ERROR CORRECTION FORM

Sequence Number: | CIBMTR Recipient ID: | Initials:

Today's Date: Month Day 20 Year | Infusion Date: Month Day 20 Year | CIBMTR Center Number:

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

Center: CRID:

Key Fields

OMB No: 0915-0310

Expiration Date: 12/31/2013

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0310. Public reporting burden for this collection of information, in combination with the IDM Form 2004 and HLA Typing Form 2005, is estimated to average 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10-33, Rockville, Maryland, 20857.

Expiration date: 12/31/2013

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Specify donor:

- ○ Autologous
- ○ NMDP unrelatedcord blood unit
- ○ NMDP unrelateddonor
- ○ Related donor
- ○ non-NMDPunrelated donor
- ○ non-NMDP cord bloodunit (include relatedand 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: __ __ __ __ - __ __- __ __

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HSCT type:
(check only one)

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

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: _____

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Center: CRID:

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 seperate 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

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

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Center: CRID:

Specify the shipping enviroment 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

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: _____

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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

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

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Center: CRID:

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

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

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

Center: CRID:

---

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

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**

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Center: CRID:

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

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 betweenlast 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 betweenlast 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 betweenlast systemic therapy and collection

○ yes ○ no ○ Not tested

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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 betweenlast systemic therapy and collection

yes no Not tested

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 betweenlast 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 betweenlast systemic therapy and collection

yes no Not tested

118 Collected cells before purging

yes no Not tested

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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

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

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

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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 10^5 ☐ Total colonies per product unknown

157 Total CFU-GM: _____ x10^5 ☐ 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

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: __ __ __ __ - __ __- __ __

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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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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 <= 103° F within 24 hours of infusion

○ yes ○ no

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197 Required medical intervention?

○ yes ○ no

198 Resolved?

○ yes ○ no

199 Fever > 103° F within 24 hours of infusion

○ yes ○ no

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

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212 Required medical intervention?

○ yes ○ no

213 Resolved?

○ yes ○ no

214 Hypotension

○ yes ○ no

215 Required medical intervention?

○ yes ○ no

216 Resolved?

○ yes ○ no

217 Hypoxia requiring oxygen (O^2) 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

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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

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

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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 allogeneneic 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

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: _____

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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

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

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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: _____

Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org.
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