Hematopoietic Stem Cell Transplant (HSCT) Infusion Form 2006

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CENTER FOR INTERNATIONAL BLOOD
& MARROW TRANSPLANT RESEARCH

Outline

- Data collection requirements
- DCIs and infusion data
- Subsequent HSCTs and infusion data
- New data elements collected on the Infusion Form

Data Collection Requirements

- One Infusion Form is completed for each HSCT product if:
  - Product was collected under the CW Bill Young Program
    - BMCC – unrelated adult donors
    - CBCC – cord blood units collected
  - Related HSCT where the recipient and donor donated research samples (only 7 centers)
  - Recipient was selected for research (harmonized) forms

Hematopoietic Stem Cell Transplant (HSCT) Infusion – Form 2006

- Only one Infusion Form
  - Same form used for Marrow, PBSC, Cord Blood Unit
  - Same form used for Autologous and Allogeneic donations
- If more than one type of HSCT product is infused, each product type will have a separate Infusion Form

Hematopoietic Stem Cell Transplant (HSCT) Infusion – Form 2006

- A series of collections (even if the collections are performed on different days) should be considered a single product if:
  - The collections are all from the same donor
  - The collections all use the same collection method and technique
  - The collections all use the same mobilization (if applicable)

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

1 ☐ yes → 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.

2 ☐ no

Hematopoietic Stem Cell Transplant (HSCT) Infusion – Form 2006 (continued)

- PBSC products (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

Definition of DCI (**D**onor **C**ellular **I**nfusion)

- Contains specific blood cells
  - Lymphocytes (DLI)
- Infused to enhance
  - graft vs. tumor reactions or
  - graft vs. viral infections [EBV]

DCI Infusion Data

- DCI infusion 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 (greater than 2-year follow-up form)

This section captures information on DCIs (question 4, answered "yes") from any donor source (unstimulated peripheral blood mononuclear cells, T cells, NK cells, other cells). Complete this DCI section for all infusions given in a 10 week period. If more than 10 weeks have elapsed between DCIs, copy and complete this section for each 10 week period. If the recipient did not recieve any DCIs, continue with the signature lines at question 621.

522. Date the first DCI was given: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

523. Specify the total number of cell infusions given within 10 weeks of the first DCI: ☐☐

524. Was the DCI infusion performed at a different institution?

1 ☐ yes → 525. Specify the institution that performed the DCI:
Name: ______
City: ______
State / Country: ______

2 ☐ no

526. Indication for DCI:

1 ☐ planned as part of initial HSCT protocol

2 ☐ treatment for relapsed, persistent or progressive disease →

Specify the method(s) of disease detection below. For each method used, if the result was positive report the first date the disease was detected; if the result was negative report the last date the method was used prior to DCI (question 522).

	positive	negative	not done / unknown			Month	Day	Year
527.	1 ☐	2 ☐	3 ☐	molecular	528. Date:	☐☐	☐☐	☐☐☐☐
529.	1 ☐	2 ☐	3 ☐	cytogenetic	530. Date:	☐☐	☐☐	☐☐☐☐
531.	1 ☐	2 ☐	3 ☐	clinical evidence / hematologic	532. Date:	☐☐	☐☐	☐☐☐☐

533. Was chemotherapy used to attempt to induce disease response prior to the first DCI?

1 ☐ yes → 534. Date of administration of final chemotherapy dose: ☐☐ Month ☐☐ Day ☐☐☐☐ Year

2 ☐ no

3 ☐ treatment for B cell lympho-proliferative disorder (PTLD, EBV lymphoma)

4 ☐ treatment for GVHD

Definition of HSCT

- Delivers CD34+ cells *which <u>include</u> Stem Cells*
  - Intended to restore hematopoiesis and immunity
  - Usually preceded by a preparative regimen which kills cancer and prevents rejection
- *However*
  - **Boosts** may not include a preparative regimen
  - **HSCT for Immune deficiency disease** may not include a preparative regimen

But these are still transplants (HSCT).

Subsequent HSCTs and the Infusion form

- Required on any subsequent HSC products infused (fresh or cryopreserved)
  - Marrow
  - PBSC (mobilized)
  - Cord Blood Unit

Key Fields

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Assigned by the CIBMTR

Hematopoietic Stem Cell Transplant (HSCT) Infusion

Registry Use Only

Sequence Number:

Date Received:

Update Pre-TED and Unique ID Form if infusion date is different than what was previously reported

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 11 to report CBU ID and donor demographics.

Today's Date: Month Day Year 2 0

Date of HSCT for which this form is being completed: Month Day Year 2 0

HSCT type: *(check only one)* ☐ autologous ☐ allogeneic, unrelated ☐ allogeneic, related ☐ syngeneic (identical twin)

Product type: *(check only one)* ☐ marrow ☐ PBSC ☐ cord blood ☐ multiple cord blood units infused ☐ other product, specify: ______

different days.

Pre-Collection Therapy

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

1 ☐ yes → Specify treatment(s): *(select all that apply)*

2 ☐ no

3 ☐ NMDP donor → **Continue with question 20**

4 ☐ cord blood unit → **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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Mail this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the transplant center.

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: ____________________

Instructions if question is product specific

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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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: ☐☐ (Month) ☐☐ (Day) 2 0 ☐☐ (Year)

38. Time at initiation of thaw (24-hour clock): ☐☐ (Hour) : ☐☐ (Minute)
   - 1 ☐ standard time
   - 2 ☐ daylight savings time

39. Time at completion of thaw (24-hour clock): ☐☐ (Hour) : ☐☐ (Minute)
   - 1 ☐ standard time
   - 2 ☐ daylight savings time

40. Was the primary container (e.g., cord blood unit bag) intact upon thawing?
   - 1 ☐ yes
   - 2 ☐ no

44. Was the product manipulated prior to infusion?

1 ☐ yes →

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 → 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: ____________

2 ☐ no

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 → 58. Specify cell selection system used:

1 ☐ CliniMACS / CliniMax
2 ☐ Isolex

2 ☐ no

2 ☐ no

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

Do not report cryopreservation as a manipulation

Autologous Products Only

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?

1 ☐ yes → Specify tumor cell detection method used, and site(s) of tumor cells:

2 ☐ no

93. Routine histopathology

1 ☐ yes → Specify site(s):

94.	1 ☐ yes	2 ☐ no	3 ☐ not tested	Circulating blood cells
95.	1 ☐ yes	2 ☐ no	3 ☐ not tested	Bone marrow, in the interval between last systemic therapy and collection
96.	1 ☐ yes	2 ☐ no	3 ☐ not tested	Collected cells, before purging

2 ☐ no

97. Polymerase chain reaction (PCR)

1 ☐ yes → Specify site(s):

98.	1 ☐ yes	2 ☐ no	3 ☐ not tested	Circulating blood cells
99.	1 ☐ yes	2 ☐ no	3 ☐ not tested	Bone marrow, in the interval between last systemic therapy and collection
100.	1 ☐ yes	2 ☐ no	3 ☐ not tested	Collected cells, before purging

2 ☐ no

101. Other molecular technique

1 ☐ yes → 102. Specify method: ______________________

Specify site(s):

103.	1 ☐ yes	2 ☐ no	3 ☐ not tested	Circulating blood cells
104.	1 ☐ yes	2 ☐ no	3 ☐ not tested	Bone marrow, in the interval between last systemic therapy and collection
105.	1 ☐ yes	2 ☐ no	3 ☐ not tested	Collected cells, before purging

2 ☐ no

106. Immunohisto-

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	Product Analysis at 2nd 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)	162. 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. ☐☐ Month ☐☐ Day 2 0 ☐☐ Year	163. ☐☐ Month ☐☐ Day 2 0 ☐☐ Year
Total volume of product:	143. ☐☐☐☐ . ☐ 1 ☐ mL 2 ☐ g	164. ☐☐☐☐ . ☐ 1 ☐ mL 2 ☐ g

You can report up to 5 different time points the product was analyzed

	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:	144. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	165. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
Mononucleated cells:	145. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	166. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
Nucleated red blood cells:	146. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	167. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
CD34+ cells:	147. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	168. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
CD3+ cells:	148. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	169. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
CD4+ cells:	149. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	170. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
CD8+ cells:	150. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested	171. ☐☐☐☐.☐☐ x 10	☐☐	☐ not tested
Viability of cells:	151. ☐☐☐ %		☐ not tested	172. ☐☐☐ %		☐ not tested
Method of testing cell viability:	152. 1 ☐ 7-AAD 2 ☐ propidium iodide 3 ☐ trypan blue 4 ☐ other method			173. 1 ☐ 7-AAD 2 ☐ propidium iodide 3 ☐ trypan blue 4 ☐ other method		
Specify other method:	153. ________________			174. ________________		
Were the colony-forming units (CFU) assessed after thawing?	154. 1 ☐ yes → **Continue with question 155** 2 ☐ no → **Continue with question 158**			175. 1 ☐ yes → **Continue with question 176** 2 ☐ no → **Continue with question 179**		

Converting Cell Dose

4.41×10^8/kg x100 = 441×10^6/kg

x 63.4 kg – weight

27959.4×10^6

÷ 431 ml - volume

64.87×10^6/ml – total cells

Also Note: 10^9/L = 10^6/ml

Specify other method:	153. ______	174. ______
Were the colony-forming units (CFU) assessed after thawing? *(cord blood product only)*	154. 1 ☐ yes → **Continue with question 155** 2 ☐ no → **Continue with question 158**	175. 1 ☐ yes → **Continue with question 176** 2 ☐ no → **Continue with question 179**
Was there growth?	155. 1 ☐ yes 2 ☐ no	176. 1 ☐ yes 2 ☐ no
Total colonies per product:	156. ☐☐☐☐ • ☐ x 10^5 ☐ unknown	177. ☐☐☐☐ • ☐ x 10^5 ☐ unknown
Total CFU-GM:	157. ☐☐☐☐ • ☐ x 10^5 ☐ unknown	178. ☐☐☐☐ • ☐ x 10^5 ☐ unknown
Were cultures performed before infusion to test the product(s) for bacterial or fungal infection? *(complete for all cell products)*	158. 1 ☐ yes → **Continue with question 159** 2 ☐ no → **Continue with question 162**	179. 1 ☐ yes → **Continue with question 180** 2 ☐ no → **Continue with question 183**
Specify results:	159. 1 ☐ positive 2 ☐ negative 3 ☐ unknown	180. 1 ☐ positive 2 ☐ negative 3 ☐ unknown
Specify organism code(s): *(see page 9 for codes)*	160. ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐	181. ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐
If code 198, 209, 219, or 259, specify organism:	161. ______	182. ______

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resistant (VRE)	106 Nocardia	501 Suspected atypical bacterial infection
135 Enterococcus (all species)	153 Pasteurella multocida	502 Suspected bacterial infection
136 Escherichia (also E. coli)	154 Propionibacterium (acnes, avidum, granulosum, other species)	
137 Flavimonas oryzihabitans		
138 Flavobacterium		

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

1 ☐ yes

2 ☐ no → 185. Date of this product infusion: ☐☐ Month ☐☐ Day 2 0 ☐☐ Year

2 ☐ no

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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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 → Specify the following adverse event(s):

2 ☐ no

	Adverse Event	Required Medical Intervention?	Resolved?
203. 1 ☐ yes 2 ☐ no	Brachycardia	204. 1 ☐ yes 2 ☐ no	205. 1 ☐ yes 2 ☐ no
206. 1 ☐ yes 2 ☐ no	Chest tighness / pain	207. 1 ☐ yes 2 ☐ no	208. 1 ☐ yes 2 ☐ no
209. 1 ☐ yes 2 ☐ no	Chills at time of infusion	210. 1 ☐ yes 2 ☐ no	211. 1 ☐ yes 2 ☐ no
212. 1 ☐ yes 2 ☐ no	Fever ≤ 103° F within 24 hours of infusion	213. 1 ☐ yes 2 ☐ no	214. 1 ☐ yes 2 ☐ no
215. 1 ☐ yes 2 ☐ no	Fever > 103° F within 24 hours of infusion	216. 1 ☐ yes 2 ☐ no	217. 1 ☐ yes 2 ☐ no
218. 1 ☐ yes 2 ☐ no	Gross hemoglobinuria	219. 1 ☐ yes 2 ☐ no	220. 1 ☐ yes 2 ☐ no
221. 1 ☐ yes 2 ☐ no	Headache	222. 1 ☐ yes 2 ☐ no	223. 1 ☐ yes 2 ☐ no
224. 1 ☐ yes 2 ☐ no	Hives	225. 1 ☐ yes 2 ☐ no	226. 1 ☐ yes 2 ☐ no
227. 1 ☐ yes 2 ☐ no	Hypertension	228. 1 ☐ yes 2 ☐ no	229. 1 ☐ yes 2 ☐ no
230. 1 ☐ yes 2 ☐ no	Hypotension	231. 1 ☐ yes 2 ☐ no	232. 1 ☐ yes 2 ☐ no
233. 1 ☐ yes 2 ☐ no	Hypoxia requiring oxygen (O_2) support	234. 1 ☐ yes 2 ☐ no	235. 1 ☐ yes 2 ☐ no
236. 1 ☐ yes 2 ☐ no	Nausea	237. 1 ☐ yes 2 ☐ no	238. 1 ☐ yes 2 ☐ no
239. 1 ☐ yes 2 ☐ no	Rigors, mild	240. 1 ☐ yes 2 ☐ no	241. 1 ☐ yes 2 ☐ no
242. 1 ☐ yes 2 ☐ no	Rigors, severe	243. 1 ☐ yes 2 ☐ no	244. 1 ☐ yes 2 ☐ no

Donor Demographic Information

This Donor Demographic Information section (questions 266–287) is to be completed for all stem cell donors except NMDP donors, NMDP cord blood units, and autologous marrow or PBSC donors. If the stem cell product was from an NMDP donor or an autologous marrow or PBSC donor, continue with question 298.

266. Donor's date of birth: ☐☐ Month ☐☐ Day ☐☐☐☐ Year ☐ date unknown

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

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

269. *(Cord blood unit only)* Is the CBU ID number also the ICCBBA ISBT 128 number?

1 ☐ yes
2 ☐ no

270. *(Cord blood unit only)* Name of cord blood bank providing CBU: ______________________

271. Donor's gender:

1 ☐ male
2 ☐ female → 272. Was the donor ever pregnant?

1 ☐ yes → 273. Specify number of pregnancies: ☐☐ ☐ unknown
2 ☐ no
3 ☐ unknown
4 ☐ not applicable, cord blood unit

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

1 ☐ yes → 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: ____________

2 ☐ no
3 ☐ unknown

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 → 290. Specify complications: ____________
2 ☐ no

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

1 ☐ yes →

292. Was the blood transfusion product autologous?

1 ☐ yes → 293. Specify number of units: ☐☐
2 ☐ no

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

1 ☐ yes → 295. Specify number of units: ☐☐
2 ☐ no

2 ☐ no

1 ☐ yes
2 ☐ no

295. Specify number of units: ☐☐

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

1 ☐ yes → 297. Specify cause of death: ____________________

2 ☐ no

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

1 ☐ yes → 299. Research sample recipient ID: ☐☐☐☐☐☐☐☐☐☐

2 ☐ no

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

1 ☐ yes → 301. Research sample donor ID: ☐☐☐☐☐☐☐☐☐☐

2 ☐ no

Pilot Study – Seven centers

302. Signed: ____________________

Person completing form

Please print name: ____________________

Phone number: (________) ____________________

Fax number: (________) ____________________

E-mail address: ____________________

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Questions

?