CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Hematopoietic Cellular Transplant (HCT) Infusion

Registry Use Only
Sequence Number:

Date Received:

OMB No: 0915-0310
Expiration Date: 10/31/2022

CIBMTR Center Number: ___ ___ ___ ___ ___

CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Event Date: __ __ __ __ / __ __ / __ __
YYY MM DD

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:_____

NMDP Product ☐ Yes ☐ No

Product Identifiers:

NMDP cord blood unit ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Registry donor ID: __ __ __ __ __ __ __ __ __ __ __ __ __ __

Non-NMDP cord blood unit ID: __ __ __ __ __ __ __ __ __ __ __ __ __ __

Global Registration for Identifier for Donors (GRID): __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

ISBT DIN: __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

Registry or UCB Bank ID: __ __ __ __

Donor DOB: __ __ __ __ / __ __ / __ __
YYYY MM DD

Donor Age: __ __ ☐ Months (use only if less than 1 year old) ☐ Years

Donor Sex ☐ Male ☐ Female

If more than one type of HCT product is infused, each product type must be analyzed and reported separately.

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

1. Did the donor receive growth and mobilizing factors, prior to any stem cell harvest, to enhance the product collection for this HCT? **Allogeneic donors only**

☐ Yes →
☐ No

2. Specify growth and mobilizing factor(s) (Check all that apply)
   - ☐ G-CSF (filgrastim, Neupogen)
   - ☐ Pegylated G-CSF (pegfilgrastim, Neulasta)
   - ☐ Plerixafor (Mozobil)
   - ☐ Other growth or mobilizing factor(s) →

3. Specify other growth or mobilizing factor(s): _____

Product Collection

4. Date of first collection for this mobilization: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

5. Were anticoagulants or other agents added to the product between collection and infusion?

☐ Yes →
☐ No

6. Specify anticoagulant(s) or other agents (check all that apply)
   - ☐ Acid citrate dextrose (ACD, ACD-A)
   - ☐ Citrate phosphate dextrose (CPD, CPD-A)
   - ☐ Ethylenediaminetetraacetic acid (EDTA)
   - ☐ Heparin
   - ☐ Other agent →

7. Specify other agent: _____

Product Transport and Receipt

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

☐ Yes →
☐ No

9. Date of receipt of product at your facility: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

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

___ ___ : ___ ___ (Hour / Minute) ☐ standard time ☐ daylight savings time

11. Specify the shipping environment of the product(s)

- ☐ Room temperature
- ☐ Cooled (refrigerator temperature, not frozen)
- ☐ Frozen (cryopreserved)
- ☐ Other shipping environment →

12. Specify other shipping environment:

_____

13. Was there any indication that the environment within the shipper was outside the expected temperature range for this product at any time during shipment?

☐ Yes ☐ No

14 Were the secondary containers (e.g., insulated shipping containers and unit cassette) intact when they arrived at your center?

☐ Yes ☐ No

15. Was the cord blood unit stored at your center prior to thawing? **(Cord blood units only)**

- ☐ Yes →
- ☐ No

16. Specify the storage method used for the cord blood unit

☐ Electric freezer ☐ Liquid nitrogen ☐ Vapor phase

17. Temperature during storage

- ☐ < -150° C
- ☐ ≥ -150° C to < -135° C
- ☐ ≥ -135° C to < -80° C
- ☐ ≥ -80° C

18. Date storage started: __ __ __ __ / __ __ / __ __
YYYY MM DD

Report the total number of cells (not cells per kilogram) prior to cryopreservation: (Information provided for the unit by the cord blood bank).

19. Total nucleated cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___ (Includes nucleated red and nucleated white cells) **(Cord blood units only)**

20. CD34+ cells **(cord blood units only)**

- ☐ Done →
- ☐ Not done

21. Total number of CD34+ cells:

___ ___ ___ ___ • ___ ___ x 10 ___ ___

Product Processing / Manipulation

22. Was the product thawed from a cryopreserved state prior to infusion?
- ☐ Yes →
- ☐ No

23. Was the entire product thawed?
- ☐ Yes
- ☐ No →

24. Specify the percent of the product that was thawed? **(Cord blood units only)**
- ☐ 80%
- ☐ 20%
- ☐ Other percent →

25. Specify other percent: __ __ %

26. Date thawing process initiated: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

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

28. Time of thaw completion (24-hour clock): ___ ___ : ___ ___ (Hour : Minute) ☐ standard time ☐ daylight savings time

29. What method was used to thaw the product?
- ☐ Waterbath
- ☐ Electric warmer
- ☐ Other method →

30. Specify other method: _____

31. Did any incidents, or product complaints occur while preparing or thawing the product? ☐ Yes ☐ No

32. Was the product **processed** prior to infusion?
- ☐ Yes →
- ☐ No

33. Specify processing (check all that apply)
- ☐ Buffy coat enriched (buffy coat preparation)
- ☐ Diluted
- ☐ Plasma reduced
- ☐ RBC reduced
- ☐ Washed

34. Was the product **manipulated** prior to infusion?
- ☐ Yes →
- ☐ No

35. Specify manipulations performed (check all that apply)
- ☐ Ex-vivo expansion ***- Go to question 41***
- ☐ Genetic manipulation (gene transfer / transduction) ***- Go to question 41***
- ☐ CD34 enriched (CD34+ selection) ***- Go to question 41***
- ☐ Ex-vivo T-cell depletion ***- Go to question 36***
- ☐ Other manipulation ***- Go to question 40***

36. Specify antibodies used (check all that apply)
- ☐ Anti CD3
- ☐ Anti CD4
- ☐ Anti CD8
- ☐ Anti CD19
- ☐ Anti CD45RA
- ☐ α/β Antibody
- ☐ Anti CD52
- ☐ Other antibody → 37. Specify other antibody: _____

38. Specify T-cell depletion method
- ☐ Antibody affinity column
- ☐ Immunomagnetic beads
- ☐ Other method → 39. Specify other method: _____

40. Specify other cell manipulation: _____

Product Analysis (All Products)

41. Specify the timepoint in the product preparation phase that the product was analyzed
☐ Product arrival (cord blood only) ☐ At infusion (final quantity infused)

42. Date of product analysis: __ __ __ __ / __ __ / __ __
YYYY MM DD

43. Total volume of product plus additives : ___ ___ ___ ___ ___ • ___mL

In this section, report the total number of cells (not cells per kilogram) and do not correct for viability.

44. Total nucleated cells (TNC) (Includes nucleated red and nucleated white cells)
- ☐ Done →
  45. Total nucleated cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___
  46. Viability of TNC
  - ☐ Done →
    47. Viability of TNC: ___ ___ ___ %
    48. Method of testing TNC viability
    - ☐ Flow cytometry based
    - ☐ Trypan blue
    - ☐ Other method → 49. Specify other method: _____
  - ☐ Not done
  - ☐ Unknown
- ☐ Not done

50. Nucleated white blood cells
- ☐ Done →
- ☐ Not done

51. Total number of nucleated white blood cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___

52. Mononuclear cells
- ☐ Done →
- ☐ Not done

53. Total number of mononuclear cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___

54. Nucleated red blood cells
- ☐ Done →
- ☐ Not done

55. Total number of nucleated red blood cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___

56. CD34+ cells
- ☐ Done →
- ☐ Not done

57. Total number of CD34+ cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___

58. Viability of CD34+ cells
- ☐ Done →
- ☐ Not done
- ☐ Unknown

59. Viability of CD34+ cells: ___ ___ ___ %

60. Method of testing CD34+ cell viability
- ☐ Flow cytometry based
- ☐ Trypan blue
- ☐ Other method →

61. Specify other method: _____

62. CD3+ cells
- ☐ Done →
- ☐ Not done

63. Total number of CD3+ cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___

64. Viability of CD3+ cells
- ☐ Done →
- ☐ Not done
- ☐ Unknown

65. Viability of CD3+ cells cells: ___ ___ ___ %

66. Method of testing CD3+ cells cell viability
- ☐ Flow cytometry based
- ☐ Trypan blue
- ☐ Other method →

67. Specify other method: _____

68. CD3+CD4+ cells
- ☐ Done →
  - 69. Total number of CD3+CD4+ cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___
  - 70. Viability of CD3+CD4+ cells
    - ☐ Done →
      - 71. Viability of CD3+CD4+ cells: ___ ___ ___ %
      - 72. Method of testing CD3+CD4+ cell viability
        - ☐ Flow cytometry based
        - ☐ Trypan blue
        - ☐ Other method →
          - 73. Specify other method: _____
    - ☐ Not done
    - ☐ Unknown
- ☐ Not done

74. CD3+CD8+ cells
- ☐ Done →
  - 75. Total number of CD3+CD8+ cells: ___ ___ ___ ___ • ___ ___ x 10 ___ ___
  - 76. Viability of CD3+CD8+ cells
    - ☐ Done →
      - 77. Viability of CD3+CD8+ cells: ___ ___ ___ %
      - 78. Method of testing CD3+CD8+ cell viability
        - ☐ Flow cytometry based
        - ☐ Trypan blue
        - ☐ Other method →
          - 79. Specify other method: _____
    - ☐ Not done
    - ☐ Unknown
- ☐ Not done

80. Were the colony-forming units (CFU) assessed after thawing? **(cord blood units only)**
- ☐ Yes →
  - 81. Was there growth? ☐ Yes ☐ No
  - 82. Total CFU-GM
    - ☐ Done →
      - 83. Total CFU-GM: ___ ___ ___ ___ • ___ x 10 ___ ___
    - ☐ Not done
  - 84. Total CFU-GEMM
    - ☐ Done →
      - 85. Total CFU-GEMM: ___ ___ ___ ___ • ___ x 10 ___ ___
    - ☐ Not done
  - 86. Total BFU-E
    - ☐ Done →
      - 87. Total BFU-E: ___ ___ ___ ___ • ___ x 10 ___ ___
    - ☐ Not done
- ☐ No

88. Were any positive cultures (for bacterial or fungal infections) obtained from the product at the transplant center? (complete for all cell products)

☐ Yes → ☐ No ☐ Pending ☐ Unknown

Specify organism code(s):

89. ___ ___ ___ 90. ___ ___ ___ 91. ___ ___ ___ 92. ___ ___ ___

93. Specify organism: _____

‡ The codes for "other organism, specify" (codes 198, 209, 219 and 259) should rarely be needed; check with your microbiology lab or HCT physician before using them.

Codes for Commonly Reported Organisms

Bacterial Infections

☐ 121 Acinetobacter (all species)
☐ 125 Bordetella pertussis (whooping cough)
☐ 128 Campylobacter (all species)
☐ 129 Capnocytophaga (all species)
☐ 171 Chlamydia (pneumoniae)
☐ 130 Citrobacter (freundii, other species)
☐ 131 Clostridium (all species except difficile)
☐ 132 Clostridium difficile
☐ 173 Corynebacterium jeikeium
☐ 134 Enterobacter (all species)
☐ 135 Enterococcus (all species)
☐ 177 Enterococcus, vancomycin resistant (VRE)
☐ 136 Escherichia (also E. coli)
☐ 139 Fusobacterium (all species)
☐ 187 Haemophilus influenzae
☐ 188 Haemophilus non-influenzae
☐ 146 Klebsiella (all species)
☐ 147 Lactobacillus (bulgaricus, acidophilus, other species)
☐ 189 Legionella pneumophila
☐ 190 Legionella non-pneumophila
☐ 103 Leptospira (all species)
☐ 148 Leptotrichia buccalis
☐ 149 Leuconostoc (all species)
☐ 104 Listeria monocytogenes
☐ 151 Micrococcus, NOS
☐ 118 Mycobacterium abscessus
☐ 112 Mycobacterium avium - intracellulare (MAC, MAI)
☐ 108 Mycobacterium cheloneae
☐ 109 Mycobacterium fortuitum
☐ 114 Mycobacterium haemophilum
☐ 115 Mycobacterium kansasii
☐ 116 Mycobacterium marinum
☐ 117 Mycobacterium mucogenicum
☐ 110 Mycobacterium tuberculosis (tuberculosis, Koch bacillus)

- ☐ 105 Mycoplasma (all species)
- ☐ 183 Neisseria gonorrhoeae
- ☐ 184 Neisseria meningitidis
- ☐ 106 Nocardia (all species)
- ☐ 153 Pasteurella multocida
- ☐ 155 Proteus (all species)
- ☐ 157 Pseudomonas or Burkholderia cepacia
- ☐ 185 Pseudomonas aeruginosa
- ☐ 186 Pseudomonas non-aeruginosa
- ☐ 159 Rhodococcus (all species)
- ☐ 107 Rickettsia (all species)
- ☐ 160 Salmonella (all species)
- ☐ 161 Serratia marcescens
- ☐ 162 Shigella (all species)
- ☐ 180 Staphylococcus (Methacillin Resistant)
- ☐ 179 Staphylococcus (Methacillin Sensitive)
- ☐ 158 Stenotrophomonas maltophilia
- ☐ 166 Stomatococcus mucilaginosis
- ☐ 181 Streptococcus, alpha-hemolytic
- ☐ 182 Streptococcus, Group B
- ☐ 178 Streptococcus pneumoniae
- ☐ 168 Treponema (syphilis)
- ☐ 169 Vibrio (all species)

Fungal Infections

- ☐ 210 Aspergillus, NOS
- ☐ 211 Aspergillus flavus
- ☐ 212 Aspergillus fumigatus
- ☐ 213 Aspergillus niger
- ☐ 215 Aspergillus terreus
- ☐ 214 Aspergillus ustus
- ☐ 270 Blastomyces (dermatitidis)
- ☐ 201 Candida albicans
- ☐ 208 Candida non-albicans
- ☐ 271 Coccidioides (all species)
- ☐ 222 Cryptococcus gattii
- ☐ 221 Cryptococcus neoformans
- ☐ 230 Fusarium (all species)
- ☐ 261 Histoplasma (capsulatum)
- ☐ 241 Mucorales (all species)
- ☐ 260 Pneumocystis (PCP / PJP)
- ☐ 242 Rhizopus (all species)
- ☐ 272 Scedosporium (all species)

☐ 240 Zygomycetes, NOS
☐ 503 Suspected fungal infection
☐ 777 Other organism

Copy questions 41-93 to report multiple instances of Product Analysis

Product Infusion

94. Date of this product infusion: __ __ __ __ / __ __ / __ __
YYYY MM DD

95. Was the entire volume of received product infused?
☐ Yes
☐ No →

96. Specify what happened to the reserved portion:
☐ Discarded
☐ Cryopreserved for future use
☐ Other fate →

97. Specify other fate: _____

98. Time product infusion initiated (24-hour clock): ___ ___ : ___ ___ ☐ standard time ☐ daylight savings time
Hour Minute

99. Date infusion stopped: __ __ __ __ / __ __ / __ __
YYYY MM DD

100. Time product infusion completed (24-hour clock): ___ ___ : ___ ___ ☐ standard time ☐ daylight savings time
Hour Minute

101. Specify the route of product infusion
☐ Intravenous
☐ Intramedullary (Intraosseous)
☐ Other route of infusion →

102. Specify other route of infusion: _____

The following questions are applicable to cord blood units only. Non-NMDP allogeneic products continue with question 144. Autologous and NMDP products continue with the signature lines.

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

☐ Yes → **Specify the following adverse event(s):**

☐ No

104. Brachycardia

☐ Yes → 105. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

106. Chest tightness / pain

☐ Yes → 107. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

108. Chills at time of infusion

☐ Yes → 109. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

110. Fever ≤ 103° F within 24 hours of infusion

☐ Yes → 111. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

112. Fever > 103° F within 24 hours of infusion

☐ Yes → 113. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

114. Gross hemoglobinuria

☐ Yes → 115. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

116. Headache
☐ Yes → 117. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No
☐ No

118. Hives
☐ Yes → 119. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No
☐ No

120. Hypertension
☐ Yes → 121. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No
☐ No

122. Hypotension
☐ Yes → 123. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No
☐ No

124. Hypoxia requiring oxygen (O_2) support
☐ Yes → 125. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No
☐ No

126. Nausea
☐ Yes → 127. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No
☐ No

128. Rigors, mild
☐ Yes → 129. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No
☐ No

130. Rigors, severe
☐ Yes → 131. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No
☐ No

132. Shortness of breath (SOB)

☐ Yes → 133. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

134. Tachycardia

☐ Yes → 135. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

136. Vomiting

☐ Yes → 137. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

138. Other expected AE

☐ Yes → 139. Specify other expected AE: _____

140. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

141. Other unexpected AE

☐ Yes → 142. Specify other unexpected AE: _____

143. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No

☐ No

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Donor / Infant Demographic Information

This Donor Demographic Information section (questions 144-170) is to be completed for all non-NMDP allogeneic donors. If the stem cell product was from an NMDP donor or an autologous donor, continue with the signature lines.

144. Was the donor ever pregnant?

- ☐ Yes →
- ☐ No
- ☐ Unknown
- ☐ Not applicable (male donor or cord blood unit)

145. Number of pregnancies

- ☐ Known →
  - 146. Specify number of pregnancies: ___ ___
- ☐ Unknown

147. Ethnicity (donor) ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Not applicable (not a resident of the USA) ☐ Unknown

148. Race (donor) (check all that apply)

- ☐ White ***- Go to Question 149***
- ☐ Black or African American ***- Go to Question 149***
- ☐ Asian ***- Go to Question 149***
- ☐ American Indian or Alaska Native ***- Go to Question 149***
- ☐ Native Hawaiian or Other Pacific Islander ***- Go to Question 149***
- ☐ Not reported ***- Go to Question 151***
- ☐ Unknown ***- Go to Question 151***

149. Race detail (donor) (check all that apply)

- ☐ Eastern European
- ☐ Mediterranean
- ☐ Middle Eastern
- ☐ North Coast of Africa
- ☐ North American
- ☐ Northern European
- ☐ Western European
- ☐ White Caribbean
- ☐ White South or Central American
- ☐ Other White
- ☐ African (both parents born in Africa)
- ☐ African American
- ☐ Black Caribbean
- ☐ Black South or Central American
- ☐ Other Black
- ☐ Alaskan Native or Aleut
- ☐ North American Indian
- ☐ American Indian, South or Central America
- ☐ Caribbean Indian
- ☐ South Asian
- ☐ Filipino (Pilipino)
- ☐ Japanese
- ☐ Korean
- ☐ Chinese
- ☐ Vietnamese

- ☐ Other Southeast Asian
- ☐ Guamanian
- ☐ Hawaiian
- ☐ Samoan
- ☐ Other Pacific Islander
- ☐ Unknown

150. Was the donor a carrier for potentially transferable genetic diseases?

- ☐ Yes →
- ☐ No

151. Specify potentially transplantable genetic disease (check all that apply)

- ☐ Sickle cell anemia
- ☐ Thalassemia
- ☐ Other hemoglobinopathy
- ☐ Other disease →

152. Specify other disease: _____

153. Was the donor / product tested for other transferable genetic or clonal abnormalities?

- ☐ Yes ***- Go to question 154***
- ☐ No ***- If this is a related donor, go to question 159; all other donor types go to signature line***
- ☐ Unknown ***- If this is a related donor, go to question 159; all other donor types go to signature line***

154. Clonal hematopoiesis of indeterminate potential (CHIP)

- ☐ Yes →
- ☐ No

155. What was the method of testing used?_____

156. Monoclonal B-cell lymphocytosis ☐ Yes ☐ No

157. Other transferable genetic or clonal abnormality

- ☐ Yes →
- ☐ No

158. Specify other transferable genetic or clonal abnormality:

_____

The following questions (160–167) 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.

159. Did this donor have a central line placed? ☐ Yes ☐ No ☐ Unknown

160. Was the donor hospitalized (inpatient) during or after the collection? ☐ Yes ☐ No

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

- ☐ Yes →
- ☐ No

162. Specify:_____

163. Did the allogeneic donor give one or more autologous transfusion units?

☐ Yes → 164. Date of collection: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

165. Number of units: __ __

☐ No

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

☐ Autologous transfusions → 167. Specify number of autologous units: ___ ___

☐ Allogenic transfusions → 168. Specify number of allogenic units: ___ ___

☐ No

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

☐ Yes → 170. Specify cause of death: _____

☐ No ***- Go to signature line***

First Name (person completing form): _____

Last Name:_____

E-mail address: _____

Date: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)