



# Hematopoietic Cellular Transplant (HCT) Infusion

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

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): \_\_\_\_\_

ISBT DIN: \_\_\_\_\_

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: \_\_\_\_\_

27. Time at initiation of thaw (24-hour clock): \_\_\_\_\_ : \_\_\_\_\_  standard time  
Hour Minute  daylight savings time

28. Time of thaw completion (24-hour clock): \_\_\_\_\_ : \_\_\_\_\_  standard time  
Hour Minute  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
- $\alpha/\beta$  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**

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

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



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

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

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 \_\_\_\_\_

70. Viability of CD3+CD4+ cells

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

- Done – **Go to question 71**
- Not done – **Go to question 74**
- Unknown – **Go to question 74**

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

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

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)

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

CIBMTR Recipient ID: \_\_\_\_\_

- 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 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*
- 155 *Proteus* (all species)
- 157 *Pseudomonas* or *Burkholderia cepacia*

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

CIBMTR Recipient ID: \_\_\_\_\_

- 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)



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

**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

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

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



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

- 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 (O<sub>2</sub>) 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**

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

CIBMTR Recipient ID: \_\_\_\_\_

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

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

CIBMTR Recipient ID: \_\_\_\_\_

### 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

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

CIBMTR Recipient ID: \_\_\_\_\_

- 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
- 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

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

- 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**

