CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Hematopoietic Cellular Transplant (HCT) Infusion

Registry Use Only

Sequence Number:

Date Received:

OMB No: 0915-0310
Expiration Date: 12/31/2013

CIBMTR Center Number: ___ ___ ___ ___ ___

CIBMTR Recipient ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Date of HCT for which this form is being completed: ___ ___ ___ ___ — ___ ___ — ___ ___
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: _____

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.

Internal use: Document number F00481 revision 2 Replaces: F00481 version 1.0 July 2007

Donor / Cord Blood Unit Identification

1. Specify donor:

☐ Autologous – ***Go to question 16***

☐ Autologous cord blood unit – ***Go to question 5***

☐ NMDP unrelated cord blood unit – ***Go to question 2***

☐ NMDP unrelated donor – ***Go to question 3***

☐ Related donor – ***Go to question 10***

☐ Related cord blood unit – ***Go to question 5***

☐ Non-NMDP unrelated donor – ***Go to question 4***

☐ Non-NMDP unrelated cord blood unit – ***Go to question 5***

2. NMDP Cord Blood Unit ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ – ***Go to question 15***

3. NMDP Donor ID: ___ ___ ___ ___ — ___ ___ ___ ___ — ___ – ***Go to question 15***

4. Non-NMDP unrelated donor ID: *(not applicable for related donor)*

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ - ***Go to question 8***

5. Non-NMDP cord blood unit ID: *(include related and autologous CBUs)*

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

6. Is the CBU ID also the ISBT DIN: number?

☐ Yes – ***Go to question 8***

☐ No – ***Go to question 7***

7. Specify the ISBT DIN number: _____

8. Registry or UCB Bank ID: ___ ___ ___ ___

9. Specify other Registry or UCB Bank: _____

10. Date of birth (donor / infant):

☐ Known – ***Go to question 11***

☐ Unknown – ***Go to question 12***

11. Date of birth (donor / infant): ___ ___ ___ ___ — ___ ___ — ___ ___ - ***Go to question 14***

Internal use: Document number F00481 revision 2 Replaces: F00481 version 1.0 July 2007

12. Age (donor / infant):

☐ Known – ***Go to question 13***

☐ Unknown – ***Go to question 14***

13. Age (donor / infant): ___ ___ ☐ Months (use only if less than 1 year old)

☐ Years

14. Sex (donor / infant):

☐ Male

☐ Female

15. Was the product derived from an NMDP adult donor, NMDP cord blood unit, or non-NMDP cord blood unit?

☐ Yes – ***Go to questions 43***

☐ No – ***Go to question 16***

Pre-Collection Therapy

16. Did the donor receive therapy, prior to any stem cell harvest, to enhance the product collection for this HCT?

☐ Yes – ***Go to questions 17***

☐ No – ***Go to question 28***

Specify therapy(s):

17. Growth and mobilizing factor(s)

☐ Yes – ***Go to questions 18***

☐ No – ***Go to question 24***

Specify growth factor(s):

18._____G-CSF

☐ Yes

☐ No

19._____Pegylated G-CSF

☐ Yes

☐ No

20._____GM-CSF

Internal use: Document number F00481 revision 2 Replaces: F00481 version 1.0 July 2007

☐ Yes

☐ No

21._____Plerixafor (Mozobil)

☐ Yes

☐ No

22._____Other growth or mobilizing factor

☐ Yes – ***Go to question 23***

☐ No – ***Go to question 24***

23. Specify other growth or mobilizing factor: _____

24._____Systemic therapy (chemotherapy) *(autologous only)*

☐ Yes ***– Go to question 25***

☐ No – ***Go to question 26***

25. Anti-CD20 (rituximab, Rituxan) *(autologous only)*

☐ Yes

☐ No

26._____Other therapy

☐ Yes – ***Go to question 27***

☐ No – ***Go to question 28***

27._____Specify other therapy: _____

Product Collection

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

29. Was more than one collection required for this HCT?

☐ Yes – ***Go to question 30***

☐ No – ***Go to question 31***

Internal use: Document number F00481 revision 2 Replaces: F00481 version 1.0 July 2007

Complete a separate CIBMTR form 2006 – HCT Infustion for each subsequent collection that was not part of this mobilization.

30._____Specify the number of subsequent days of collection in this episode: ___

31. Were anticoagulants added to the product during collection?

☐ Yes – ***Go to questions 32***

☐ No – ***Go to question 37***

Specify anticoagulant(s):

32._____Acid citrate dextrose (ACD)

☐ Yes

☐ No

33._____Citrate phosphate dextrose (CPD)

☐ Yes

☐ No

34. Heparin

☐ Yes

☐ No

35._____Other anticoagulant

☐ Yes – ***Go to question 36***

☐ No – ***Go to question 37***

36._____Specify other anticoagulant:
_____

37. Were anticoagulants added to the product before freezing?

☐ Yes – ***Go to questions 38***

☐ No – ***Go to question 43***

Specify anticoagulant(s):

38._____Acid citrate dextrose (ACD)

☐ Yes

☐ No

39._____Citrate phosphate dextrose (CPD)

☐ Yes

☐ No

40. Heparin

☐ Yes

☐ No

41._____Other anticoagulant

☐ Yes – ***Go to question 42***

☐ No – ***Go to question 43***

42._____Specify:
_____

Product Transport and Receipt

43. Was this product collected off-site and shipped to your facility?

☐ Yes – ***Go to question 44***

☐ No – ***Go to question 57***

44._____Date of receipt of product at your facility: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

45. Time of receipt of product (24-hour clock): ___ ___ : ___ ___
Hour Minute

☐ standard time

☐ daylight savings time

46._____Specify the shipping environment of the product(s):

☐ Frozen gel pack (refrigerator temperature) – ***If product is cord blood, go to question 48; all other products go to question 57***

☐ Frozen cord blood unit(s) – ***Go to question 48***

☐ Room temperature per transplant center request – ***If product is cord blood, go to question 48; all other products go to question 57***

☐ Other shipping environment – ***Go to question 47***

47._____Specify other shipping environment:
_____
– ***If product is cord blood, go to question 48; all other products go to question 57***

Internal use: Document number F00481 revision 2 Replaces: F00481 version 1.0 July 2007

48._____Was there any indication that the environment within the shipper was outside the expected temperature range for this product at any time during shipment? **(Cord blood units only)**

☐ Yes

☐ No

49.Were the secondary containers (e.g., insulated shipping containers and unit cassette) intact when they arrived at your center? **(Cord blood units only)**

☐ Yes

☐ No

50._____Was the cord blood unit stored at your center prior to thawing? **(Cord blood units only)**

☐ Yes – ***Go to questions 51***

☐ No – ***Go to question 54***

51._____Specify the storage method used for the cord blood unit:

☐ Electric freezer

☐ Liquid nitrogen

☐ Vapor phase

52._____Temperature during storage:

☐ < -150° C

☐ ≥ -150° C to < -135° C

☐ ≥ -135° C to < -80° C

☐ ≥ -80° C

53._____Date storage started: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

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

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

55. CD34+ cells **(Cord blood units only)**

☐ Done – ***Go to question 56***

☐ Not done – ***Go to question 57***

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

Product Processing / Manipulation

57. Was a fresh product received (e.g. not frozen)? *(NMDP products only)*

- ☐ Yes – ***Go to question 58***
- ☐ No – ***Go to question 59***
- ☐ Not applicable (cord blood unit) – ***Go to question 59***

58. Was the entire fresh product cryopreserved at your facility prior to infusion? *(NMDP products only)*

- ☐ Yes
- ☐ No

59. Was the product thawed from a cryopreserved state prior to infusion?

- ☐ Yes – ***Go to question 60***
- ☐ No – ***Go to question 71***

60._____Was the entire product thawed?

- ☐ Yes – ***Go to question 64***
- ☐ No – ***Go to questions 61***

61._____Was only a compartment of the bag thawed? *(Cord blood units only)*

- ☐ Yes
- ☐ No

62. Were there multiple product bags?

- ☐ Yes – ***Go to question 63***
- ☐ No – ***Go to question 64***

63._____Specify number of bags thawed: ___ ___

64._____Date thawing process initiated: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

65. ___ ___ : ___ ___
Hour Minute

Time at initiation of thaw (24-hour clock):
- ☐ standard time
- ☐ daylight savings time

Internal use: Document number F00481 revision 2 Replaces: F00481 version 1.0 July 2007

66. Time product ready for infusion or expansion (24-hour clock): ___ ___ : ___ ___ ☐ standard time

Hour Minute ☐ daylight savings time

67._____Was the primary container (e.g., cord blood unit bag) intact upon thawing?

☐ Yes

☐ No

68._____What method was used to thaw the product?

☐ Waterbath – ***Go to question 70***

☐ Electric warmer – ***Go to question 70***

☐ Other method – ***Go to question 69***

69._____Specify other method:
_____

70. Did any adverse events, incidents, or product complaints occur while preparing or thawing the product?

☐ Yes

☐ No

71. Was the product manipulated prior to infusion?

☐ Yes – ***Go to questions 72***

☐ No – ***If autologous product, go to question 109; if allogeneic product, go to question 158***

72._____Specify portion manipulated:

☐ Entire product

☐ Portion of product

Specify all methods used to manipulate the product:

73._____Washed

☐ Yes

☐ No

74._____Diluted

☐ Yes

☐ No

75. Buffy coat enriched (buffy coat preparation)

☐ Yes

☐ No

76. B cell reduced

☐ Yes

☐ No

77. CD8 reduced

☐ Yes

☐ No

78. Plasma reduced (removal)

☐ Yes

☐ No

79. RBC reduced

☐ Yes

☐ No

80._____Cultured (ex-vivo expansion)

☐ Yes

☐ No

81. Genetic manipulation (gene transfer / transduction)

☐ Yes

☐ No

82._____PUVA treated

☐ Yes

☐ No

83._____CD34 enriched (CD34+ selection)

☐ Yes

☐ No

84._____CD133 enriched

☐ Yes

☐ No

85._____Monocyte enriched

☐ Yes

☐ No

86._____Mononuclear cells enriched

☐ Yes

☐ No

87._____T-cell depletion

☐ Yes – ***Go to questions 88***

☐ No – ***Go to question 94***

Specify method:

88._____Antibody affinity column

☐ Yes – **Report the antibodies used for T-cell depletion at question 96**

☐ No

89._____Antibody coated plates

☐ Yes – **Report the antibodies used for T-cell depletion at question 96**

☐ No

90._____Antibody coated plates and soybean lectin

☐ Yes – **Report the antibodies used for T-cell depletion at question 96**

☐ No

91._____Antibody + toxin

☐ Yes – **Report the antibodies used for T-cell depletion at question 96**

☐ No

92._____Immunomagnetic beads

☐ Yes – **Report the antibodies used for T-cell depletion at question 96**

☐ No

93._____CD34 affinity column plus sheep red blood cell rosetting

☐ Yes

☐ No

94._____Other cell manipulation

☐ Yes – ***Go to question 93***

☐ No – ***Go to question 96***

95._____Specify other cell manipulation:
_____

96._____Were antibodies used during product manipulation?

☐ Yes – ***Go to questions 97***

☐ No – ***Go to question 109***

Specify antibodies:

97._____Anti CD2

☐ Yes

☐ No

98._____Anti CD3

☐ Yes

☐ No

99._____Anti CD4

☐ Yes

☐ No

100._____Anti CD5

☐ Yes

☐ No

101._____Anti CD6

☐ Yes

☐ No

102._____Anti CD7

☐ Yes

☐ No

103._____Anti CD8

☐ Yes

☐ No

104._____Anti CD19

☐ Yes

☐ No

105. α/β antibody

☐ Yes

☐ No

106._____Anti CD52 (Campath)

☐ Yes

☐ No

107._____Other antibody

☐ Yes – ***Go to question 108***

☐ No – ***Go to question 109***

108._____Specify other antibody: _____

Autologous Products Only

The following section refers to autologous products only, including autologous cord blood; if this is not an autologous HCT, continue with the Product Analysis section at question 158.

109. Were tumor cells detected in the recipient or autologous product prior to HCT?

☐ Yes – ***Go to question 110***

☐ No – ***Go to question 136***

Specify tumor cell detection method used and site(s) of tumor cells:

110. Routine histopathology

☐ Yes – ***Go to questions 111***

☐ No – ***Go to question 114***

Specify site(s):

111. Circulating blood cells

☐ Yes

☐ No

☐ Not done

112. Bone marrow (in the interval between last systemic therapy and collection)

- ☐ Yes
- ☐ No
- ☐ Not done

113. Collected cells (before purging)

- ☐ Yes
- ☐ No
- ☐ Not done

114. Polymerase chain reaction (PCR)

- ☐ Yes – ***Go to questions 115***
- ☐ No – ***Go to question 118***

Specify site(s):

115. Circulating blood cells

- ☐ Yes
- ☐ No
- ☐ Not done

116. Bone marrow (in the interval between last systemic therapy and collection)

- ☐ Yes
- ☐ No
- ☐ Not done

117. Collected cells (before purging)

- ☐ Yes
- ☐ No
- ☐ Not done

118. Other molecular technique

- ☐ Yes – ***Go to questions 119***
- ☐ No – ***Go to question 123***

119. Specify method:

Specify site(s):

120. Circulating blood cells

- ☐ Yes
- ☐ No
- ☐ Not done

121. Bone marrow (in the interval between last systemic therapy and collection)

- ☐ Yes
- ☐ No
- ☐ Not done

122. Collected cells (before purging)

- ☐ Yes
- ☐ No
- ☐ Not done

123. Immunohistochemistry

- ☐ Yes – ***Go to questions 124***
- ☐ No – ***Go to question 127***

Specify site(s):

124. Circulating blood cells

- ☐ Yes
- ☐ No
- ☐ Not done

125. Bone marrow (in the interval between last systemic therapy and collection)

- ☐ Yes
- ☐ No
- ☐ Not done

126. Collected cells (before purging)

- ☐ Yes
- ☐ No
- ☐ Not done

127. Cell culture technique

- ☐ Yes – ***Go to questions 128***
- ☐ No – ***Go to question 131***

Specify site(s):

128. Circulating blood cells

- ☐ Yes
- ☐ No
- ☐ Not done

129. Bone marrow (in the interval between last systemic therapy and collection)

- ☐ Yes
- ☐ No
- ☐ Not done

130. Collected cells (before purging)

- ☐ Yes
- ☐ No
- ☐ Not done

131. Other technique

- ☐ Yes – ***Go to questions 132***
- ☐ No – ***Go to question 136***

132. Specify:

Specify site(s):

133. Circulating blood cells

- ☐ Yes
- ☐ No
- ☐ Not done

134. Bone marrow (in the interval between last systemic therapy and collection)

- ☐ Yes
- ☐ No
- ☐ Not done

135. Collected cells (before purging)

☐ Yes

☐ No

☐ Not done

136. Was the product treated to remove malignant cells (purged)?

☐ Yes – ***Go to question 137***

☐ No – ***Go to question 158***

Specify method(s) used:

137._____Monoclonal antibody

☐ Yes – ***Go to question 138***

☐ No – ***Go to question 139***

138._____Specify monoclonal antibody:
_____

139._____4-hydroperoxycyclophosphamide (4HC)

☐ Yes

☐ No

140._____Mafosfamide

☐ Yes

☐ No

141._____Other drug

☐ Yes – ***Go to question 142***

☐ No – ***Go to question 143***

142._____Specify other drug:
_____

143._____Elutriation

☐ Yes

☐ No

144._____Immunomagnetic column

☐ Yes

☐ No

145._____Toxin

☐ Yes – ***Go to question 146***

☐ No – ***Go to question 147***

146._____Specify toxin:
_____

147. CD34 selection (other than preparation of mononuclear fraction)

☐ Yes – ***Go to question 148***

☐ No – ***Go to question 149***

148._____Specify method:
_____

149._____Other method

☐ Yes – ***Go to question 150***

☐ No – ***Go to question 151***

150._____Specify:
_____

Specify if tumor cells were detected in the graft after purging by each method used:

151._____Routine histopathology

☐ Yes

☐ No

☐ Not done

152._____Polymerase chain reaction (PCR)

☐ Yes

☐ No

☐ Not done

153._____Other molecular technique

☐ Yes

☐ No

☐ Not done

154._____Immunohistochemistry

☐ Yes

Internal use: Document number F00481 revision 2 Replaces: F00481 version 1.0 July 2007

☐ No

☐ Not done

155._____Cell culture technique

☐ Yes

☐ No

☐ Not done

156. Other

☐ Yes – ***Go to question 157***

☐ No – ***Go to question 158***

☐ Not done – ***Go to question 158***

157._____Specify:
_____

Product Analysis (All Products)

Product Analysis

158. Specify the timepoint in the product preparation phase that the product was analyzed:

☐ Product arrival

☐ Pre-cryopreservation

☐ Post-thaw

☐ At infusion (final quantity infused)

159. Date of product analysis: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

160. Total volume of product plus additives : ___ ___ ___ ___ • ___ ☐ mL
☐ g

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

161. Total nucleated cells (TNC) *(Includes nucleated red and nucleated white cells)*

☐ Done – ***Go to question 162***

☐ Not done – ***Go to question 163***

162. Total nucleated cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___

163. Nucleated white blood cells

☐ Done – ***Go to question 164***

☐ Not done – ***Go to question 165***

164. Total number of nucleated white blood cells: ___ ___ ___ ___ ● ___ ___ x 10 ___ ___

165. Mononuclear cells

☐ Done – ***Go to question 166***

☐ Not done – ***Go to question 167***

166. Total number of mononuclear cells: ___ ___ ___ ___ ● ___ ___ x 10 ___ ___

167. Nucleated red blood cells

☐ Done – ***Go to question 168***

☐ Not done – ***Go to question 169***

168. Total number of nucleated red blood cells: ___ ___ ___ ___ ● ___ ___ x 10 ___ ___

169. CD34+ cells

☐ Done – ***Go to question 170***

☐ Not done – ***Go to question 171***

170. Total number of CD34+ cells: ___ ___ ___ ___ ● ___ ___ x 10 ___ ___

171. CD3+ cells

☐ Done – ***Go to question 172***

☐ Not done – ***Go to question 173***

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

173. CD3+CD4+ cells

☐ Done – ***Go to question 174***

☐ Not done – ***Go to question 175***

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

175. CD3+CD8+ cells

☐ Done – ***Go to question 176***

☐ Not done – ***Go to question 177***

176. Total number of CD3+CD8+ cells: ___ ___ ___ ___ ● ___ ___ x 10 ___ ___

177. Viability of cells

☐ Done – ***Go to question 178***

☐ Not done – ***Go to question 181***

178. Viability of cells: ___ ___ ___ %

179. Method of testing cell viability:

☐ 7-AAD – ***Go to question 181***

☐ Propidium iodide – ***Go to question 181***

☐ Trypan blue – ***Go to question 181***

☐ Other method – ***Go to question 180***

180. Specify other method: _____

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

☐ Yes – ***Go to questions 182***

☐ No – ***Go to question 187***

182._____Was there growth?

☐ Yes

☐ No

183. Total CFU-GM

☐ Done – ***Go to question 184***

☐ Not done – ***Go to question 185***

184. Total CFU-GM: ___ ___ ___ ___ ● ___ x 10 ___ ___

185. Total BFU-E

☐ Done – ***Go to question 186***

☐ Not done – ***Go to question 187***

186. Total BFU-E: ___ ___ ___ ___ ● ___ x 10 ___ ___

187. Were cultures performed before infusion to test the product(s) for bacterial or fungal infection? *(complete for all cell products)*

☐ Yes – ***Go to questions 188***

☐ No – ***Go to question 196***

188. Specify results:

- ☐ Positive
- ☐ Negative
- ☐ Unknown

Specify organism code(s):

189._____ ___ ___

190._____ ___ ___

191._____ ___ ___

192._____ ___ ___

193._____ ___ ___

194._____ ___ ___

195._____Specify organism: _____

Copy questions 158 -195 to report multiple instances of Product Analysis

‡ The codes for "other organism, specify" (codes 198, 209, 219 and 259) should rarely be needed; check with your microbiology lab or HSCT physician before using them.

Codes for Commonly Reported Organisms

Bacterial Infections

121 Acinetobacter

122 Actinomyces

123 Bacillus

124 Bacteroides (gracillis, uniformis, vulgaris, other species)

125 Bordetella pertussis (whooping cough)

126 Borrelia (Lyme disease)

127 Branhamella or Moraxella catarrhalis (other species)

128 Campylobacter (all species)

129 Capnocytophaga

171 Chlamydia pneumoniae

172 Other chlamydia, specify

113 Chlamydia, NOS

130 Citrobacter (freundii, other species)

131 Clostridium (all species except difficile)

132 Clostridium difficile

173 Corynebacterium jeikeium

133 Corynebacterium (all nondiptheria species)

101 Coxiella

134 Enterobacter

177 Enterococcus, vancomycin resistant (VRE)

135 Enterococcus (all species)

136 Escherichia (also E. coli)

137 Flavimonas oryzihabitans

138 Flavobacterium

139 Fusobacterium

144 Haemophilus (all species, including influenzae)

145 Helicobacter pylori

146 Klebsiella

147 Lactobacillus (bulgaricus, acidophilus, other species)

102 Legionella

103 Leptospira

148 Leptotrichia buccalis

149 Leuconostoc (all species)

104 Listeria

150 Methylobacterium

151 Micrococcus, NOS

112 Mycobacterium avium–intracellulare (MAC, MAI)

174 Mycobacterium species (cheloneae, fortuitum, haemophilum, kansasii, mucogenicum

110 Mycobacterium tuberculosis (tuberculosis, Koch bacillus)

175 Other mycobacterium, specify

176 Mycobacterium, NOS

105 Mycoplasma

152 Neisseria (gonorrhoea, meningitidis, other species)

106 Nocardia

153 Pasteurella multocida

154 Propionibacterium (acnes, avidum, granulosum, other species)

155 Proteus

156 Pseudomonas (all species except cepacia & maltophilia)

157 Pseudomonas or Burkholderia cepacia

158 Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia

159 Rhodococcus

107 Rickettsia

160 Salmonella (all species)

161 Serratia marcescens

162 Shigella

163 Staphylococcus, coagulase negative (not aureus)

164 Staphylococcus aureus

165 Staphylococcus, NOS

166 Stomatococcus mucilaginosis

167 Streptococcus (all species except Enterococcus)

178 Streptococcus pneumoniae

168 Treponema (syphilis)

169 Vibrio (all species)

197 Multiple bacteria at a single site, specify bacterial codes

198 Other bacteria, specify ‡

501 Suspected atypical bacterial infection

502 Suspected bacterial infection

Fungal Infections

200 Candida, NOS

201 Candida albicans

206 Candida guillermondi

202 Candida krusei

207 Candida lusitaniae

203 Candida parapsilosis

204 Candida tropicalis

205 Candida (Torulopsis) glabrata

209 Other Candida, specify ‡

210 Aspergillus, NOS

211 Aspergillus flavus

212 Aspergillus fumigatus

213 Aspergillus niger

219 Other Aspergillus, specify ‡

220 Cryptococcus species

230 Fusarium species

261 Histoplasmosis

240 Zygomycetes, NOS

241 Mucormycosis

242 Rhizopus

250 Yeast, NOS

259 Other fungus, specify ‡

260 Pneumocystis (PCP / PJP)

503 Suspected fungal infection

Product Infusion

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

197. Was more than one product infused? (e.g., marrow and PBSC, PBSC and cord blood, two different cords, etc.)

☐ Yes – ***Go to question 198***

☐ No – ***Go to question 199***

198.___Was the product infusion described on this insert intended to produce hematopoietic engraftment?

☐ Yes

☐ No

199. Date infusion started: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

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

201. Date infusion stopped: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

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

203. Total volume of product plus additives intended for infusion: ___ ___ ___ ___ • ___ mL

204. Was the entire volume of product infused?

☐ Yes – ***Go to question 207***

☐ No – ***Go to question 205***

205. Specify what happened to the reserved portion:

☐ Discarded – ***Go to question 207***

☐ Cryopreserved for future use – ***Go to question 207***

☐ Other fate – ***Go to question 206***

206._____Specify other fate: _____

207. Specify the route of product infusion:

☐ Intravenous – ***Go to question 209***

☐ Intramedullary – ***Go to question 209***

☐ Intraperitoneal – ***Go to question 209***

☐ Other route of infusion – ***Go to question 208***

208._____Specify other route of infusion: _____

The following questions refer to all stem cell products except for autologous marrow or autologous PBSC products. If this HCT used an autologous marrow or autologous PBSC product, continue with the signature lines.

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

☐ Yes – ***Go to question 210***

☐ No – ***Go to question 250***

Specify the following adverse event(s):

210._____Brachycardia

☐ Yes – ***Go to question 211***

☐ No – ***Go to question 212***

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

☐ Yes

☐ No

212._____Chest tightness / pain

☐ Yes – ***Go to question 213***

☐ No – ***Go to question 214***

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

☐ Yes

☐ No

214._____Chills at time of infusion

☐ Yes – ***Go to question 215***

☐ No – ***Go to question 216***

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

☐ Yes

☐ No

216._____Fever ≤ 103° F within 24 hours of infusion

☐ Yes – ***Go to question 217***

☐ No – ***Go to question 218***

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

☐ Yes

☐ No

218._____Fever > 103° F within 24 hours of infusion

☐ Yes – ***Go to question 219***

☐ No – ***Go to question 220***

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

☐ Yes

☐ No

220._____Gross hemoglobinuria

☐ Yes – ***Go to question 221***

☐ No – ***Go to question 222***

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

☐ Yes

☐ No

222._____Headache

☐ Yes– ***Go to question 223***

☐ No – ***Go to question 224***

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

☐ Yes

☐ No

224._____Hives

☐ Yes – ***Go to question 225***

☐ No – ***Go to question 226***

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

☐ Yes

☐ No

226._____Hypertension

☐ Yes – ***Go to question 227***

☐ No – ***Go to question 228***

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

☐ Yes

☐ No

228._____Hypotension

☐ Yes – ***Go to question 229***

☐ No – ***Go to question 230***

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

☐ Yes

☐ No

230._____Hypoxia requiring oxygen (O_2) support

☐ Yes – ***Go to question 231***

☐ No – ***Go to question 232***

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

☐ Yes

☐ No

232._____Nausea

☐ Yes – ***Go to question 233***

☐ No – ***Go to question 234***

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

☐ Yes

☐ No

234._____Rigors, mild

☐ Yes – ***Go to question 235***

☐ No – ***Go to question 236***

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

☐ Yes

☐ No

236._____Rigors, severe

☐ Yes – ***Go to question 237***

☐ No – ***Go to question 238***

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

☐ Yes

☐ No

238._____Shortness of breath (SOB)

☐ Yes – ***Go to question 239***

☐ No – ***Go to question 240***

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

☐ Yes

☐ No

240._____Tachycardia

☐ Yes – ***Go to question 241***

☐ No – ***Go to question 242***

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

☐ Yes

☐ No

242._____Vomiting

☐ Yes – ***Go to question 243***

☐ No – ***Go to question 244***

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

☐ Yes

☐ No

244._____Other expected AE

☐ Yes – ***Go to questions 245***

☐ No – ***Go to question 247***

245._____Specify other expected AE:
_____

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

☐ Yes

☐ No

247._____Other unexpected AE

☐ Yes – ***Go to questions 248***

☐ No – ***Go to question 250***

248._____Specify other unexpected AE:
_____

249. 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 250–270) 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.

250. Was the donor ever pregnant?

☐ Yes – ***Go to question 251***

☐ No – ***Go to question 253***

☐ Unknown – ***Go to question 253***

☐ Not applicable (male donor or cord blood unit) – ***Go to question 253***

251. Number of pregnancies

☐ Known – ***Go to question 252***

☐ Unknown – ***Go to question 253***

252. Specify number of pregnancies: ___ ___

253. Specify blood type:

☐ A

☐ B

☐ AB

☐ O

254. Specify Rh factor:

☐ Positive

☐ Negative

255. Did this donor have a central line placed?

☐ Yes – ***Go to question 256***

☐ No – ***Go to question 258***

☐ Not applicable (cord blood unit or marrow product) – ***Go to question 258***

256._____Specify the site of the central line placement:

☐ Femoral ***– Go to question 258***

☐ Subclavian ***– Go to question 258***

☐ Internal jugular ***– Go to question 258***

☐ Other site ***– Go to question 257***

257._____Specify other site:
_____

258. Ethnicity (donor):

☐ Hispanic or Latino

☐ Not Hispanic nor Latino

☐ Unknown

259. Race: (donor)

Internal use: Document number F00481 revision 2 Replaces: F00481 version 1.0 July 2007

- ☐ White
- ☐ Black or African American
- ☐ Asian American Indian or Alaska Native
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Not reported
- ☐ Unknown

260. Race detail: (donor)

- ☐ 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 (both parents born in Africa)
- ☐ African American
- ☐ Black Caribbean
- ☐ Black South or Central American
- ☐ 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

Copy questions 259 – 260 to report more than one race.

261. What is the biological relationship of the donor to the recipient?

- ☐ Sibling – ***Go to question 264***
- ☐ Half-sibling – ***Go to question 264***
- ☐ Syngeneic (identical) twin – ***Go to question 264***
- ☐ Fraternal twin – ***Go to question 264***
- ☐ Recipient's child – ***Go to question 264***
- ☐ Other biological relative – ***Go to question 262***
- ☐ Unrelated – ***Go to question 264***

262._____Specify the biological relationship of the donor to the recipient:

- ☐ Mother – ***Go to question 264***
- ☐ Father – ***Go to question 264***
- ☐ Maternal aunt – ***Go to question 264***
- ☐ Maternal uncle – ***Go to question 264***
- ☐ Maternal cousin – ***Go to question 264***
- ☐ Paternal aunt – ***Go to question 264***
- ☐ Paternal uncle – ***Go to question 264***
- ☐ Paternal cousin – ***Go to question 264***
- ☐ Other biological relative – ***Go to question 263***

263._____Specify:
_____

264. Was the donor / product tested for potentially transplantable genetic diseases?

- ☐ Yes – ***Go to questions 265***
- ☐ No – ***If this is a related donor, go to question 272; all other donor types go to signature line***
- ☐ Unknown – ***If this is a related donor, go to question 272; all other donor types go to signature line***

Specify disease(s) tested:

265. Sickle cell anemia

- ☐ Yes – ***Go to question 266***
- ☐ No ***- Go to question 267***

266. Specify results:

- ☐ Positive
- ☐ Carrier of the trait
- ☐ Negative

267._____Thalassemia

- ☐ Yes - ***Go to question 268***
- ☐ No - ***Go to question 269***

268. Specify results:

- ☐ Positive
- ☐ Carrier of the trait
- ☐ Negative

269._____Other disease

- ☐ Yes – ***Go to question 270***
- ☐ No – ***If this is a related donor, go to question 272; all other donor types go to signature line***

270._____Specify other disease:
_____

271. Specify results:

- ☐ Positive
- ☐ Carrier of the trait
- ☐ Negative

The following questions (272–285) 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.

272. Was the donor hospitalized (inpatient) during or after the collection?

- ☐ Yes
- ☐ No

273. Did the donor experience any life-threatening complications during or after the collection?

- ☐ Yes – ***Go to question 274***
- ☐ No – ***Go to question 275***

274._____Specify:
_____

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275. Did the donor receive blood transfusions as a result of the collection?

☐ Yes – ***Go to question 276***

☐ No – ***Go to question 280***

276. Was the blood transfusion product autologous?

☐ Yes – ***Go to question 277***

☐ No – ***Go to question 278***

277._____Specify number of units: ___ ___

278._____Was the blood transfusion product allogeneic (homologous)?

☐ Yes – ***Go to question 279***

☐ No – ***Go to question 280***

279._____Specify number of units: ___ ___

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

☐ Yes – ***Go to question 281***

☐ No – ***Go to question 282***

281._____Specify cause of death:
_____

282. Did the recipient submit a research sample to the NMDP/CIBMTR repository? *(Related donors only)*

☐ Yes – ***Go to question 283***

☐ No – ***Go to question 284***

283._____Research sample recipient ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

284. Did the donor submit a research sample to the NMDP/CIBMTR repository? *(Related donors only)*

☐ Yes – ***Go to question 285***

☐ No – ***Go to signature line***

285._____Research sample donor ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

First Name: _____

Person completing form

Last Name: _____

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Recipient ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

E-mail address: _____

Date: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD