

Form 2006 R3.0: Hematopoietic Stem Cell Transplant (HSCT) Infusion

Center: _____

CRID: _____

Key Fields

OMB No: 0915-0310

Expiration Date: 12/31/2013

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Expiration date: 12/31/2013

Sequence Number: _____

Date Received: ____-____-____

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Specify donor:

- Autologous
- NMDP unrelated cord blood unit
- NMDP unrelated donor
- Related donor
- non-NMDP unrelated donor
- non-NMDP cord blood unit (include related and autologous CBUs)

NMDP cord blood unit ID: _____

NMDP Donor ID: _____

Donor's / infant's date of birth: ____-____-____

Donor's / infant's gender:

- male
- female

Non-NMDP unrelated donor / cord blood unit ID: *(not applicable for related donor)* _____

Registry or UCB Bank ID: _____

Specify other Registry or UCB Bank: _____

Is the CBU ID also the ICCBBA ISBT 128 number?

- yes
- no

Mother's age at donation: _____ age unknown

Today's Date: ____-____-____

Date of HSCT for which this form is being completed: ____-____-____

HSCT type:

(check only one)

- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- syngeneic (identical twin)

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Product type:

(check only one)

- marrow PBSC Cord blood other product

specify _____

Pre-Collection Therapy

Questions: 1 - 10

1 Did the donor receive treatment, prior to any stem cell harvest, to enhance the product collection for this HSCT? (If the HSCT product was from an NMDP donor, or the product is cord blood unit, then continue with question 20.)

- Yes No NMDP donor cord blood unit

Specify treatment(s): (select all that apply)

2 Chemotherapy (autologous only)

- yes - Report details on disease-specific insert
 no

3 Anti-CD20 (rituximab, Rituxan) (autologous only)

- yes - Report details on disease-specific insert
 no

4 Growth factor(s):

- yes no

If yes, specify growth factor(s):

5 G-CSF

- yes no

6 GM-CSF

- yes no

7 Other

- yes no

8 Specify: _____

9 Other treatment

- yes no

10 Specify treatment: _____

Product Collection

Questions: 11 - 19

11 Date of product collection: ____ - ____ - ____

12 Was more than one collection required for this HSCT?

- yes no

Complete a separate product form for each subsequent collection that was not part of this mobilization.

13 Specify the number of subsequent days of collection in this episode: _____

14 Were anticoagulants added to the product during collection?

- yes no

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Specify anticoagulant (s):

15 Acid citrate dextrose (ACD)

- yes no

16 Citrate phosphate dextrose (CPD)

- yes no

17 Heparin

- yes no

18 Other anticoagulant

- yes no

19 Specify: _____

Product Transport and Receipt

Questions: 20 - 30

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

- yes no

21 Date of receipt of product at your facility: ____ - ____ - ____

22 Time of receipt of product (24-hour clock): _____

- standard time
 daylight savings time

Specify the shipping environment of the product(s):

23 Specify the shipping environment of the product(s):

- Frozen gel pack
 frozen cord blood unit(s)
 Room temperature per transplant center request
 Other temperature

24 Specify shipping environment: _____

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

- yes no

26 Was the cord blood unit completely frozen when it arrived at your center? (Cord blood product only)

- yes no

27 Was the cord blood unit stored at your center prior to thawing? (Cord blood product only)

- yes no

28 Specify the storage method used for the cord blood unit:

- Liquid nitrogen Vapor phase Electric freezer

29 Temperature during storage: _____

30 Date storage started: ____ - ____ - ____

Product Processing / Manipulation

Questions: 31 - 91

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Center:

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31 Was a fresh product received, then cryopreserved at your facility prior to infusion?

- Yes
- No
- not applicable, cord blood unit

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

- yes
- no

33 Was the entire product thawed?

- yes
- no

34 Was a compartment of the bag thawed?

- yes
- no

35 Were there multiple product bags?

- yes
- no

36 Specify number of bags thawed: _____

37 Date thawing process initiated: ____ - ____ - ____

38 Time at initiation of thaw (24-hour clock): _____

- standard time
- daylight savings time

39 Time at completion of thaw (24-hour clock): _____

- standard time
- daylight savings time

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

- yes
- no

41 What method was used to thaw the product?

- no wash - thawed at bedside, then infused
- DMSO dilution - thawed in lab (added dextran and albumin), then infused
- washed - thawed in lab (added dextran and albumin), spun and reconstituted in dextran albumin, then infused
- Other method

42 Specify: _____

43 Did any adverse events or incidents occur while thawing the product?

- yes
- no

44 Was the product manipulated prior to the infusion?

- yes
- no

45 Specify portion manipulated:

- entire product
- portion of product

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Center:

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Specify all methods used to manipulate the product:

46 ABO incompatibility (RBC depletion)

yes no

Specify method:

47 Buffy coat preparation

yes no

48 Cell separator (i.e., COBE Spectra)

yes no

49 Density gradient separation (i.e., Ficoll)

yes no

50 Plasma removal

yes no

51 Sedimentation (i.e., hetastarch)

yes no

52 Other

yes no

53 Specify other method: _____

54 Ex-vivo expansion

yes no

55 Genetic manipulation (gene transfer / transduction)

yes no

56 Volume reduction

yes no

57 CD34+ selection

yes no

58 Specify manufacturer:

CliniMACS / CliniMax Isolex Other

59 Specify: _____

60 T-cell depletion

yes no

Specify method:

61 Antibody affinity column

yes - Report the antibodies used for T-cell depletion at question 73

no

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Center:

CRID:

62 Antibody coated plates

- yes - Report the antibodies used for T-cell depletion at question 73
- no

63 Antibody coated plates and soybean lectin

- yes - Report the antibodies used for T-cell depletion at question 73
- no

64 Antibody + complement

- yes - Report the antibodies used for T-cell depletion at question 73
- no

65 Antibody + toxin

- yes - Report the antibodies used for T-cell depletion at question 73
- no

66 Immunomagnetic beads

- yes - Report the antibodies used for T-cell depletion at question 73
- no

67 Elutriation

- yes
- no

68 CD34 affinity column plus sheep red blood cell rosetting

- yes
- no

69 Other

- yes
- no

70 Specify other method: _____

71 Other cell manipulation

- yes
- no

72 Specify: _____

73 Were antibodies used during product manipulation?

- yes
- no

Specify antibodies:

74 Anti CD2

- yes
- no

75 anti CD3

- yes
- no

76 Anti CD4

- yes
- no

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Center:

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77 anti CD5

yes no

78 anti CD6

yes no

79 anti CD7

yes no

80 anti CD8

yes no

81 anti CD34

yes no

82 Anti TCR alpha / beta (T10-B9)

yes no

83 OKT-3

yes no

84 other CD3

yes no

85 Specify: _____

86 anti CD52

yes no

Specify antibodies:

87 campath-NOS

yes no

88 campath-1G

yes no

89 campath-1H

yes no

90 other antibody

yes no

91 Specify: _____

Autologous Products Only

Questions: 92 - 140

The following section refers to autologous products only, including autologous cord blood; if this is not an autologous HSCT, continue with the Product Analysis section at question 141.

92 Were tumor cells detected in the recipient or autologous product prior to HSCT?

yes no

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Center:

CRID:

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

93 Routine histopathology

yes no

Specify site(s):

94 Circulating blood cells

yes no Not tested

95 Bone marrow, in the interval between last systemic therapy and collection

yes no Not tested

96 Collected cells, before purging

yes no Not tested

97 Polymerase chain reaction (PCR)

yes no

Specify site(s):

98 Circulating blood cells

yes no Not tested

99 Bone marrow, in the interval between last systemic therapy and collection

yes no Not tested

100 Collected cells, before purging

yes no Not tested

101 Other molecular technique

yes no

102 Specify method: _____

Specify site(s):

103 Circulating blood cells

yes no Not tested

104 Bone marrow, in the interval between last systemic therapy and collection

yes no Not tested

105 Collected cells, before purging

yes no Not tested

106 Immunohistochemistry

yes no

Specify site(s):

107 Circulating blood cells

yes no Not tested

108 Bone marrow, in the interval between last systemic therapy and collection

yes no Not tested

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Center: _____

CRID: _____

109 Collected cells, before purging

yes no Not tested

110 Cell culture technique

yes no

Specify site(s): _____

111 Circulating blood cells

yes no Not tested

112 Bone marrow, in the interval between last systemic therapy and collection

yes no Not tested

113 Collected cells, before purging

yes no Not tested

114 Other technique

yes no

115 Specify: _____

Specify site(s): _____

116 Circulating blood cells

yes no Not tested

117 Bone marrow, in the interval between last systemic therapy and collection

yes no Not tested

118 Collected cells before purging

yes no Not tested

119 Was the product treated to remove malignant cells (purged)? (*autologous product only*)

yes no

Specify method(s) used: _____

120 Monoclonal antibody

yes no

121 Specify: _____

122 4-hydroperoxycyclophosphamide (4HC)

yes no

123 Mafosfamide

yes no

124 Other drug

yes no

125 Specify: _____

126 Elutriation

yes no

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Center:

CRID:

127 Immunomagnetic column

- yes no

128 Toxin

- yes no

129 Specify: _____

130 Positive stem cell selection (other than preparation of mononuclear fraction)

- yes no

131 Specify method: _____

132 Other method

- yes no

133 Specify: _____

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

134 Routine histopathology

- yes no Not tested

135 Polymerase chain reaction (PCR)

- yes no Not tested

136 Other molecular technique

- yes no Not tested

137 Immunohistochemistry

- yes no Not tested

138 Cell culture technique

- yes no Not tested

139 Other

- yes no Not tested

140 If yes, specify: _____

Product Analysis (All Products)

Questions: 141 - 166

Product Analysis (1)

Questions: 141 - 166

141 Specify the time point in the product preparation phase that the product was analyzed:

- Product arrival
- post-processing, pre-cryopreservation / manipulation
- Post-thaw
- post-manipulation
- At infusion

142 Date of product analysis: ____ - ____ - ____

143 Total volume of product: _____ mL g

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Center: _____

CRID: _____

144 Total number of nucleated cells: _____ x 10 Exponent _____

Nucleated cells not tested

145 Total number of mononucleated cells: _____ x 10 Exponent _____

Mononucleated cells not tested

146 Total number of nucleated red blood cells: _____ x 10 Exponent _____

Nucleated red blood cells not tested

147 Total number of CD34+ cells: _____ x 10 Exponent _____

CD34+ cells not tested

148 Total number of CD3+ cells: _____ x 10 Exponent _____

CD3+ cells not tested

149 Total number of CD4+ cells: _____ x 10 Exponent _____

CD4+ cells not tested

150 Total number of CD8+ cells: _____ x 10 Exponent _____

CD8+ cells not tested

151 Viability of cells: _____ % Viability of cells not tested

152 Method of testing cell viability:

7-AAD Propidium iodide Trypan blue Other method

153 Specify other method: _____

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

yes no

155 Was there growth?

yes no

156 Total colonies per product: _____ x 10⁵ Total colonies per product unknown

157 Total CFU-GM: _____ x10⁵ Unknown

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

yes no

159 Specify results:

Positive Negative Unknown

Specify organism(s):

160 _____

161 _____

162 _____

163 _____

164 _____

165 _____

166 If codes 198, 209, 219, or 259, specify organism: _____

Product Infusion

Questions: 167 - 249

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Center: _____

CRID: _____

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

- yes no

168 Was the product infusion described on this insert intended to produce hematopoietic engraftment?

- yes no

169 Date of this product infusion: _____

170 Time product infusion initiated (24-hour clock): _____

- standard time
 daylight savings time

171 Time product infusion completed (24-hour clock): _____

- standard time
 daylight savings time

172 Total volume of product plus additives infused: _____

173 Specify the route of product infusion:

- intravenous
 intramedullary
 intraperitoneal
 other route of infusion

174 Specify: _____

175 Did the volume of infused product include any added agents?

- yes no

Specify agent(s) added:

176 ACD

- yes no

177 Albumin

- yes no

178 Antibiotic

- yes no

179 Dextran

- yes no

180 Heparin

- yes no

181 Other

- yes no

182 Specify agent: _____

183 Was the entire volume of product infused?

- yes no

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Center:

CRID:

184 Specify what happened to the reserved portion:

- discarded
- cryopreserved for future use
- other fate

185 Specify: _____

The following questions refer to all stem cell products except for autologous marrow and autologous PBSC products. If this HSCT used an autologous marrow or autologous PBSC product, continue with the signature lines at question 280.

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

- yes
- no

Specify the following adverse event(s):

187 Brachycardia

- yes
- no

188 Required medical intervention?

- yes
- no

189 Resolved?

- yes
- no

190 Chest tightness / pain

- yes
- no

191 Required medical intervention?

- yes
- no

192 Resolved?

- yes
- no

193 Chills at time of infusion

- yes
- no

194 Required medical intervention?

- yes
- no

195 Resolved?

- yes
- no

196 Fever $\leq 103^\circ$ F within 24 hours of infusion

- yes
- no

197 Required medical intervention?

- yes
- no

198 Resolved?

- yes
- no

199 Fever $> 103^\circ$ F within 24 hours of infusion

- yes
- no

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Center:

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200 Required medical intervention?

yes no

201 Resolved?

yes no

202 Gross hemoglobinuria

yes no

203 Required medical intervention?

yes no

204 Resolved?

yes no

205 Headache

yes no

206 Required medical intervention?

yes no

207 Resolved?

yes no

208 Hives

yes no

209 Required medical intervention?

yes no

210 Resolved?

yes no

211 Hypertension

yes no

212 Required medical intervention?

yes no

213 Resolved?

yes no

214 Hypotension

yes no

215 Required medical intervention?

yes no

216 Resolved?

yes no

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Center:

CRID:

217 Hypoxia requiring oxygen (O₂) support

yes no

218 Required medical intervention?

yes no

219 Resolved?

yes no

220 Nausea

yes no

221 Required medical intervention?

yes no

222 Resolved?

yes no

223 Rigors, mild

yes no

224 Required medical intervention?

yes no

225 Resolved?

yes no

226 Rigors, severe

yes no

227 Required medical intervention?

yes no

228 Resolved?

yes no

229 Shortness of breath (SOB)

yes no

230 Required medical intervention?

yes no

231 Resolved?

yes no

232 Tachycardia

yes no

233 Required medical intervention?

yes no

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Center:

CRID:

234 Resolved?

yes no

235 Vomiting

yes no

236 Required medical intervention?

yes no

237 Resolved?

yes no

238 Other expected AE

yes no

239 Specify: _____

240 Required medical intervention?

yes no

241 Resolved?

yes no

242 Other unexpected AE

yes no

243 Specify: _____

244 Required medical intervention?

yes no

245 Resolved?

yes no

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

yes no

247 Specify the most likely cause of the adverse event:

regimen related product reaction drug reaction other illness other reason

248 Specify illness: _____

249 Specify reason: _____

Donor / Infant Demographic Information

Questions: 250 - 280

The Donor Demographic Information section (questions 250-265) is to be completed for all non-NMDP allogeneic donors. If the stem cell product was from an NMDP donor or an autologous marrow or PBSC donor, continue with the signature lines at question 280.

250 (Female donor only) Was the donor ever pregnant?

- Yes
- No
- Unknown
- not applicable / cord blood unit

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Center: _____

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251 Specify number of pregnancies: _____ Number of pregnancies unknown

252 Donor's blood type and Rh factor:

- A positive A negative B positive B negative AB positive AB negative O positive O negative Unknown

253 Did this donor have a central line placed?

- Yes
 No
 not applicable, cord blood unit or marrow product

254 Specify the site of the central line placement:

- femoral subclavian internal jugular Other site

255 Specify site: _____

256 Donor's ethnicity:

- Hispanic or Latino
 not Hispanic nor Latino
 Unknown

Donor Race (1)

Questions: 257 - 257

257 Donor's race: (Mark the group(s) in which the donor is a member. Check all that apply.) _____

258 What is the relationship of the donor to the recipient?

- sibling recipient's child other relative Unrelated

259 Specify the relationship of the donor to the recipient:

- parent aunt uncle cousin other relative

260 Specify: _____

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

- yes no Unknown

Specify disease(s) tested:

262 Sickle cell anemia

- yes no

263 Thalassemia

- yes no

264 Other

- yes no

265 Specify: _____

The following questions 266-279 apply only to allogeneic non-NMDP donors. If the stem cell product was from an autologous donor or NMDP donor, or was a cord blood unit, then continue with the signature lines at question 280.

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

- yes no

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Center: _____

CRID: _____

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

yes no

268 Specify: _____

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

yes no

270 Was the blood transfusion product autologous?

yes no

271 Specify number of units: _____

272 Was the blood transfusion product allogeneic (homologous)?

yes no

273 Specify number of units: _____

274 Did the donor die as a result of the collection?

yes no

275 Specify cause of death: _____

276 Did the recipient submit a research sample? (Related donors only)

yes no

277 Research sample recipient ID: _____

278 Did the donor submit a research sample? (Related donors only)

yes no

279 Research sample donor ID: _____

280 First Name: _____

Last Name: _____

Fax number: _____

Phone number: _____

E-mail address: _____