**Hematopoietic Cellular Transplant (HCT) Infusion**

<table>
<thead>
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<th>Registry Use Only</th>
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<tr>
<td>Sequence Number:</td>
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<td>Date Received:</td>
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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):** | __ __ __ __ __ __ __ __ __ __ |
| **ISBT DIN:** | __ __ __ __ __ __ __ __ __ __ |
| **Registry or UCB Bank ID:** | __ __ __ |
| **Donor DOB:** | __ __ __ - __ __ - __
| **Donor age:** | __ | ☐ Months (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 question 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*
   - Plerixafor (Mozobil) – *Go to question 4*
   - Other growth or mobilizing factor(s) – *Go to question 3*

3. Specify other growth or mobilizing factor(s): ______________________ – *Go to question 4*

**Product Collection**

4. Date of first collection for this mobilization: ___ ___ ___ ___ — ___ ___ — ___ ___ YYYY MM DD

5. Were anticoagulants or other agents added to the product between collection and infusion?
   - 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*

7. Specify other agent: ______________________
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

9. Date of receipt of product at your facility: ___ ___ ___ ___ – ___ ___ ___ __

10. Time of receipt of product (24-hour clock): ______:______

11. 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

16. Specify the storage method used for the cord blood unit
   - ☐ Electric freezer
   - ☐ Liquid nitrogen
   - ☐ Vapor phase

17. Temperature during storage
Report the total number of cells (not cells per kilogram) prior to cryopreservation: (Information provided for the unit by the cord blood bank).

19. Total nucleated cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___ (Includes nucleated red and nucleated white cells) (Cord blood units only)

20. CD34+ cells (Cord blood units only)
   □ Done – Go to question 21
   □ Not done – Go to question 22

21. Total number of CD34+ cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___

Product Processing / Manipulation

22. Was the product thawed from a cryopreserved state prior to infusion?
   □ Yes – Go to question 23
   □ 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 that was thawed (Cord blood units only)
   □ 80%
   □ 20%
   □ Other percent– Go to question 25

25. Specify other percent: ___ ___ %

26. Date thawing process initiated: ___ ___ ___ ___ — ___ ___ — ___ ___ YYYY MM DD
27. Time at initiation of thaw (24-hour clock): __________:__________  □ standard time
    □ daylight savings time

28. Time of thaw completion (24-hour clock): __________:__________  □ standard time
    □ daylight savings time

29. What 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 any incidents or product complaints occur while preparing or thawing the product?
    □ Yes
    □ No

32. Was the product processed prior to infusion?
    □ Yes – Go to question 33
    □ No – Go to question 34

33. Specify processing (check all that apply)
    □ Buffy coat enriched (buffy coat preparation)
    □ Diluted
    □ Plasma reduced
    □ RBC reduced
    □ Washed

34. Was the product manipulated prior to infusion?
    □ Yes – Go to question 35
    □ No – Go to question 41

35. Specify manipulations performed (check all that apply)
    □ Ex-vivo expansion – Go to question 41
    □ Genetic manipulation (gene transfer / transduction) – Go to question 41
    □ CD34 enriched (CD34+ selection) – Go to question 41
    □ Ex-vivo T-cell depletion – Go to question 36
    □ Other manipulation – Go to question 40

36. Specify antibodies used (check all that apply)
CIBMTR Center Number: __________
CIBMTR Recipient ID: __________

- Anti CD3
- Anti CD4
- Anti CD8
- Anti CD19
- Anti CD45RA
- 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)

42. Date of product analysis: __ __ __ __ __ __ __ __ __ __ 
    YYYY MM DD

43. Total volume of product plus additives: ___ ___ ___ ___ mL

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 ____

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

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
59. Viability of CD34+ cells: ___ ___ ___ %

60. Method of testing CD34+ cell viability
   □ Flow cytometry based (7-AAD, AOPI, and AOEB)
   □ Trypan blue
   □ Other method – Go to question 61

61. Specify other method: ________________________________

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
   □ Unknown – Go to question 68

65. Viability of CD3+ cells: ___ ___ ___ %

66. Method of testing CD3+ cell viability
   □ Flow cytometry based (7-AAD, AOPI, and AOEB)
   □ Trypan blue
   □ Other method – Go to question 67

67. Specify other method: ________________________________

68. CD3+CD4+ cells
   □ Done – Go to question 69
   □ Not done – Go to question 74

69. Total number of CD3+CD4+ cells: ___ ___ ___ ● ___ ___ x 10 ___ ___
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

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
   □ 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)
- 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 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 (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

Product Infusion

92. Date of this product infusion: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY   MM  DD

93. Was the entire volume of received product infused?
   □ Yes – Go to question 96
   □ No – Go to question 94

94. Specify what happened to the reserved portion
   □ Discarded – Go to question 96
   □ Cryopreserved for future use – Go to question 96
   □ Other fate – Go to question 95

95. Specify other fate: _________________________________

96. Time product infusion initiated (24-hour clock): ___:___
    Hour:Minute  □ standard time
               □ daylight savings time

97. Date infusion stopped: ___ ___ ___ ___ - ___ ___ — ___ ___
    YYYY  MM  DD

98. Time product infusion completed (24-hour clock): ___:___
    Hour:Minute  □ standard time
               □ daylight savings time

99. Specify the route of product infusion
   □ Intravenous – Go to question 101
   □ 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 ≤ 103° 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
   ☐ 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
In the Medical Director’s judgment, was the adverse event a direct result of the infusion?
   □ Yes
   □ No

Hypoxia requiring oxygen (O₂) support
   □ Yes – Go to question 123
   □ No – Go to question 124

In the Medical Director’s judgment, was the adverse event a direct result of the infusion?
   □ Yes
   □ No

Nausea
   □ Yes – Go to question 125
   □ No – Go to question 126

In the Medical Director’s judgment, was the adverse event a direct result of the infusion?
   □ Yes
   □ No

Rigors, mild
   □ Yes – Go to question 127
   □ No – Go to question 128

In the Medical Director’s judgment, was the adverse event a direct result of the infusion?
   □ Yes
   □ No

Rigors, severe
   □ Yes – Go to question 129
   □ No – Go to question 130

In the Medical Director’s judgment, was the adverse event a direct result of the infusion?
   □ Yes
   □ No

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

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 question 148
   - Unknown – Go to question 148

147. Race detail (donor) (check all that apply)
   - Eastern European
   - Mediterranean
   - Middle Eastern
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 question 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**

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: _________ - _________ - _________
   YYYY    MM    DD

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
    - 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 – Go to question 168
    - No – Go to question First Name

168. Specify cause of death: __________________________

First Name: __________________________________________
    (Person completing form)

Last Name: __________________________________________

E-mail address: ________________________________________

Date: _________ - _________ - _________
   YYYY    MM    DD