question 112
 - 111. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 112. Gross hemoglobinuria
 - □ Yes Go to question 113

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- □ No Go to question 114
- 113. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No

114. Headache

- □ Yes- Go to question 115
- □ No Go to question 116
- 115. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No

116. Hives

- □ Yes Go to question 117
- □ No Go to question 118
- 117. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes

 - No
- 118. Hypertension
 - □ Yes Go to question 119
 - □ No Go to question 120
 - 119. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No

120. Hypotension

- □ Yes Go to question 121
- □ No Go to question 122
- 121. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 122. Hypoxia requiring oxygen (O₂) support □ Yes – Go to question 123
 - □ No Go to question 124

- 123. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes

 - No
- 124. Nausea
 - □ Yes Go to question 125
 - □ No Go to question 126
 - 125. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 126. Rigors, mild
 - □ Yes Go to question 127
 - □ No Go to question 128
 - 127. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 128. Rigors, severe
 - □ Yes Go to question 129
 - □ No Go to question 130
 - 129. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 130. Shortness of breath (SOB)
 - □ Yes Go to question 131
 - □ No Go to question 132
 - 131. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 132. Tachycardia
 - □ Yes Go to question 133
 - □ No Go to question 134
 - 133. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes

□ No

- 134. Vomiting
 - □ Yes Go to question 135
 - □ No Go to question 136
 - 135. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 136. Other expected AE
 - □ Yes Go to question 137
 - □ No Go to question 139
 - 137. Specify other expected AE:
 - 138. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No
- 139. Other unexpected AE
 - □ Yes Go to question 140
 - □ No Go to question 142

140. Specify other unexpected AE:

- 141. In the Medical Director's judgment, was the adverse event a direct result of the infusion? Yes
 - No

Donor / Infant Demographic Information

This Donor Demographic Information section (questions 142-168) is to be completed for all non-NMDP allogeneic donors. If the stem cell product was from an NMDP donor or an autologous donor, continue with the signature lines.

142. Was the donor ever pregnant?

- □ Yes Go to question 143
- □ No Go to question 145
- □ Unknown *Go to question 145*
- □ Not applicable (male donor or cord blood unit) Go to question 145

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- 143. Number of pregnancies
 - □ Known Go to question 144
 - □ Unknown Go to question 145
 - 144. Specify number of pregnancies: _____

145. Ethnicity (donor)

- □ Hispanic or Latino
- Not Hispanic or Latino
- □ Not applicable (not a resident of the USA)
- □ Unknown
- 146. Race (donor) (check all that apply)
 - □ White
 - Black or African American
 - □ Asian
 - American Indian or Alaska Native
 - Native Hawaiian or Other Pacific Islander
 - □ Not reported *Go to guestion 148*
 - □ Unknown– Go to question 148
 - 147. Race detail (donor) (check all that apply)
 - Eastern European
 - □ Mediterranean
 - □ Middle Eastern
 - North Coast of Africa
 - North American
 - □ Northern European
 - □ Western European
 - □ White Caribbean
 - White South or Central American
 - □ Other White
 - □ African
 - □ African American
 - Black Caribbean
 - □ Black South or Central American

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- □ Other Black
- Alaskan Native or Aleut
- □ North American Indian
- American Indian, South or Central America
- □ Caribbean Indian
- □ South Asian
- □ Filipino (Pilipino)
- □ Japanese
- □ Korean
- □ Chinese
- □ Vietnamese
- Other Southeast Asian
- □ Guamanian
- Hawaiian
- □ Samoan
- Other Pacific Islander
- □ Unknown
- 148. Was the donor a carrier for potentially transferable genetic diseases? □ Yes- Go to question 149
 - □ No- Go to question 151
 - 149. Specify potentially transferable genetic disease (check all that apply)
 - □ Sickle cell anemia
 - □ Thalassemia
 - Other hemoglobinopathy
 - □ Other disease- *Go to guestion 150*
 - 150. Specify other disease: _____
- 151. Was the donor / product tested for other transferable genetic or clonal abnormalities? □ Yes – Go to question 152
 - □ No If this is a related donor, go to question 157; all other donor types go to signature line
 - Unknown If this is a related donor, go to question 157; all other donor types go to signature line
 - 152. Clonal hematopoiesis of indeterminate potential (CHIP)
 - □ Yes- Go to question 153
 - □ No- Go to question 154

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- 153. What was the method of testing used? _____
- 154. Monoclonal B-cell lymphocytosis
 - □ Yes
 - 🗆 No
- 155. Other transferable genetic or clonal abnormality
 - Yes- Go to question 156
 - □ No- Go to question 157

156. Specify other transferable genetic or clonal abnormality:

The following questions (157 - 168) apply only to allogeneic related donors. If the stem cell product was from an autologous donor, Non-NMDP unrelated donor, NMDP donor, or was a cord blood unit, then continue with the signature lines.

- 157. Did this donor have a central line placed?
 - □ Yes
 - □ No
- 158. Was the donor hospitalized (inpatient) during or after the collection? □ Yes

 - □ No
- 159. Did the donor experience any life-threatening complications during or after the collection?
 □ Yes Go to question 160
 - □ No Go to question 161
 - 160. Specify: _____
- 161. Did the allogeneic donor give one or more autologous transfusion units?
 □ Yes Go to question 162
 - □ No *Go to question 164*
 - 162. Date of collection: _______ _____ ______ ______
 - 163. Number of units: _____
- 164. Did the donor receive blood transfusions as a result of the collection?
 □ Autologous transfusions *Go to question 165*
 - □ Allogeneic transfusions- *Go to question 166*

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	□ No – Go to question 167
	165. Specify number of autologous units:
	166. Specify number of allogeneic units:
167.	Did the donor die as a result of the collection? □ Yes – <i>Go to question 168</i>
	□ No – Go to question First Name
	168. Specify cause of death:
First Name:	
Last N	Name:
E-ma	il address:
Date:	YYYYMMDD