Hematopoietic Stem Cell Transplant (HSCT) Product Form

Presented by:
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Data Collection Changes

- One product form is completed for each HSCT product if (proposed changes):
  - Product was collected under the CW Bill Young Program
    - BMCC – unrelated adult donors
    - CBCC – cord blood units collected
  - Recipient was selected for research (harmonized) forms

Data Collection Changes (Continued)

- Additional questions may be added to collect limited product data needed to fulfill the requirements of the SCTOD contract to the pre-TED
  - Data would be collected on autologous and related/unrelated donors not covered under the CW Bill Young Program

Data Collection Changes

- DCI product data is reported on the follow-up forms
  - Form 2100 – 100 day follow-up form
  - Form 2200 – 6 month to 2 year follow-up form
  - Form 2300 - > 2 year follow-up form

Product Form

- Includes the following 3 forms
  - Infectious Disease Markers – Form 2004
  - Confirmation of HLA Typing – Form 2005
  - Hematopoietic Stem Cell Transplant (HSCT) Product – Form 2006 (proposed name change to Infusion Form)

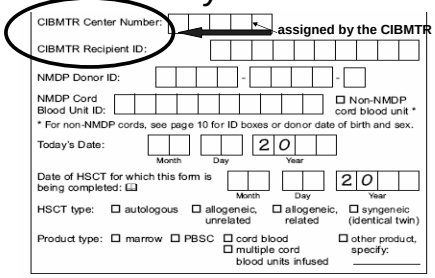
Hematopoietic Stem Cell Transplant (HSCT) Product – Form 2006

- Only one product form
  - Same form used for Marrow, PBSC, Cord Blood Unit
  - Same form used for Autologous and Allogeneic donations
- PBSC (pertains to NMDP Transplant Centers)
  - Day 1 and 2 collections will be treated as one product
  - No longer have to report the laboratory values for each bag
  - Will not be required to report WBC differential on product

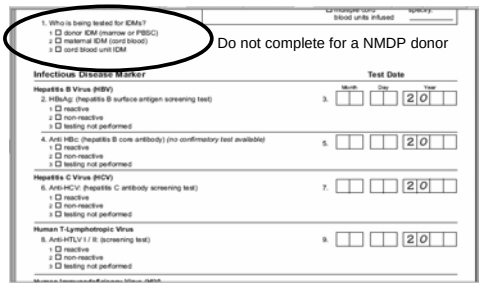
Product Form

- A product form will be required on any cryopreserved products infused
- Cryopreserved products that are infused as a subsequent HSCT will not require an Infectious Disease Markers – Form 2004 or a Confirmation of HLA Typing – Form 2005

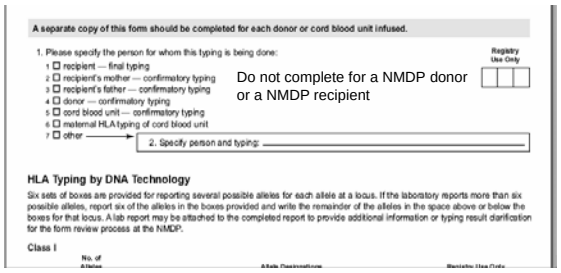
Key Fields



Infectious Disease Markers – Form 2004



Confirmation of HLA Typing Form 2005



A separate copy of this form should be completed for each donor or cord blood unit infused.

1. Please specify the person for whom this typing is being done: — Registry Use Only

1 ☐ recipient — final typing
2 ☐ recipient's mother — confirmatory typing
3 ☐ recipient's father — confirmatory typing
4 ☐ donor — confirmatory typing
5 ☐ cord blood unit — confirmatory typing
6 ☐ maternal HLA typing of cord blood unit
7 ☐ other → 2. Specify person and typing:

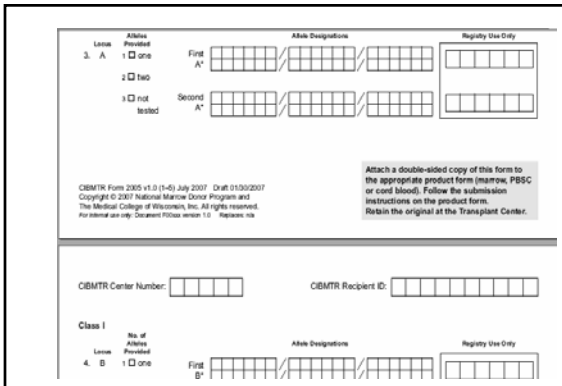
Do not complete for a NMDP donor or a NMDP recipient

HLA Typing by DNA Technology

Six sets of boxes are provided for reporting several possible alleles for each allele at a locus. If the laboratory reports more than six possible alleles, report six of the alleles in the boxes provided and write the remainder of the alleles in the space above or below the boxes for that locus. A lab report may be attached to the completed report to provide additional information or typing result clarification for the form review process at the NMDP.

Class I

No. of Alleles — Allele Designations — Registry Use Only



Locus — Alleles Provided — Allele Designations — Registry Use Only

3. A — 1 ☐ one — First A* — / — / — /
2 ☐ two
3 ☐ not tested — Second A* — / — / — /

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Attach a double-sided copy of this form to the appropriate product form (marrow, PBSC or cord blood). Follow the submission instructions on the product form. Retain the original at the Transplant Center.

CIBMTR Center Number: ☐☐☐☐☐ CIBMTR Recipient ID: ☐☐☐☐☐☐☐☐☐

Class I

No. of Alleles — Locus — Alleles Provided — Allele Designations — Registry Use Only

4. B — 1 ☐ one — First B* — / — / — /

Hematopoietic Stem Cell Transplant (HSCT) Product – Form 2006

CIBMTR

Hematopoietic Stem Cell Transplant (HSCT) Product

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number: ☐☐☐☐☐
CIBMTR Recipient ID: ☐☐☐☐☐☐☐☐☐
NMDP Donor ID: ☐☐☐☐-☐☐☐☐-☐
NMDP Cord Blood Unit ID: ☐☐☐☐☐☐☐☐ ☐ Non-NMDP cord blood unit *
* For non-NMDP cords, see page 10 for ID boxes or donor date of birth and sex.
Today's Date: ☐☐ (Month) ☐☐ (Day) 20☐☐ (Year)
Date of HSCT for which this form is being completed: ☐ ☐☐ (Month) ☐☐ (Day) 20☐☐ (Year)
HSCT type: ☐ autologous ☐ allogeneic, unrelated ☐ allogeneic, related ☐ syngeneic (identical twin)
Product type: ☐ marrow ☐ PBSC ☐ cord blood ☐ multiple cord blood units infused ☐ other product, specify:

This form must be completed for all recipients who receive a HSCT product. If more than one HSCT product is collected, each product 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.

This form must be completed for all recipients who receive a HSCT product. If more than one HSCT product is collected, each product 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.

Pre-Collection Therapy

1. Did the donor receive treatment, prior to any stem cell harvest, to enhance the product collection for this HSCT?
   - 1 ☐ yes → Specify treatment(s):
     - 2. 1 ☐ yes 2 ☐ no (autologous only) Chemotherapy → **Report details on disease-specific insert**
     - 3. 1 ☐ yes 2 ☐ no (autologous only) Rituximab (anti-CD20, 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: ______
   - 2 ☐ no
   - 3 ☐ NMDP donor → **Continue with question 29**
   - 4 ☐ cord blood unit → **Continue with question 29**

Product Collection

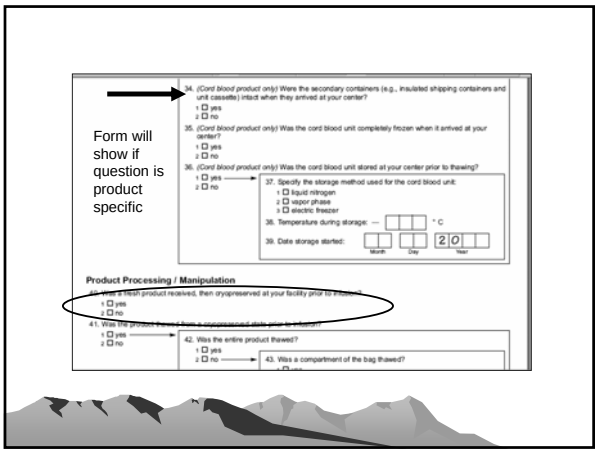
11. Date of product collection: ☐☐ ☐☐ 2 0 ☐☐ (Month, Day, Year)

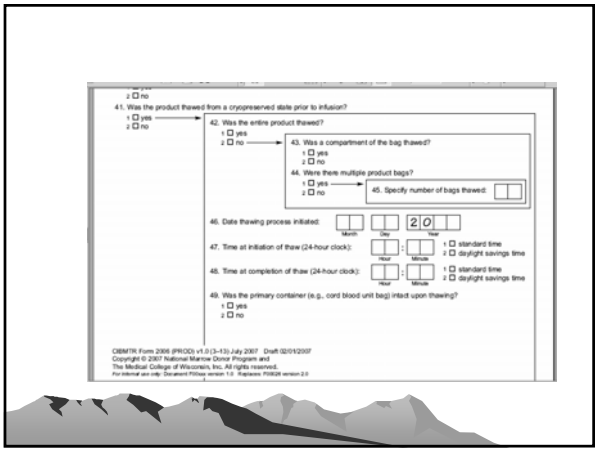
12. Was more than one collection required for this HSCT? 🕮
   - 1 ☐ yes → Specify the date and number of all collections performed:
     - 13. Date of second collection episode: ☐☐ ☐☐ 2 0 ☐☐ (Month, Day, Year) — 14. Number of collections in this episode: ☐
     - 15. Date of third collection episode: ☐☐ ☐☐ 2 0 ☐☐ — 16. Number of collections in this episode: ☐
     - 17. Date of fourth collection episode: ☐☐ ☐☐ 2 0 ☐☐ — 18. Number of collections in this episode: ☐
   - 2 ☐ no

19. Were anticoagulants added to the product during collection?
   - 1 ☐ yes → Specify anticoagulant(s):
     - 20. Acid citrate dextrose (ACD)
       - 1 ☐ yes → 21. Specify volume of ACD added: ☐☐☐.☐ mL
       - 2 ☐ no
     - 22. Citrate phosphate dextrose (CPD)
       - 1 ☐ yes → 23. Specify volume of CPD added: ☐☐☐.☐ mL
       - 2 ☐ no
     - 24. Heparin
       - 1 ☐ yes → 25. Specify volume of heparin added: ☐☐☐.☐ mL
       - 2 ☐ no
     - 26. Other anticoagulant
       - 1 ☐ yes → 27. Specify other anticoagulant: ______
       - 28. Specify volume of anticoagulant added: ☐☐☐.☐ mL
       - 2 ☐ no
   - 2 ☐ no

Product Transport and Receipt

29. Was this product collected off-site and shipped to your facility?
   - 1 ☐ yes →
     - 30. Date of receipt of product at your facility: ☐☐ ☐☐ 2 0 ☐☐ (Month, Day, Year)
     - 31. Time of receipt of product (24-hour clock): ☐☐ : ☐☐ (Hour, Minute) 1 ☐ standard time 2 ☐ daylight savings time
     - 32. Specify the shipping temperature of product(s):
       - 1 ☐ frozen gel pack
       - 2 ☐ frozen cord blood unit(s)
       - 3 ☐ room temperature per transplant center request
       - 4 ☐ other temperature → 33. Specify: ______
   - 2 ☐ no


Form will show if question is product specific
34. (Cord blood product only) Were the secondary containers (e.g., insulated shipping containers and unit cassette) intact when they arrived at your center?
35. (Cord blood product only) Was the cord blood unit completely frozen when it arrived at your center?
36. (Cord blood product only) Was the cord blood unit stored at your center prior to thawing?
37. Specify the storage method used for the cord blood unit:
liquid nitrogen
vapor phase
electric freezer
38. Temperature during storage:
39. Date storage started:
Product Processing / Manipulation
41. Was the product thawed from a cryopreserved state prior to infusion?
42. Was the entire product thawed?
43. Was a compartment of the bag thawed?


41. Was the product thawed from a cryopreserved state prior to infusion?
42. Was the entire product thawed?
43. Was a compartment of the bag thawed?
44. Were there multiple product bags?
45. Specify number of bags thawed:
46. Date thawing process initiated:
47. Time at initiation of thaw (24-hour clock):
48. Time at completion of thaw (24-hour clock):
49. Was the primary container (e.g., cord blood unit bag) intact upon thawing?
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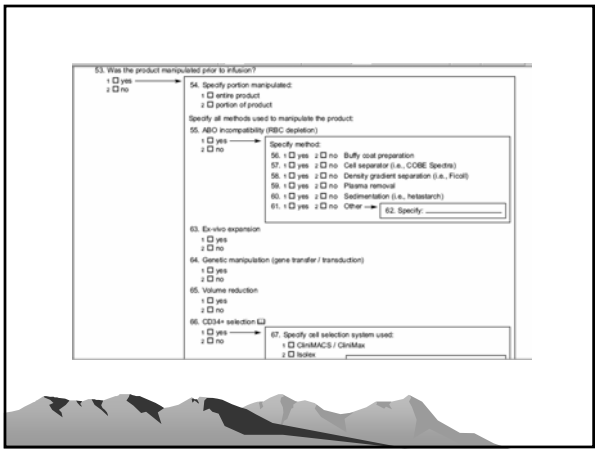
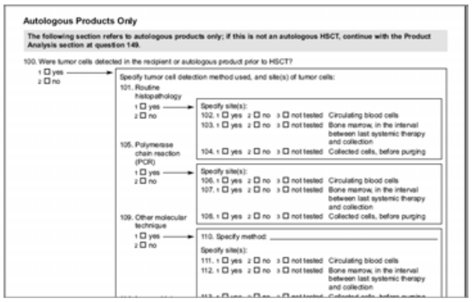

53. Was the product manipulated prior to infusion?
54. Specify portion manipulated:
entire product
portion of product
Specify all methods used to manipulate the product:
55. ABO incompatibility (RBC depletion)
Specify method:
56. Buffy coat preparation
57. Cell separator (i.e., COBE Spectra)
58. Density gradient separation (i.e., Ficoll)
59. Plasma removal
60. Sedimentation (i.e., hetastarch)
61. Other
62. Specify:
63. Ex-vivo expansion
64. Genetic manipulation (gene transfer / transduction)
65. Volume reduction
66. CD34+ selection
67. Specify cell selection system used:
CliniMACS / ClinMax
Isolex



Autologous Products Only

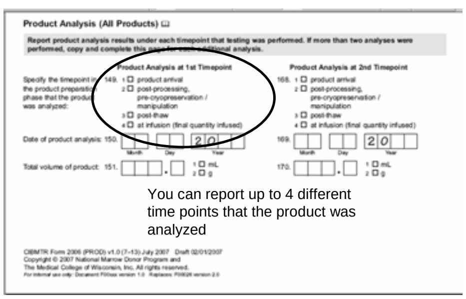
The following section refers to autologous products only; if this is not an autologous HSCT, continue with the Product Analysis section at question 149.

100. Were tumor cells detected in the recipient or autologous product prior to HSCT?
1 ☐ yes → Specify tumor cell detection method used, and site(s) of tumor cells:
2 ☐ no

101. Routine histopathology
1 ☐ yes → Specify site(s):
2 ☐ no
102. 1 ☐ yes 2 ☐ no 3 ☐ not tested Circulating blood cells
103. 1 ☐ yes 2 ☐ no 3 ☐ not tested Bone marrow, in the interval between last systemic therapy and collection
104. 1 ☐ yes 2 ☐ no 3 ☐ not tested Collected cells, before purging

105. Polymerase chain reaction (PCR)
1 ☐ yes → Specify site(s):
2 ☐ no
106. 1 ☐ yes 2 ☐ no 3 ☐ not tested Circulating blood cells
107. 1 ☐ yes 2 ☐ no 3 ☐ not tested Bone marrow, in the interval between last systemic therapy and collection
108. 1 ☐ yes 2 ☐ no 3 ☐ not tested Collected cells, before purging

109. Other molecular technique
1 ☐ yes → 110. Specify method: ______
2 ☐ no
Specify site(s):
111. 1 ☐ yes 2 ☐ no 3 ☐ not tested Circulating blood cells
112. 1 ☐ yes 2 ☐ no 3 ☐ not tested Bone marrow, in the interval between last systemic therapy and collection



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 this page for each additional analysis.

	Product Analysis at 1st Timepoint	Product Analysis at 2nd Timepoint
Specify the timepoint in the product preparation phase that the product was analyzed:	149. 1 ☐ product arrival 2 ☐ post-processing, pre-cryopreservation / manipulation 3 ☐ post-thaw 4 ☐ at infusion (final quantity infused)	168. 1 ☐ product arrival 2 ☐ post-processing, pre-cryopreservation / manipulation 3 ☐ post-thaw 4 ☐ at infusion (final quantity infused)
Date of product analysis:	150. __ __ (Month) __ __ (Day) 2 0 __ __ (Year)	169. __ __ (Month) __ __ (Day) 2 0 __ __ (Year)
Total volume of product:	151. ☐☐☐.☐ 1 ☐ mL 2 ☐ g	170. ☐☐☐.☐ 1 ☐ mL 2 ☐ g

You can report up to 4 different time points that the product was analyzed

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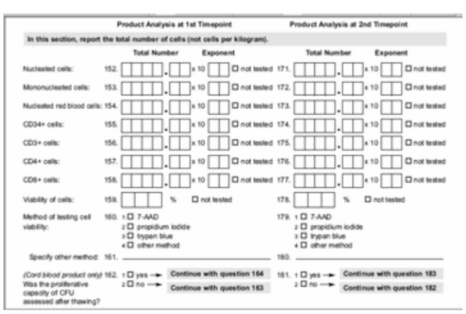
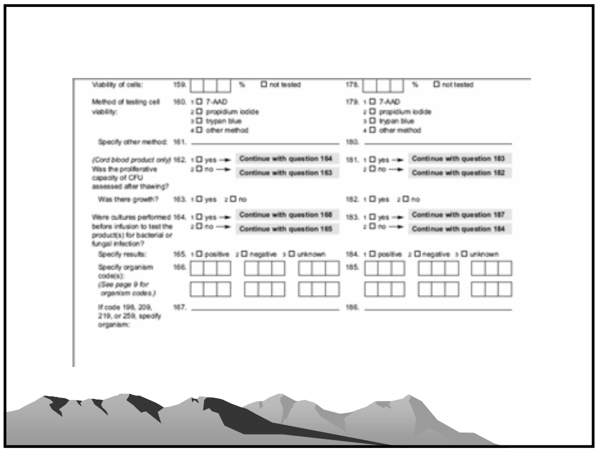
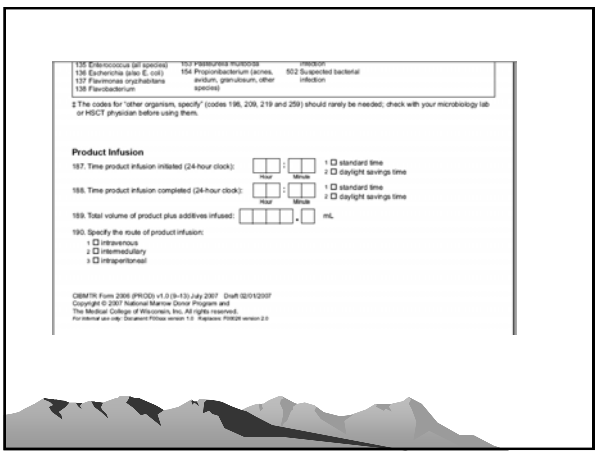


	Product Analysis at 1st Timepoint			Product Analysis at 2nd Timepoint		
In this section, report the total number of cells (not cells per kilogram).						
	Total Number	Exponent		Total Number	Exponent	
Nucleated cells:	152. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	171. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
Mononucleated cells:	153. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	172. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
Nucleated red blood cells:	154. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	173. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
CD34+ cells:	155. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	174. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
CD3+ cells:	156. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	175. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
CD4+ cells:	157. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	176. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
CD8+ cells:	158. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	177. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
Viability of cells:	159. ☐☐☐ %		☐ not tested	178. ☐☐☐ %		☐ not tested
Method of testing cell viability:	160. 1 ☐ 7-AAD 2 ☐ propidium iodide 3 ☐ trypan blue 4 ☐ other method			179. 1 ☐ 7-AAD 2 ☐ propidium iodide 3 ☐ trypan blue 4 ☐ other method		
Specify other method:	161. ______			180. ______		
(Cord blood product only) Was the proliferative capacity of CFU assessed after thawing?	162. 1 ☐ yes → **Continue with question 164** 2 ☐ no → **Continue with question 163**			181. 1 ☐ yes → **Continue with question 183** 2 ☐ no → **Continue with question 182**		



Viability of cells:	159. ☐☐☐ % ☐ not tested	178. ☐☐☐ % ☐ not tested
Method of testing cell viability:	160. 1 ☐ 7-AAD 2 ☐ propidium iodide 3 ☐ trypan blue 4 ☐ other method	179. 1 ☐ 7-AAD 2 ☐ propidium iodide 3 ☐ trypan blue 4 ☐ other method
Specify other method:	161. ____	180. ____
(Cord blood product only) Was the proliferative capacity of CFU assessed after thawing?	162. 1 ☐ yes → **Continue with question 164** 2 ☐ no → **Continue with question 163**	181. 1 ☐ yes → **Continue with question 183** 2 ☐ no → **Continue with question 182**
Was there growth?	163. 1 ☐ yes 2 ☐ no	182. 1 ☐ yes 2 ☐ no
Were cultures performed before infusion to test the product(s) for bacterial or fungal infection?	164. 1 ☐ yes → **Continue with question 168** 2 ☐ no → **Continue with question 165**	183. 1 ☐ yes → **Continue with question 187** 2 ☐ no → **Continue with question 184**
Specify results:	165. 1 ☐ positive 2 ☐ negative 3 ☐ unknown	184. 1 ☐ positive 2 ☐ negative 3 ☐ unknown
Specify organism code(s): *(See page 9 for organism codes.)*	166. ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐	185. ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐
If code 198, 209, 219, or 259, specify organism:	167. ____	186. ____



135 Enterococcus (all species)
136 Escherichia (also E. coli)
137 Flavimonas oryzihabitans
138 Flavobacterium
153 Pasteurella multocida
154 Propionibacterium (acnes, avidum, granulosum, other species)
infection
502 Suspected bacterial 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

187. Time product infusion initiated (24-hour clock): ☐☐ : ☐☐ (Hour : Minute) 1 ☐ standard time 2 ☐ daylight savings time

188. Time product infusion completed (24-hour clock): ☐☐ : ☐☐ (Hour : Minute) 1 ☐ standard time 2 ☐ daylight savings time

189. Total volume of product plus additives infused: ☐☐☐☐ . ☐ mL

190. Specify the route of product infusion:
1 ☐ intravenous
2 ☐ intermedullary
3 ☐ intraperitoneal

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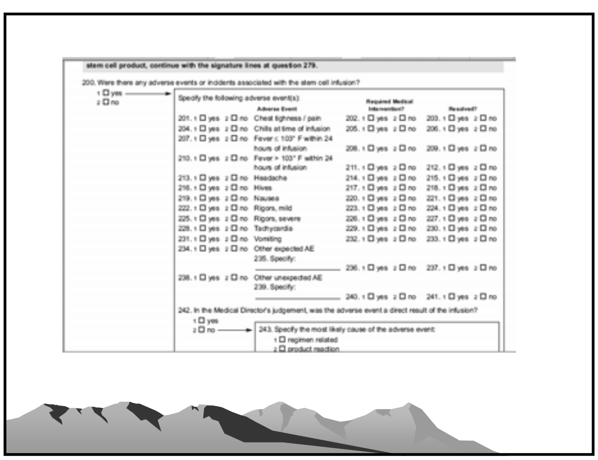
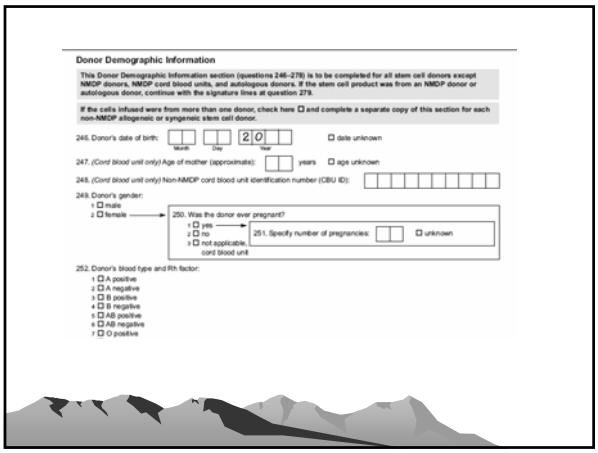


stem cell product, continue with the signature lines at question 279.

200. Were there any adverse events or incidents associated with the stem cell infusion?
1 ☐ yes → Specify the following adverse event(s):
2 ☐ no

	Adverse Event	Required Medical Intervention?	Resolved?
201. 1 ☐ yes 2 ☐ no	Chest tightness / pain	202. 1 ☐ yes 2 ☐ no	203. 1 ☐ yes 2 ☐ no
204. 1 ☐ yes 2 ☐ no	Chills at time of infusion	205. 1 ☐ yes 2 ☐ no	206. 1 ☐ yes 2 ☐ no
207. 1 ☐ yes 2 ☐ no	Fever ≤ 103° F within 24 hours of infusion	208. 1 ☐ yes 2 ☐ no	209. 1 ☐ yes 2 ☐ no
210. 1 ☐ yes 2 ☐ no	Fever > 103° F within 24 hours of infusion	211. 1 ☐ yes 2 ☐ no	212. 1 ☐ yes 2 ☐ no
213. 1 ☐ yes 2 ☐ no	Headache	214. 1 ☐ yes 2 ☐ no	215. 1 ☐ yes 2 ☐ no
216. 1 ☐ yes 2 ☐ no	Hives	217. 1 ☐ yes 2 ☐ no	218. 1 ☐ yes 2 ☐ no
219. 1 ☐ yes 2 ☐ no	Nausea	220. 1 ☐ yes 2 ☐ no	221. 1 ☐ yes 2 ☐ no
222. 1 ☐ yes 2 ☐ no	Rigors, mild	223. 1 ☐ yes 2 ☐ no	224. 1 ☐ yes 2 ☐ no
225. 1 ☐ yes 2 ☐ no	Rigors, severe	226. 1 ☐ yes 2 ☐ no	227. 1 ☐ yes 2 ☐ no
228. 1 ☐ yes 2 ☐ no	Tachycardia	229. 1 ☐ yes 2 ☐ no	230. 1 ☐ yes 2 ☐ no
231. 1 ☐ yes 2 ☐ no	Vomiting	232. 1 ☐ yes 2 ☐ no	233. 1 ☐ yes 2 ☐ no
234. 1 ☐ yes 2 ☐ no	Other expected AE 235. Specify: ____	236. 1 ☐ yes 2 ☐ no	237. 1 ☐ yes 2 ☐ no
238. 1 ☐ yes 2 ☐ no	Other unexpected AE 239. Specify: ____	240. 1 ☐ yes 2 ☐ no	241. 1 ☐ yes 2 ☐ no

242. In the Medical Director's judgement, was the adverse event a direct result of the infusion?
1 ☐ yes
2 ☐ no → 243. Specify the most likely cause of the adverse event:
1 ☐ regimen related
2 ☐ product reaction



Donor Demographic Information

This Donor Demographic Information section (questions 246–278) is to be completed for all stem cell donors except NMDP donors, NMDP cord blood units, and autologous donors. If the stem cell product was from an NMDP donor or autologous donor, continue with the signature lines at question 279.

If the cells infused were from more than one donor, check here ☐ and complete a separate copy of this section for each non-NMDP allogeneic or syngeneic stem cell donor.

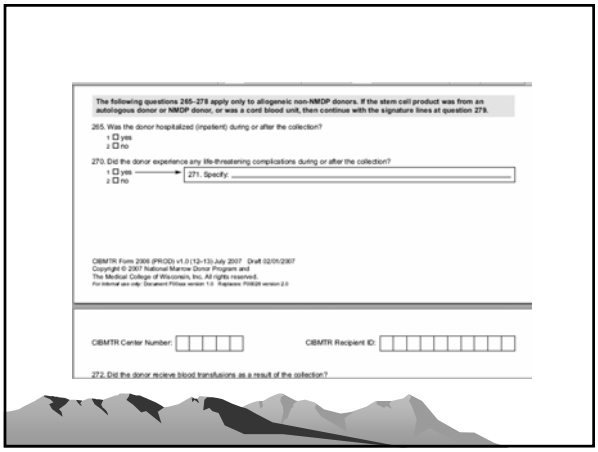
246. Donor's date of birth: ☐☐ Month ☐☐ Day 2 0 ☐☐ Year ☐ date unknown

247. *(Cord blood unit only)* Age of mother (approximate): ☐☐ years ☐ age unknown

248. *(Cord blood unit only)* Non-NMDP cord blood unit identification number (CBU ID): ☐☐☐☐☐☐☐☐☐☐

249. Donor's gender:
1 ☐ male
2 ☐ female → 250. Was the donor ever pregnant?
1 ☐ yes → 251. Specify number of pregnancies: ☐☐ ☐ unknown
2 ☐ no
3 ☐ not applicable, cord blood unit

252. 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



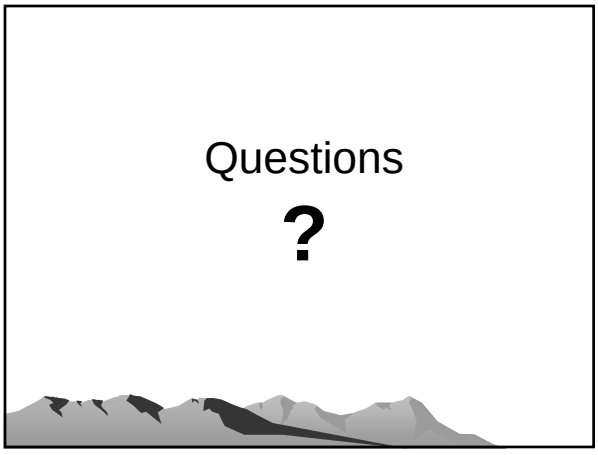
The following questions 265–278 apply only to allogeneic non-NMDP donors. If the stem cell product was from an autologous donor or NMDP donor, or was a cord blood unit, then continue with the signature lines at question 279.

265. Was the donor hospitalized (inpatient) during or after the collection?
1 ☐ yes
2 ☐ no

270. Did the donor experience any life-threatening complications during or after the collection?
1 ☐ yes → 271. Specify: _____
2 ☐ no

CIBMTR Center Number: ☐☐☐☐☐ CIBMTR Recipient ID: ☐☐☐☐☐☐☐☐☐☐

272. Did the donor recieve blood transfusions as a result of the collection?



Questions

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Financial Disclosure

Stock holder: Amgen, Pfizer and Medtronic