

ERROR CORRECTION FORM

Sequence Number:

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CIBMTR Recipient ID:

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Initials:

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Today's Date:

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Month	Day	Year			

Infusion Date:

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Month	Day	Year			

CIBMTR Center Number:

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Hematopoietic Stem Cell Transplant (HSCT) Infusion

Registry Use Only

Sequence Number:

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Date Received:

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OMB No: 0915-0310
Expiration Date: 10/31/2010

CIBMTR Recipient ID:

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Donor ID:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

NMDP Cord Blood Unit ID:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Non-NMDP cord blood unit *

* For non-NMDP cords, see page 11 to report CBU ID and donor demographics.

Today's Date:

				2	0		
Month	Day	Year					

Date of HSCT for which this form is being completed:

				2	0		
Month	Day	Year					

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: _____
 multiple cord blood units infused

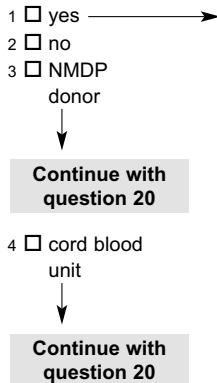
Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0310. Public reporting burden for this collection of information, 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.

This form must be completed for all recipients who receive a HSCT product. If more than one type of HSCT product is infused, each product type must be analyzed and reported separately. Questions followed by the symbol indicate additional information necessary to complete the question is referenced in the forms instruction manual; A indicates an appendix.

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.

Pre-Collection Therapy

- 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 a cord blood unit, then continue with question 20.)



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

2. 1 yes 2 no (autologous only)
Chemotherapy → **Report details on disease-specific insert**

3. 1 yes 2 no (autologous only)
Anti-CD20 (rituximab, Rituxan) → **Report details on disease-specific insert**

4. 1 yes 2 no Growth factor(s) →

If yes, specify growth factor(s):

5. 1 yes 2 no G-CSF

6. 1 yes 2 no GM-CSF

7. 1 yes 2 no Other → 8. Specify: _____

9. 1 yes 2 no Other treatment → 10. Specify treatment: _____

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Today's Date:

Month Day

2 0
Year

Infusion Date:

Month Day

2 0
Year

CIBMTR Center Number:

CIBMTR Center Number:

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Product Collection

11. Date of product collection:

Month Day

2 0
Year

12. Was more than one collection required for this HSCT?

- 1 yes
2 no

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

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

14. Were anticoagulants added to the product during collection?

- 1 yes
2 no

Specify anticoagulant(s):

15. Acid citrate dextrose (ACD)

- 1 yes
2 no

16. Citrate phosphate dextrose (CPD)

- 1 yes
2 no

17. Heparin

- 1 yes
2 no

18. Other anticoagulant

- 1 yes
2 no

19. Specify other anticoagulant: _____

Product Transport and Receipt

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

- 1 yes
2 no

21. Date of receipt of product at your facility:

Month Day

2 0
Year

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

Hour Minute
:
1 standard time
2 daylight savings time

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

- 1 frozen gel pack
2 frozen cord blood unit(s)
3 room temperature per transplant center request
4 other
temperature

24. Specify shipping environment: _____

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

- 1 yes
2 no

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Month	Day	Year			

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Month	Day	Year			

CIBMTR Center Number:

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

- 1 yes
2 no

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

- 1 yes
2 no

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

- 1 liquid nitrogen
2 vapor phase
3 electric freezer

29. Temperature during storage: —

--	--	--	--

 ° C

30. Date storage started:

				2	0		
Month	Day	Year					

Product Processing / Manipulation

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

- 1 yes
2 no
3 not applicable, cord blood unit

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

- 1 yes
2 no

33. Was the entire product thawed?

- 1 yes
2 no

34. Was a compartment of the bag thawed?

- 1 yes
2 no

35. Were there multiple product bags?

- 1 yes
2 no

36. Specify number of bags thawed:

--	--

37. Date thawing process initiated:

		2	0		
Month	Day	Year			

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

		:			1 <input type="checkbox"/> standard time 2 <input type="checkbox"/> daylight savings time
Hour	Minute				

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

		:			1 <input type="checkbox"/> standard time 2 <input type="checkbox"/> daylight savings time
Hour	Minute				

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

- 1 yes
2 no

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Month	Day	Year					

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41. What method was used to thaw the product?

- 1 no wash — thawed at bedside, then infused
- 2 DMSO dilution — thawed in lab (added dextran and albumin), then infused
- 3 washed — thawed in lab (added dextran and albumin), spun and reconstituted in dextran albumin, then infused
- 4 other method → 42. Specify other thaw method: _____

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

- 1 yes
- 2 no

44. Was the product manipulated prior to infusion?

- 1 yes →
- 2 no

If autologous product, continue with question 92; if allogeneic product, continue with question 141.

45. Specify portion manipulated:

- 1 entire product
- 2 portion of product

Specify all methods used to manipulate the product:

46. ABO incompatibility (RBC depletion)

- 1 yes →
- 2 no

Specify method:

- 47. 1 yes 2 no Buffy coat preparation
- 48. 1 yes 2 no Cell separator (i.e., COBE Spectra)
- 49. 1 yes 2 no Density gradient separation (i.e., Ficoll)
- 50. 1 yes 2 no Plasma removal
- 51. 1 yes 2 no Sedimentation (i.e., hetastarch)
- 52. 1 yes 2 no Other → 53. Specify: _____

54. Ex-vivo expansion

- 1 yes
- 2 no

55. Genetic manipulation (gene transfer / transduction)

- 1 yes
- 2 no

56. Volume reduction

- 1 yes
- 2 no

57. CD34+ selection

- 1 yes →
- 2 no

58. Specify cell selection system used:

- 1 CliniMACS / CliniMax
- 2 Isolex
- 3 other → 59. Specify system: _____

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

- 1 yes
2 no

Specify method(s) used:

120. 1 yes 2 no Monoclonal antibody →

121. If yes, specify: _____

122. 1 yes 2 no 4-hydroperoxycyclophosphamide (4HC)

123. 1 yes 2 no Mafosfamide

124. 1 yes 2 no Other drug →

125. If yes, specify: _____

126. 1 yes 2 no Elutriation

127. 1 yes 2 no Immunomagnetic column

128. 1 yes 2 no Toxin →

129. If yes, specify: _____

130. 1 yes 2 no Positive stem cell selection (other than preparation of mononuclear fraction) →

131. If yes, specify method: _____

132. 1 yes 2 no Other method →

133. If yes, specify: _____

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

134. 1 yes 2 no 3 not tested Routine histopathology

135. 1 yes 2 no 3 not tested Polymerase chain reaction (PCR)

136. 1 yes 2 no 3 not tested Other molecular technique

137. 1 yes 2 no 3 not tested Immunohistochemistry

138. 1 yes 2 no 3 not tested Cell culture technique

139. 1 yes 2 no 3 not tested Other →

140. If yes, specify: _____

Product Analysis (All Products)

Report product analysis results under each timepoint that testing was performed. If more than two analyses were performed, copy and complete pages 7–8 for each additional analysis.

Product Analysis at 1st Timepoint

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

141. 1 product arrival
2 post-processing, pre-cryopreservation / manipulation
3 post-thaw
4 post-manipulation
5 at infusion (final quantity infused)

Date of product analysis: 142.

		2	0
--	--	---	---

Month Day Year

Total volume of product: 143.

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 1 mL
2 g

Product Analysis at 2nd Timepoint

142. 1 product arrival
2 post-processing, pre-cryopreservation / manipulation
3 post-thaw
4 post-manipulation
5 at infusion (final quantity infused)

143.

		2	0
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Month Day Year

144.

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 1 mL
2 g

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Codes for Commonly Reported Organisms			
Bacterial Infections	139 Fusobacterium	155 Proteus	Fungal Infections
121 Acinetobacter	144 Haemophilus (all species, including influenzae)	156 Pseudomonas (all species except cepacia & maltophilia)	200 Candida, NOS
122 Actinomyces	145 Helicobacter pylori	157 Pseudomonas or Burkholderia cepacia	201 Candida albicans
123 Bacillus	146 Klebsiella	158 Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia	206 Candida guilliermondii
124 Bacteroides (gracillis, uniformis, vulgaris, other species)	147 Lactobacillus (bulgaricus, acidophilus, other species)	159 Rhodococcus	202 Candida krusei
125 Bordetella pertussis (whooping cough)	102 Legionella	107 Rickettsia	207 Candida lusitanae
126 Borrelia (Lyme disease)	103 Leptospira	160 Salmonella (all species)	203 Candida parapsilosis
127 Branhamella or Moraxella catarrhalis (other species)	148 Leptotrichia buccalis	161 Serratia marcescens	204 Candida tropicalis
128 Campylobacter (all species)	149 Leuconostoc (all species)	162 Shigella	205 Candida (Torulopsis) glabrata
129 Capnocytophaga	104 Listeria	163 Staphylococcus, coagulase negative (not aureus)	209 Other Candida, specify ‡
171 Chlamydia pneumoniae	150 Methylobacterium	164 Staphylococcus aureus	210 Aspergillus, NOS
172 Other chlamydia, specify	151 Micrococcus, NOS	165 Staphylococcus, NOS	211 Aspergillus flavus
113 Chlamydia, NOS	112 Mycobacterium avium-intracellulare (MAC, MAI)	166 Stomatococcus mucilaginosus	212 Aspergillus fumigatus
130 Citrobacter (freundii, other species)	174 Mycobacterium species (cheloneae, fortuitum, haemophilum, kansasii, mucogenicum)	167 Streptococcus (all species except Enterococcus)	213 Aspergillus niger
131 Clostridium (all species except difficile)	110 Mycobacterium tuberculosis (tuberculosis, Koch bacillus)	178 Streptococcus pneumoniae	219 Other Aspergillus, specify ‡
132 Clostridium difficile	175 Other mycobacterium, specify	168 Treponema (syphilis)	220 Cryptococcus species
173 Corynebacterium jeikeium	176 Mycobacterium, NOS	169 Vibrio (all species)	230 Fusarium species
133 Corynebacterium (all non-diphtheria species)	105 Mycoplasma	197 Multiple bacteria at a single site, specify bacterial codes	261 Histoplasmosis
101 Coxiella	152 Neisseria (gonorrhoea, meningitidis, other species)	198 Other bacteria, specify ‡	240 Zygomycetes, NOS
134 Enterobacter	106 Nocardia	501 Suspected atypical bacterial infection	241 Mucormycosis
177 Enterococcus, vancomycin resistant (VRE)	153 Pasteurella multocida	502 Suspected bacterial infection	242 Rhizopus
135 Enterococcus (all species)	154 Propionibacterium (acnes, avidum, granulosum, other species)		250 Yeast, NOS
136 Escherichia (also E. coli)			259 Other fungus, specify ‡
137 Flavimonas oryzihabitans			260 Pneumocystis (PCP / PJP)
138 Flavobacterium			503 Suspected fungal infection

‡ 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.

Product Infusion

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

- 1 yes
2 no

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

- 1 yes
2 no

185. Date of this product infusion:

		2	0		
Month	Day	Year			

186. Time product infusion initiated (24-hour clock):

		:		
Hour	Minute			

- 1 standard time
2 daylight savings time

187. Time product infusion completed (24-hour clock):

		:		
Hour	Minute			

- 1 standard time
2 daylight savings time

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188. Total volume of product plus additives infused:

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 .

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 mL

189. Specify the route of product infusion:

- 1 intravenous
- 2 intramedullary
- 3 intraperitoneal
- 4 other route of infusion →

190. Specify route of infusion: _____

191. Did the volume of infused product include any added agents?

- 1 yes →
- 2 no

Specify agent(s) added:

- 192. 1 yes 2 no ACD
- 193. 1 yes 2 no Albumin
- 194. 1 yes 2 no Antibiotic
- 195. 1 yes 2 no Dextran
- 196. 1 yes 2 no Heparin
- 197. 1 yes 2 no Other →

198. Specify agent: _____

199. Was the entire volume of product infused?

- 1 yes →
- 2 no

200. Specify what happened to the reserved portion:

- 1 discarded
- 2 cryopreserved for future use
- 3 other fate →

201. Specify: _____

The following questions refer to all stem cell products except for autologous marrow or autologous PBSC products. If this HSCT used an autologous marrow or autologous PBSC product, continue with question 298.

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

- 1 yes →
- 2 no

Specify the following adverse event(s):

	Adverse Event	Required Medical Intervention?	Resolved?
203. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Brachycardia	204. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	205. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
206. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Chest tightness / pain	207. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	208. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
209. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Chills at time of infusion	210. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	211. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
212. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Fever ≤ 103° F within 24 hours of infusion	213. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	214. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
215. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Fever > 103° F within 24 hours of infusion	216. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	217. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
218. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Gross hemoglobinuria	219. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	220. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
221. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Headache	222. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	223. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
224. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Hives	225. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	226. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
227. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Hypertension	228. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	229. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
230. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Hypotension	231. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	232. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
233. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Hypoxia requiring oxygen (O ₂) support	234. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	235. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
236. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Nausea	237. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	238. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
239. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Rigors, mild	240. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	241. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no
242. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	Rigors, severe	243. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	244. 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no

CIBMTR Form 2006 (INF) v1.0 (10-13) July 2007
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Fax this form to your designated campus (Milwaukee 414-456-6165 or Minneapolis 612-627-5895).

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Month	Day	Year								

Infusion Date:

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Month	Day	Year								

CIBMTR Center Number:

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CIBMTR Center Number:

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CIBMTR Recipient ID:

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274. Donor's blood type and Rh factor:

- 1 A positive
- 2 A negative
- 3 B positive
- 4 B negative
- 5 AB positive
- 6 AB negative
- 7 O positive
- 8 O negative
- 9 unknown

275. Did this donor have a central line placed?

- 1 yes →
- 2 no
- 3 not applicable, cord blood unit or marrow product

276. Specify the site of the central line placement:

- 1 femoral
- 2 subclavian
- 3 internal jugular
- 4 other site →

277. Specify site: _____

278. Donor's ethnicity:

- 1 Hispanic or Latino
- 2 not Hispanic nor Latino
- 3 unknown

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

White

- 1 Eastern European
- 2 Mediterranean
- 3 Middle Eastern
- 4 North Coast of Africa
- 5 North American
- 6 Northern European
- 7 Western European
- 8 White Caribbean
- 9 White South or Central American
- 10 Other White

Black or African American

- 11 African (both parents born in Africa)
- 12 African American
- 13 Black Caribbean
- 14 Black South or Central American

American Indian or Alaska Native

- 15 Alaskan Native or Aleut
- 16 North American Indian

- 17 American Indian, South or Central America
- 18 Caribbean Indian

Asian

- 19 South Asian
- 20 Filipino (Pilipino)
- 21 Japanese
- 22 Korean
- 23 Chinese
- 24 Vietnamese
- 25 Other Southeast Asian

Native Hawaiian or Other Pacific Islander

- 26 Guamanian
- 27 Hawaiian
- 28 Samoan
- 29 Other Pacific Islander

Decline

- 30 Donor declines to provide race
- 31 Donor's race unknown

280. What is the relationship of the donor to the recipient?

- 1 sibling
- 2 recipient's child
- 3 other relative →
- 4 unrelated

281. Specify the relationship of the donor to the recipient:

- 1 parent
- 2 aunt
- 3 uncle
- 4 cousin
- 5 other

relative → 282. Specify relationship: _____

ERROR CORRECTION FORM

Sequence Number:

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CIBMTR Recipient ID:

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Initials:

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Today's Date:

		2	0		
Month	Day	Year			

Infusion Date:

		2	0		
Month	Day	Year			

CIBMTR Center Number:

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CIBMTR Center Number:

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CIBMTR Recipient ID:

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

- 1 yes
- 2 no
- 3 unknown

Specify disease(s) tested:

284. 1 yes 2 no Sickle cell anemia

285. 1 yes 2 no Thalassemia

286. 1 yes 2 no Other

287. Specify genetic disease: _____

The following questions 288–297 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 question 298.

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

- 1 yes
- 2 no

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

- 1 yes
- 2 no

290. Specify complications: _____

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

- 1 yes
- 2 no

292. Was the blood transfusion product autologous?

- 1 yes
- 2 no

293. Specify number of units:

--	--

294. Was the blood transfusion product allogeneic (homologous)?

- 1 yes
- 2 no

295. Specify number of units:

--	--

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

- 1 yes
- 2 no

297. Specify cause of death: _____

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

- 1 yes
- 2 no

299. Research sample recipient ID:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

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

- 1 yes
- 2 no

301. Research sample donor ID:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

302. Signed: _____

Person completing form

Please print name: _____

Phone number: (_____) _____

Fax number: (_____) _____

E-mail address: _____

CIBMTR Form 2006 (INF) v1.0 (13–13) July 2007
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Fax this form to your designated campus (Milwaukee 414-456-6165 or Minneapolis 612-627-5895).