



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**

CIBMTR Center Number: _____ CIBMTR Recipient ID: _____

- 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?

CIBMTR Center Number: _____ CIBMTR Recipient ID: _____

- 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)

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

- 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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

- 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)

CIBMTR Center Number: _____ CIBMTR Recipient ID: _____

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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

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 (O₂) 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)

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

- 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: _____

CIBMTR Center Number: _____ CIBMTR Recipient ID: _____

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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

- 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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

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

CIBMTR Center Number: _____ CIBMTR Recipient ID: _____

- 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**

