



# Hematopoietic Cellular Transplant (HCT) Infusion

OMB No: 0915-0310  
Expiration Date: 09/30/2028

## Registry Use Only

Sequence Number:

Date Received:

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CIBMTR Center Number: \_\_\_\_\_

CIBMTR Research ID: \_\_\_\_\_

Event date: \_\_\_\_\_

YYYY

MM

DD

HCT type (check only one)

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

Product type (check only one)

- ☐ Bone marrow
- ☐ PBSC
- ☐ Single cord blood unit
- ☐ Other product

Specify: \_\_\_\_\_

NMDP Product

- ☐ Yes
- ☐ No

**Product Identifiers:**

CIBMTR Center Number: \_\_\_\_\_ CIBMTR Recipient ID: \_\_\_\_\_

NMDP cord blood unit ID: \_\_\_\_\_ NMDP donor ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Registry donor ID: \_\_\_\_\_

Non-NMDP cord blood unit ID: \_\_\_\_\_

Global Registration Identifier for Donors (GRID): \_\_\_\_\_

Registry or UCB Bank ID: \_\_\_\_\_

Donor DOB: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
                    YYYY        MM        DD

Donor age: \_\_\_\_ ☐ Months (use only if less than 1 year old)

☐ Years

Donor sex: ☐ Male ☐ Female







CIBMTR Center Number: \_\_\_\_\_ CIBMTR Recipient ID: \_\_\_\_\_

28. Specify other method used to thaw the product: \_\_\_\_\_

29. Did any incidents or product complaints occur while preparing or thawing the product?

☐ Yes

☐ No

30. Was the product **processed** prior to infusion?

☐ Yes – **Go to question 31**

☐ No – **Go to question 32**

31. Specify processing (*check all that apply*)

☐ Buffy coat enriched (*buffy coat preparation*)

☐ Diluted

☐ Plasma reduced

☐ RBC reduced

☐ Washed

32. Was the product **manipulated** prior to infusion?

☐ Yes – **Go to question 33**

☐ No – **Go to question 42**

33. Specify manipulations performed (*check all that apply*)

☐ Ex-vivo expansion – **Go to question 34**

☐ Genetic manipulation (gene transfer / transduction) – **Go to question 36**

☐ CD34 enriched (CD34+ selection) – **Go to question 42**

☐ Ex-vivo T-cell depletion – **Go to question 37**

☐ Negative fraction – **Go to question 42**

☐ Other manipulation – **Go to question 41**

34. Specify ex-vivo expansion

☐ Omidubicel (OMISIRGE)

☐ Other method

35. Specify other ex-vivo expansion: \_\_\_\_\_

36. Specify genetic manipulation: (gene transfer / transduction) \_\_\_\_\_

37. Specify antibodies used (*check all that apply*)

☐ Anti CD3

☐ Anti CD4



CIBMTR Center Number: \_\_\_\_\_ CIBMTR Recipient ID: \_\_\_\_\_

48. Method of testing TNC viability

- ☐ Flow cytometry based (*includes 7-AAD, AOPI, and AOEB*) – **Go to question 50**
- ☐ Trypan blue – **Go to question 50**
- ☐ Other method – **Go to question 49**

49. Specify other method of testing TNC viability: \_\_\_\_\_

50. Nucleated white blood cells

- ☐ Done – **Go to question 51**
- ☐ Not done – **Go to question 52**

51. Total number of nucleated white blood cells: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

52. Mononuclear cells

- ☐ Done – **Go to question 53**
- ☐ Not done – **Go to question 54**

53. Total number of mononuclear cells: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

54. Nucleated red blood cells

- ☐ Done – **Go to question 55**
- ☐ Not done – **Go to question 56**

55. Total number of nucleated red blood cells: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

56. CD34+ cells

- ☐ Done – **Go to question 57**
- ☐ Not done – **Go to question 62**

57. Total number of CD34+ cells: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

58. Viability of CD34+ cells

- ☐ Done – **Go to question 59**
- ☐ Not done – **Go to question 62**

59. Viability of CD34+ cells: \_\_\_\_\_ %

60. Method of testing CD34+ cell viability

- ☐ Flow cytometry based (*7-AAD, AOPI, and AOEB*) – **Go to question 62**



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- ☐ Trypan blue – **Go to question 62**
- ☐ Other method – **Go to question 61**

61. Specify other method of testing CD34+ cell viability: \_\_\_\_\_

62. CD3+ cells

- ☐ Done – **Go to question 63**
- ☐ Not done – **Go to question 68**

63. Total number of CD3+ cells: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

64. Viability of CD3+ cells

- ☐ Done – **Go to question 65**
- ☐ Not done – **Go to question 68**

65. Viability of CD3+ cells: \_\_\_\_\_ %

66. Method of testing CD3+ cell viability

- ☐ Flow cytometry based (*7-AAD, AOPI, and AOEB*) – **Go to question 68**
- ☐ Trypan blue– **Go to question 68**
- ☐ Other method – **Go to question 67**

67. Specify other method of testing CD3+ cell viability: \_\_\_\_\_

68. CD3+CD4+ cells

- ☐ Done – **Go to question 69**
- ☐ Not done – **Go to question 70**

69. Total number of CD3+CD4+ cells: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

70. CD3+CD8+ cells

- ☐ Done – **Go to question 71**
- ☐ Not done – **Go to question 72**

71. Total number of CD3+CD8+ cells: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

72. Were the colony-forming units (CFU) assessed after thawing? (**Cord blood units only**)

- ☐ Yes – **Go to question 73**
- ☐ No – **Go to question 78**

73. Was there growth?

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☐ Yes

☐ No

74. Indicate which assessments were carried out (*check all that apply*)

☐ Total CFU-GM – **Go to question 75**

☐ Total CFU-GEMM – **Go to question 76**

☐ Total BFU-E – **Go to question 77**

75. Total CFU-GM: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

76. Total CFU-GEMM: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

77. Total BFU-E: \_\_\_\_\_ • \_\_\_\_\_ x 10 \_\_\_\_\_

78. 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 79**

☐ No – **Go to question 84**

☐ Pending – **Go to question 84**

☐ Unknown– **Go to question 84**

**Specify organism code(s):**

79. \_\_\_\_\_

80. \_\_\_\_\_

81. \_\_\_\_\_

82. \_\_\_\_\_

83. Specify other 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)

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- ☐ 130 *Citrobacter* (*freundii*, other species)
- ☐ 131 *Clostridium* (all species except *difficile*)
- ☐ 132 *Clostridium difficile*
- ☐ 173 *Corynebacterium jeikeium*
- ☐ 196 *Cutibacterium acnes* (*Propionibacterium*)
- ☐ 134 *Enterobacter* (all species)
- ☐ 135 *Enterococcus* (all species)
- ☐ 177 *Enterococcus*, vancomycin resistant (VRE)
- ☐ 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 chelonae*
- ☐ 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*

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- ☐ 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 mucilaginosus*
- ☐ 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* (dermatitis)
- ☐ 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)

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- ☐ 242 Rhizopus (all species)
- ☐ 272 Scedosporium (all species)
- ☐ 240 Zygomycetes, NOS
- ☐ 503 Suspected fungal infection
- ☐ 777 Other organism

## Product Infusion

84. Date of this product infusion: \_\_\_\_\_  
 YYY Y MM DD

85. Was the entire volume of the product received by the center infused?

- ☐ Yes – **Go to question 88**
- ☐ No – **Go to question 86**

86. Specify what happened to the reserved portion (*check all that apply*)

- ☐ Discarded – **Go to question 88**
- ☐ Cryopreserved for future use – **Go to question 88**
- ☐ Research – **Go to question 88**
- ☐ Training or Quality Control – **Go to question 88**
- ☐ Other fate – **Go to question 87**

87. Specify other fate: \_\_\_\_\_

88. Time product infusion initiated (24-hour clock):      Hour :      Minute ☐ standard time  
☐ daylight savings time

89. Date infusion stopped: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 YYY Y MM DD

90. Time product infusion completed (24-hour clock):        Hour        Minute ☐ standard time ☐ daylight savings time

91. Specify the route of product infusion

- ☐ Intravenous – **Go to question 93**
- ☐ Intramedullary (*Intraosseous*) – **Go to question 93**
- ☐ Other route of infusion – **Go to question 92**

92. Specify other route of infusion:

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**The following questions are applicable to cord blood units only. Non-NMDP allogeneic products continue with question 134. Autologous and NMDP products go to end of form.**

93. Were there any adverse events or incidents associated with the stem cell infusion?

☐ Yes – **Go to question 94**

☐ No – **Go to question 134**

**Specify the following adverse event(s)**

94. Brachycardia

☐ Yes – **Go to question 95**

☐ No – **Go to question 96**

95. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

96. Chest tightness / pain

☐ Yes – **Go to question 97**

☐ No – **Go to question 98**

97. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

98. Chills at time of infusion

☐ Yes – **Go to question 99**

☐ No – **Go to question 100**

99. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

100. Fever  $\leq 103^{\circ}$  F within 24 hours of infusion

☐ Yes – **Go to question 101**

☐ No – **Go to question 102**

101. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

102. Fever  $> 103^{\circ}$  F within 24 hours of infusion

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☐ Yes – **Go to question 103**

☐ No – **Go to question 104**

103. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

104. Gross hemoglobinuria

☐ Yes – **Go to question 105**

☐ No – **Go to question 106**

105. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

106. Headache

☐ Yes– **Go to question 107**

☐ No – **Go to question 108**

107. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

108. Hives

☐ Yes – **Go to question 109**

☐ No – **Go to question 110**

109. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

110. Hypertension

☐ Yes – **Go to question 111**

☐ No – **Go to question 112**

111. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

112. Hypotension

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☐ Yes – **Go to question 113**

☐ No – **Go to question 114**

113. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

114. Hypoxia requiring oxygen (O<sub>2</sub>) support

☐ Yes – **Go to question 115**

☐ No – **Go to question 116**

115. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

116. Nausea

☐ Yes – **Go to question 117**

☐ No – **Go to question 118**

117. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

118. Rigors, mild

☐ Yes – **Go to question 119**

☐ No – **Go to question 120**

119. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

120. Rigors, severe

☐ Yes – **Go to question 121**

☐ No – **Go to question 122**

121. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

122. Shortness of breath (SOB)



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☐ Yes – **Go to question 123**

☐ No – **Go to question 124**

123. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

124. Tachycardia

☐ Yes – **Go to question 125**

☐ No – **Go to question 126**

125. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

126. Vomiting

☐ Yes – **Go to question 127**

☐ No – **Go to question 128**

127. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

128. Other expected AE

☐ Yes – **Go to question 129**

☐ No – **Go to question 131**

129. Specify other expected AE: \_\_\_\_\_

130. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

131. Other unexpected AE

☐ Yes – **Go to question 132**

☐ No – **Go to question 134**

132. Specify other unexpected AE: \_\_\_\_\_

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133. In the clinician's judgment, was the adverse event a direct result of the infusion?

☐ Yes

☐ No

#### Donor / Infant Demographic Information

**This Donor Demographic Information section (questions 134-159) 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 to the end of the form.**

134. Was the donor ever pregnant?

☐ Yes – **Go to question 135**

☐ No – **Go to question 137**

☐ Unknown – **Go to question 137**

135. Number of pregnancies

☐ Known – **Go to question 136**

☐ Unknown – **Go to question 137**

136. Specify number of pregnancies: \_\_\_\_\_

137. Geographic ancestry (*select one or more options that closest identifies the donor's background*)

☐ Asian – **Go to question 138**

☐ Black or African – **Go to question 138**

☐ Hispanic or Latino – **Go to question 138**

☐ Indigenous American – **Go to question 138**

☐ Jewish – **Go to question 138**

☐ Middle Eastern or North African – **Go to question 138**

☐ Pacific Islander – **Go to question 138**

☐ White – **Go to question 138**

☐ Not otherwise specified – **Go to question 139**

☐ Prefer not to answer – **Go to question 139**

138. Geographic ancestry detail (*select one or more options that closest identifies the donor's background*)

##### Asian

☐ Caribbean Indian

☐ Chinese

☐ Filipino

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- ☐ Indian
- ☐ Japanese
- ☐ Korean
- ☐ Malaysian
- ☐ Mongolian
- ☐ Pakistani
- ☐ Taiwanese
- ☐ Thai
- ☐ Vietnamese
- ☐ Other Indian Subcontinent (*e.g. Bangladeshi, Nepali, Sri Lankan, etc.*)
- ☐ Other Southeast Asian (*e.g. Cambodian, Indonesian, Singaporean, etc.*)
- ☐ Not otherwise specified Asian

#### **Black or African**

- ☐ African American
- ☐ Black Caribbean (*e.g. Haitian, Jamaican, etc.*)
- ☐ Black South or Central American
- ☐ East African (*e.g. Ethiopian, Kenyan, Somali, Tanzanian, etc.*)
- ☐ South African (*e.g. Angolan, Botswanan, Mozambican, Zambian, Zimbabwean, etc.*)
- ☐ West African (*e.g. Ghanaian, Malian, Nigerian, Senegalese, etc.*)
- ☐ Not otherwise specified Black/African

#### **Hispanic or Latino**

- ☐ Brazilian
- ☐ Caribbean Hispanic (*e.g. Dominican*)
- ☐ Cuban
- ☐ Mexican
- ☐ Puerto Rican
- ☐ South / Central American Hispanic
- ☐ Not otherwise specified Hispanic / Latino

#### **Indigenous American**

- ☐ Alaska Native
- ☐ Indigenous Caribbean
- ☐ Indigenous North American
- ☐ Indigenous South / Central American

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- ☐ Not otherwise specified Indigenous American

**Jewish**

- ☐ Ashkenazi
- ☐ Mizrahi
- ☐ Sephardi
- ☐ Not otherwise specified Jewish

**Middle Eastern or North African**

- ☐ Arab Peninsula (*e.g. Emirati, Kuwaiti, Saudi, Yemeni etc.*)
- ☐ Central Asian (*e.g. Afghan, Iranian, Kazakhstani, Turkish, etc.*)
- ☐ East Mediterranean (*e.g. Iraqi, Jordanian, Lebanese, Syrian, etc.*)
- ☐ North African (*e.g. Algerian, Egyptian, Moroccan, etc.*)
- ☐ Not otherwise specified Middle Eastern / North African

**Pacific Islander**

- ☐ Melanesian (*e.g. Fijian, Papua New Guinean, etc.*)
- ☐ Micronesian (*e.g. Chamorro, Guamanian, Marshallese, etc.*)
- ☐ Native Hawaiian
- ☐ Polynesian (*e.g. Māori, Samoan, Tongan, etc.*)
- ☐ Not otherwise specified Pacific Islander

**White**

- ☐ Eastern European (*e.g. Bulgarian, Georgian, Polish, Romanian, Ukrainian etc.*)
- ☐ Northern European (*e.g. Finnish, Norwegian, Swedish etc.*)
- ☐ Russian or Former Soviet Union
- ☐ Southern European (*e.g. Greek, Italian, Portuguese, Spanish, etc.*)
- ☐ Western European (*e.g. British, French, German, Irish, Scottish, etc.*)
- ☐ White Caribbean
- ☐ White South or Central American
- ☐ Not otherwise specified White

139. Was the donor a carrier for potentially transferable genetic diseases?

- ☐ Yes— **Go to question 140**
- ☐ No— **Go to question 142**

140. Specify potentially transferable genetic disease (**check all that apply**)

- ☐ Sickle cell anemia
- ☐ Thalassemia

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- ☐ Other hemoglobinopathy
- ☐ Other disease– **Go to question 141**

141. Specify other transferable genetic disease: \_\_\_\_\_

142. Was the donor / product tested for other transferable genetic or clonal abnormalities?
- ☐ Yes – **Go to question 143**
  - ☐ No – **If this is a related donor, go to question 148; all other donor types go to end of form**
  - ☐ Unknown – **If this is a related donor, go to question 148; all other donor types go to end of form**

143. Clonal hematopoiesis of indeterminate potential (CHIP)
- ☐ Yes– **Go to question 144**
  - ☐ No– **Go to question 145**

144. What was the method of testing used? \_\_\_\_\_

145. Monoclonal B-cell lymphocytosis
- ☐ Yes
  - ☐ No

146. Other transferable genetic or clonal abnormality
- ☐ Yes– **Go to question 147**
  - ☐ No– **Go to question 148**

147. Specify other transferable genetic or clonal abnormality: \_\_\_\_\_

**The following questions (148 - 159) 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 to the end of the form.**

148. Did this donor have a central line placed?
- ☐ Yes
  - ☐ No
149. Was the donor hospitalized (inpatient) during or after the collection?
- ☐ Yes
  - ☐ No
150. Did the donor experience any life-threatening complications during or after the collection?
- ☐ Yes – **Go to question 151**
  - ☐ No – **Go to question 152**

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151. Specify life-threatening complication experienced: \_\_\_\_\_

152. Did the allogeneic donor give one or more autologous transfusion units?

☐ Yes – **Go to question 153**

☐ No – **Go to question 155**

153. Date of collection: \_\_\_\_-\_\_\_\_-\_\_\_\_  
                                    YYYY                    MM                    DD

154. Number of units: \_\_\_\_

155. Did the donor receive blood transfusions as a result of the collection? (*check all that apply*)

☐ Autologous transfusions – **Go to question 156**

☐ Allogeneic transfusions– **Go to question 157**

☐ No – **Go to question 158**

156. Specify number of autologous units: \_\_\_\_

157. Specify number of allogeneic units: \_\_\_\_

158. Did the donor die as a result of the collection?

☐ Yes – **Go to question 159**

☐ No – **Go to end of form**

159. Specify cause of death: \_\_\_\_\_