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 R4.0: Hematopoietic Cellular Transplant (HCT) Infusion

Center: CRID:

Key Fields

OMB No: 0915-0310

Expiration Date: 1/31/2020

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 is estimated to average 1.0 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 10-29, Rockville, Maryland, 20857.

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Date of HCT for which this form is being completed: __ __ __ __ - __ __- __ __

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: _____

Donor/Cord Blood Unit Identification

Questions: 1 - 15

1 Specify donor

- Autologous
- Autologous cord blood unit
- NMDP unrelated cord blood unit
- NMDP unrelated donor
- Related donor
- Related cord blood unit
- Non-NMDP unrelated donor
- Non-NMDP unrelated cord blood unit

2 NMDP cord blood unit ID: _____

3 NMDP donor ID: _____

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

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

6 Is the CBU ID also the ISBT DIN number?

yes no

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 Unknown

11 Date of birth: __ __ __ __ - __ __- __ __
(donor/infant)

12 Age
(donor/infant)

Known Unknown

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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
- no

Pre-Collection Therapy — Questions: 16 - 27

16 Did the donor receive therapy, prior to any stem cell harvest, to enhance the product collection for this HCT?
- yes
- no

17 Growth and mobilizing factor(s)
- yes
- no

18 G-CSF
- yes
- no

19 Pegylated G-CSF
- yes
- no

20 GM-CSF
- yes
- no

21 Plerixafor (Mozobil)
- yes
- no

22 Other growth or mobilizing factor
- yes
- no

23 Specify other growth or mobilizing factor: _____

24 Systemic therapy (chemotherapy) (autologous only)
- yes
- no

25 Anti-CD20 (rituximab, Rituxan) (autologous only)
- yes
- no

26 Other therapy
- yes
- no

27 Specify other therapy: _____

Product Collection — Questions: 28 - 42

28 Date of first collection for this mobilization: __ __ __ __ - __ __- __ __

29 Was more than one collection required for this HCT?
- yes
- no

Complete a separate CIBMTR form 2006 – HCT Infusion 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
- no

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
- no

36 Specify other anticoagulant: _____

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37 Were anticoagulants added to the product before freezing?
yes no

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 no

42 Specify other anticoagulant: _____

Product Transport and Receipt

Questions: 43 - 56

43 Was this product collected off-site and shipped to your facility?
yes no

44 Date of receipt of product at your facility: __ __ __ __ - __ __- __ __

45 Time of receipt of product (24-hour clock): _____
standard time
daylight savings time

46 Specify the shipping environment of the product(s)
Frozen gel pack (refrigerator temperature)
Frozen cord blood unit(s)
Room temperature per transplant center request
Other shipping environment

47 Specify other shipping environment: _____

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?
yes no

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: __ __ __ __ - __ __- __ __

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 Not done

56 Total number of CD34+ cells: _____ x 10 _____

Product Processing / Manipulation

Questions: 57 - 108

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Center: CRID:

57 Was a fresh product received (e.g. not frozen)?
(NMDP products only)
- Yes
- No
- not applicable, cord blood unit

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 no

60 Was the entire product thawed?
yes no

61 Was only a compartment of the bag thawed?
(Cord blood units only)
yes no

62 Were there multiple product bags?
yes no

63 Specify number of bags thawed: _____

64 Date thawing process initiated: __ __ __ __ - __ __- __ __

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

66 Time product ready for infusion or expansion (24-hour clock): _____
- standard time
- 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 Electric warmer Other method

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 no

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

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Center: CRID:

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 no

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 no

95 Specify other cell manipulation: _____

96 Were antibodies used during product manipulation?
yes no

Specify antibodies:

97 Anti CD2
yes no

98 Anti CD3
yes no

99 Anti CD4
yes no

100 Anti CD5
yes no

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Center: CRID:

101 Anti CD6
yes no

102 Anti CD7
yes no

103 Anti CD8
yes no

104 Anti CD19
yes no

105 a/ß antibody
yes no

106 Anti CD52
(Campath)
yes no

107 Other antibody
yes no

108 Specify other antibody: _____

Autologous Products Only

Questions: 109 - 157

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 no

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

110 Routine histopathology
yes no

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 no

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 no

119 Specify method: _____

Specify site(s):

120 Circulating blood cells
Yes No Not done

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Center: CRID:

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 no

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 no

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 no

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 no

Specify method(s) used:

137 Monoclonal antibody
yes no

138 Specify monoclonal antibody: _____

139 4-hydroperoxycyclophosphamide (4HC)
yes no

140 Mafosfamide
yes no

141 Other drug
yes no

142 Specify other drug: _____

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Center: CRID:

143 Elutriation
yes no

144 Immunomagnetic column
yes no

145 Toxin
yes no

146 Specify toxin: _____

147 CD34 selection
(other than preparation of mononuclear fraction)
yes no

148 Specify method: _____

149 Other method
yes no

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 No Not done

155 Cell culture technique
Yes No Not done

156 Other
Yes No Not done

157 Specify: _____

Product Analysis (All Products) — Questions: 158 - 195

Product Analysis (1) — Questions: 158 - 195

158 Specify the timepoint in the product preparation phase that the product was analyzed
Product arrival Pre-cryopreservation Post-thaw At infusion

159 Date of product analysis: __ __ __ __ - __ __- __ __

160 Total volume of product plus additives: _____ mL

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 Not done

162 Total nucleated cells: _____ x 10 _____

163 Nucleated white blood cells
Done Not done

164 Total number of nucleated white blood cells: _____ x 10 _____

165 Mononuclear cells
Done Not done

166 Total number of mononuclear cells: _____ x 10 _____

167 Nucleated red blood cells
Done Not done

168 Total number of nucleated red blood cells: _____ x 10 _____

169 CD34+ cells
Done Not done

170 Total number of CD34+ cells: _____ x 10 _____

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171 CD3+ cells
- Done - Not done

172 Total number of CD3+ cells: _____ x 10 _____

173 CD3+CD4+ cells
- Done - Not done

174 Total number of CD3+CD4+ cells: _____ x 10 _____

175 CD3+CD8+ cells
- Done - Not done

176 Total number of CD3+CD8+ cells: _____ x 10 _____

177 Viability of cells
- Done - Not done

178 Viability of cells: _____ %

179 Method of testing cell viability
- 7-AAD - Propidium iodide - Trypan blue - Other method

180 Specify other method: _____

181 Were the colony-forming units (CFU) assessed after thawing?
(Cord blood units only)
- yes - no

182 Was there growth?
- yes - no

183 Total CFU-GM
- Done - Not done

184 Total CFU-GM: _____ x 10 _____

185 Total BFU-E
- Done - Not done

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 - no

188 Specify results
- Positive - Negative - Unknown

Specify organism(s):

189 _____

190 _____

191 _____

192 _____

193 _____

194 _____

195 Specify organism: _____

Product Infusion

Questions: 196 - 249

196 Date of this product infusion: __ __ __ __ - __ __- __ __

197 Was more than one product infused?
(e.g., marrow and PBSC, PBSC and cord blood, two different cords, etc.)
- yes - no

198 Was the product infusion described on this insert intended to produce hematopoietic engraftment?
- yes - no

199 Date infusion started: __ __ __ __ - __ __- __ __

200 Time product infusion initiated (24-hour clock): _____
- standard time
- daylight savings time

201 Date infusion stopped: __ __ __ __ - __ __- __ __

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202 Time product infusion completed (24-hour clock): _____
- standard time
- daylight savings time

203 Total volume of product plus additives intended for infusion: _____ mL

204 Was the entire volume of product infused?
- yes
- no

205 Specify what happened to the reserved portion
- discarded
- cryopreserved for future use
- other fate

206 Specify other fate: _____

207 Specify the route of product infusion
- intravenous
- intramedullary
- intraperitoneal
- other route of infusion

208 Specify other route of infusion: _____

The following questions refer to all stem cell products except for autologous marrow and 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
- no

Specify the following adverse event(s):

210 Brachycardia
- yes
- no

211 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
- yes
- no

212 Chest tightness / pain
- yes
- no

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
- no

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
- no

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
- no

219 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
- yes
- no

220 Gross hemoglobinuria
- yes
- no

221 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
- yes
- no

222 Headache
- yes
- no

223 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
- yes
- no

224 Hives
- yes
- no

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225 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
yes no

226 Hypertension
yes no

227 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
yes no

228 Hypotension
yes no

229 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
yes no

230 Hypoxia requiring oxygen (O2) support
yes no

231 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
yes no

232 Nausea
yes no

233 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
yes no

234 Rigors, mild
yes no

235 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
yes no

236 Rigors, severe
yes no

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 no

239 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
yes no

240 Tachycardia
yes no

241 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
yes no

242 Vomiting
yes no

243 In the Medical Director's judgment, was the adverse event a direct result of the infusion?
yes no

244 Other expected AE
yes no

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 no

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

Questions: 250 - 285

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The Donor Demographic Information section (questions 250-270) is to be completed for all non-NMDP allogeneneic 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
- No
- Unknown
- Not applicable (male donor or cord blood unit)

251 Number of pregnancies

Known Unknown

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
- No
- Not applicable (cord blood unit or marrow product)

256 Specify the site of the central line placement

femoral subclavian internal jugular Other site

257 Specify other site: _____

258 Ethnicity (donor)

- Hispanic or Latino
- Not Hispanic or Latino
- Not applicable (not a resident of the USA)
- Unknown

Race (1) **Questions: 259 - 260**

259 Race _____ (donor)

260 Race detail _____ (donor)

261 What is the biological relationship of the donor to the patient? _____

262 Specify the biological relationship of the donor to the recipient _____

263 Specify: _____

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

yes no Unknown

Specify disease(s) tested:

265 Sickle cell anemia

yes no

266 Specify results

Positive Carrier of the trait Negative

267 Thalassemia

yes no

268 Specify results

Positive Carrier of the trait Negative

269 Other disease

yes no

270 Specify other disease: _____

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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 ○ no

274 Specify: _____

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

○ yes ○ no

276 Was the blood transfusion product autologous?

○ yes ○ no

277 Specify number of units: _____

278 Was the blood transfusion product allogeneic (homologous)?

○ yes ○ no

279 Specify number of units: _____

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

○ yes ○ no

281 Specify cause of death: _____

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

○ yes ○ no

283 Research sample recipient ID: _____

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

○ yes ○ no

285 Research sample donor ID: _____

First Name: _____

Last Name: _____

E-mail address: _____

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

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