HCT Infusion Form (F2006 R5)

Janet Brunner-Grady, PA-C
Program Director- CIBMTR Data Operations

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

The CIBMTR® (Center for International Blood and Marrow Transplant Research®) is a research collaboration between the National Marrow Donor Program® (NMDP)/Be The Match® and the Medical College of Wisconsin (MCW).

Disclosures

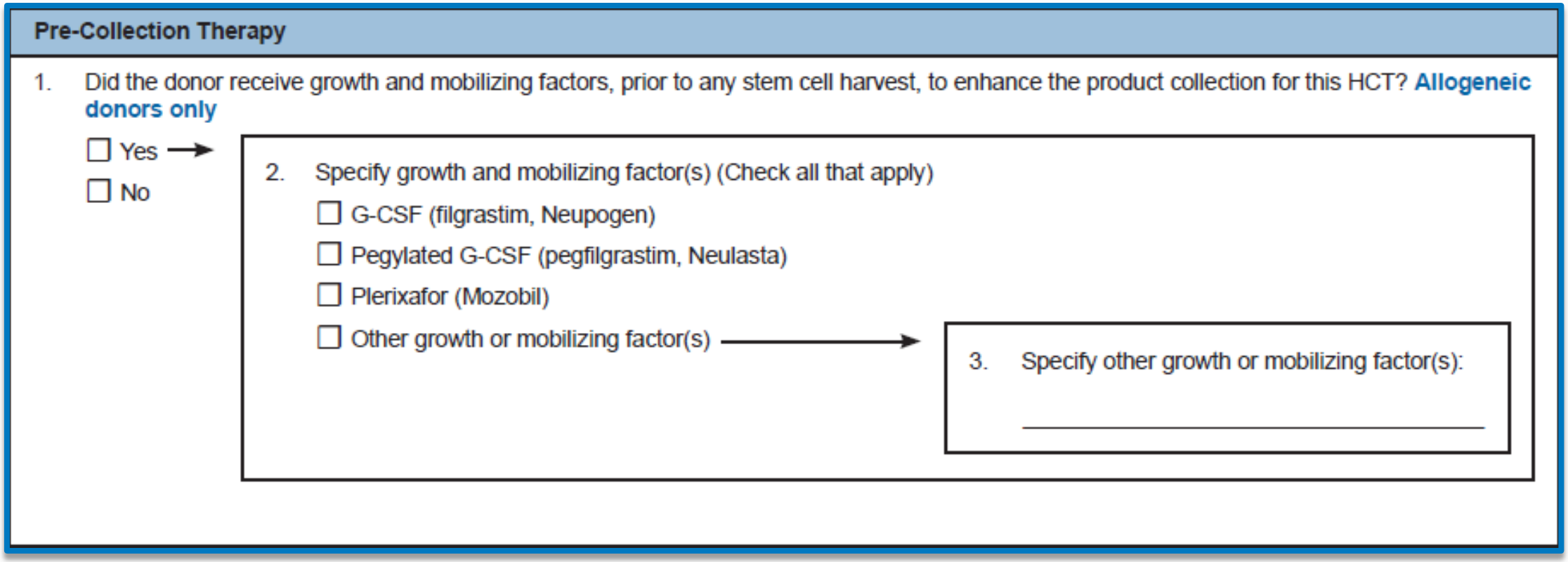
- I have no relevant conflicts of interest to disclose.

Overview of Form

- Pre-collection Therapy
- Product Collection
- Product Transport & Receipt
- Product Processing / Manipulation
- Product Analysis
- Product Infusion
- Donor / Infant Demographic Information

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Pre-Collection Therapy (Q1-3)



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)

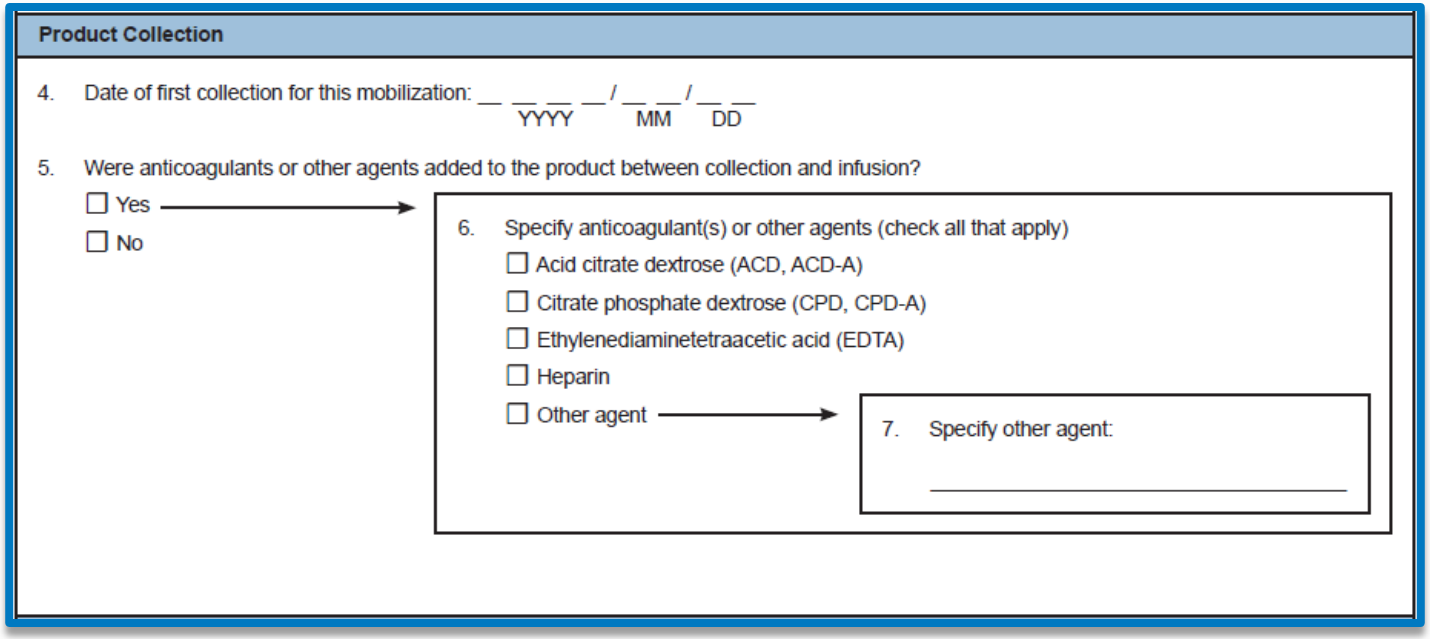
☐ G-CSF (filgrastim, Neupogen)
☐ Pegylated G-CSF (pegfilgrastim, Neulasta)
☐ Plerixafor (Mozobil)
☐ Other growth or mobilizing factor(s) →

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

_____

This question is only enabled for PBSC and bone marrow products from non-NMDP donors.

Product Collection (Q4-7)



Product Collection

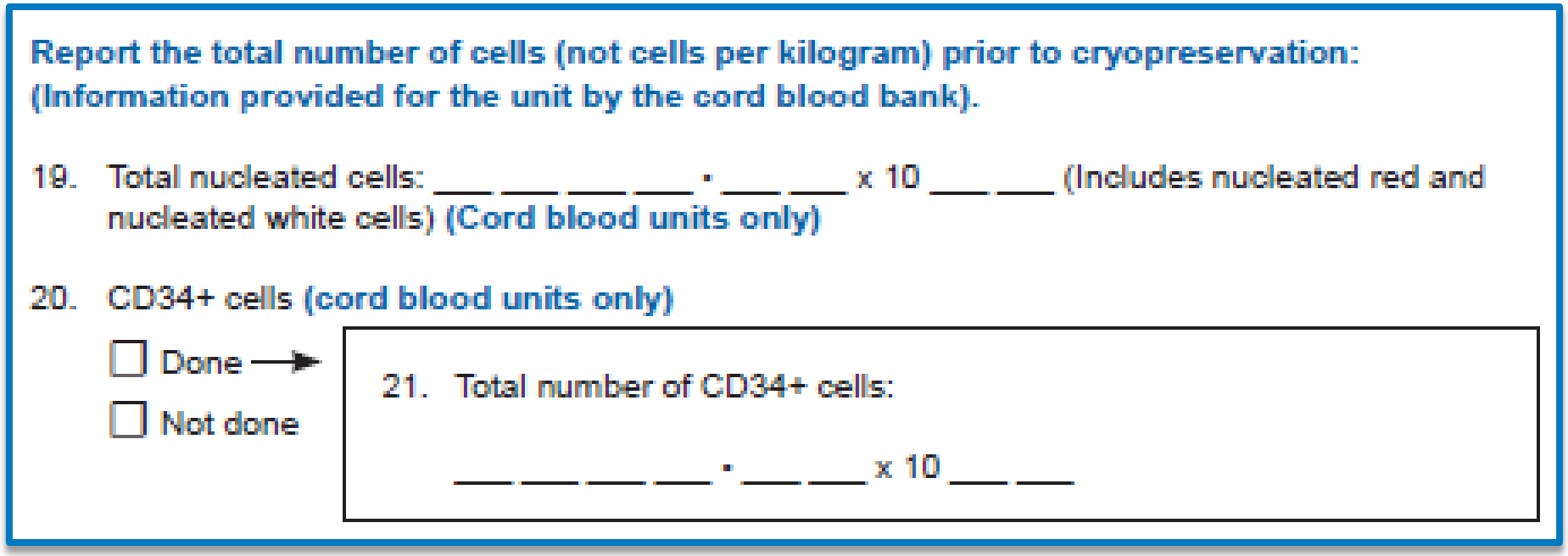
4. Date of first collection for this mobilization: __ __ __ __ / __ __ / __ __
   YYYY MM DD

5. Were anticoagulants or other agents added to the product between collection and infusion?
   - ☐ Yes → 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: _____
   - ☐ No

- The date of collection should be reported as the first date the stem cell collection was performed.
- If a collection event occurred over multiple days, enter the first date the collection began.

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Product Transport & Receipt (Q8-21)



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

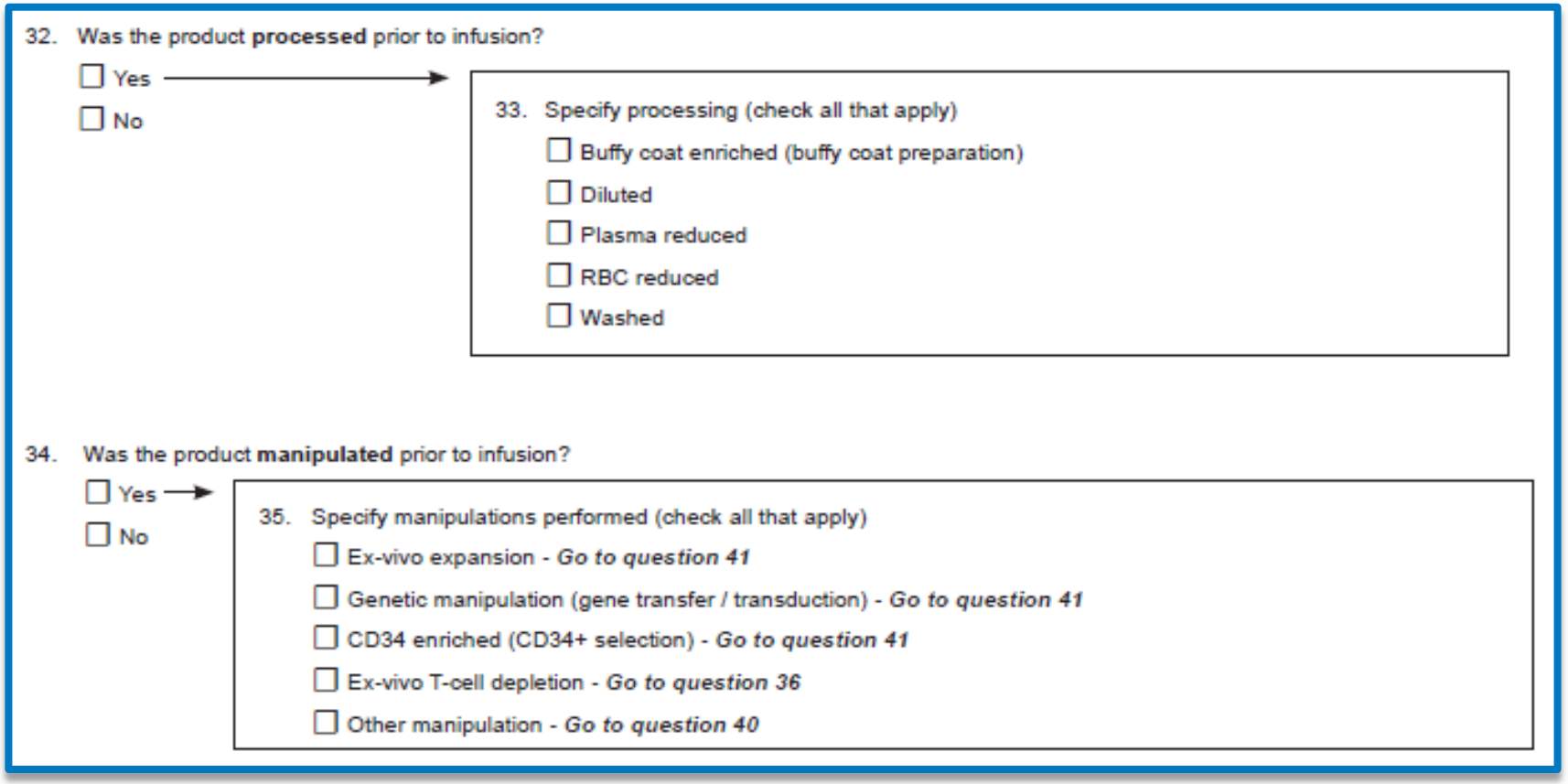
21. Total number of CD34+ cells:

___ ___ ___ ___ . ___ ___ x 10 ___ ___

- The product transport & receipt section is completed for products collected off-site and shipped to the transplant center;
- Questions 19-21 apply only to cord blood products

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Product Processing / Manipulation (Q22-40)



Product processing and manipulation have been separated into two categories for reporting purposes.

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Product Processing / Manipulation

- Why would a product be “processed” prior to infusion?
  - Major ABO incompatibility
    - If the donor’s erythrocytes are incompatible with the recipient’s plasma, they need to be removed prior to infusion.
  - Example: Recipient’s ABO type was “A” and the donor’s ABO type was “B”.
    - Since the recipient’s ABO type is A, their plasma would contain anti-B antibodies, which could hemolyze the donor’s RBCs if not removed before infusion.
    - Since the RBCs were removed, you would report the product was “RBC reduced”.

Product Processing / Manipulation

- Why would a product be “manipulated” prior to infusion?
  - Increase the number of hematopoietic progenitor cells (HPCs) per kg in products for adult recipients (generally associated with CBUs)
    - (e.g., ex-vivo expansion)
  - GVHD prophylaxis
    - (e.g., ex-vivo T-cell depletion, CD34+ selection)

Product Analysis (Q41-93)

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)

- The only timepoint required for all product types is **At Infusion**.
- For CBUs, both **At Infusion** and **At Arrival** timepoints are required.

Product Analysis Date

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

For the **At Infusion** timepoint, report the date the product was analyzed which may be different than the infusion date (reflective of the cell counts reported for this timepoint).

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Product Analysis

- **Cryopreserved Product:** Report the complete analysis (adjusted for the volume infused) performed upon either at arrival of the product or prior to cryopreservation for the **At Infusion** timepoint.
  - If the cryopreserved product is contained in multiple bags, report the sum of the cell counts for the bags infused.
  - If the cryopreserved product is contained in a single bag, report the cell counts for the volume *infused*.
  - If a complete analysis is performed post-thaw, this analysis should be reported for the **At Infusion** timepoint; however, this is unlikely.

Product Analysis

- **Cryopreserved Product:** What to report for the product analysis **At Infusion** depends on each center's practice.

Example 1: Upon receiving an autologous PBSC product, the TC lab completes a TNC, CD34, and viability analysis prior to the product being cryopreserved on 4/3/2020.

- The product is frozen in 6 bags, each bag containing 1.1 x 10^6/kg CD34+ cells.
- The infusion orders indicate a dose of 3.0 x 10^6/kg CD34+ cells.
- The only analysis performed prior to infusion was viability.
- Three of the 6 bags were infused for a total dose of 3.3 x 10^6/kg CD34+ cells.

Product Analysis

- **Cryopreserved Product continued-**

Example 1:

- Q41 At Infusion timepoint
- Q42 Date of product analysis (2020/04/03)
- Q57 Total number of CD34+ cells to report is **231 x 10^6 CD34+ cells.** How was that determined?
  Three of the 6 bags were infused.
  Each bag contained 1.1 x 10^6/kg CD34+ cells for a total number of CD34+ cells = **3.3 x 10^6/kg**. Multiply that number by the recipient's weight (70 kg) = **231 x 10^6 CD34+ cells .**

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Product Analysis

- **Cryopreserved Product:**

Example 2: Upon receiving an autologous PBSC product, the TC lab completed a TNC, CD34, and viability analysis prior to the product being cryopreserved on 4/3/2020.

- The product was frozen in 6 bags, each bag containing 1.1 x 10^6/kg CD34+ cells with a volume of 100 mls.
- The infusion orders indicated a dose of 3.0 x 10^6/kg CD34+ cells.
- Three of the 6 bags were infused for a total dose of 3.3 x 10^6/kg CD34+ cells on 5/4/2020.
- One week (4/27/2020) prior to infusion, a segment from one of the 3 bags chosen was analyzed for TNC, CD34+ & viability.

Product Analysis

- **Cryopreserved Product continued-**

Example 2:
The analysis from 4/27/2020 revealed a CD34 count of **7.0 x 10^5/ml**. The volume/bag = 100 mls. Each bag contained 700 x 10^5 CD34+ cells (or 70 x 10^6 CD34+ cells).

- Q41 **At Infusion** timepoint
- Q42 Date of product analysis (**2020/04/27**)
- Q57 Total number of CD34+ cells to report is **210 x 10^6 CD34+ cells.** How was that determined?
  Three of the 6 bags were infused.
  Since each bag contained 70 x 10^6 CD34/bag & three bags were infused for a total of 210 x 10^6 CD34 cells.

Product Analysis

- **Processed Product:** Report the last analysis performed prior to infusion for the **At Infusion** timepoint.

Example: Upon receiving a PBSC product, the transplant center completes a TNC, CD34, and viability analysis and then the product is RBC reduced. After processing, the CD34 and viability are analyzed again.

The results of the analysis performed after RBC reduction (CD34 and viability) should be reported for the **At Infusion** timepoint.

- In this scenario, the analysis for the TNC performed prior to RBC reduction will **not** be reported.

Product Infusion (Q94-143)

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

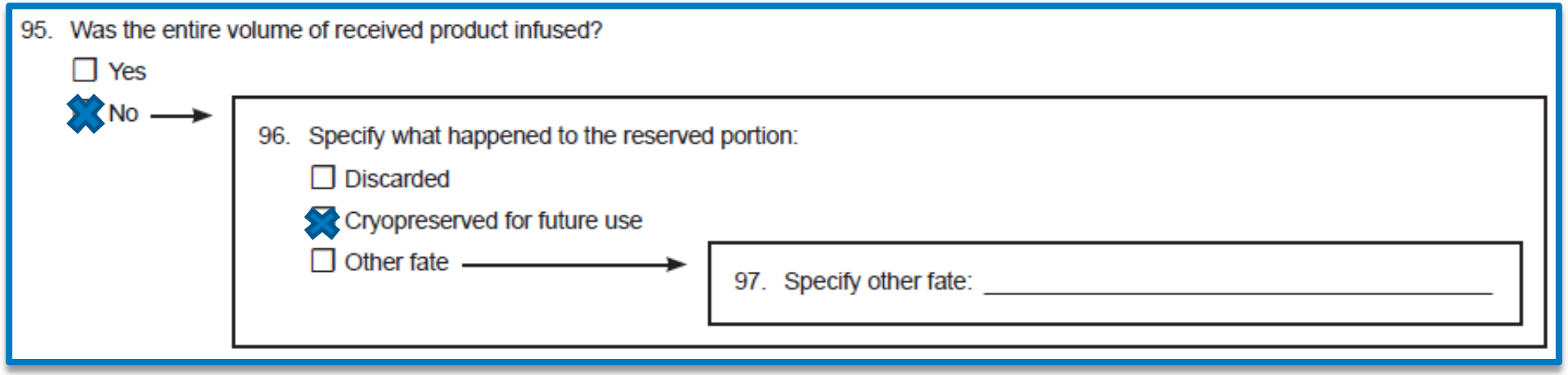
99. Date infusion stopped: __ __ __ __ / __ __ / __ __
YYYY MM DD

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

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Product Infusion Example

Example 1: A PBSC product is collected and arrives at the transplant center in four bags. Two of the bags are infused fresh, and the remaining two bags are cryopreserved for future use. Since a portion of the product received was not infused, **No** should be reported for question 95.


95. Was the entire volume of received product infused?

☐ Yes

☒ No →

96. Specify what happened to the reserved portion:

☐ Discarded

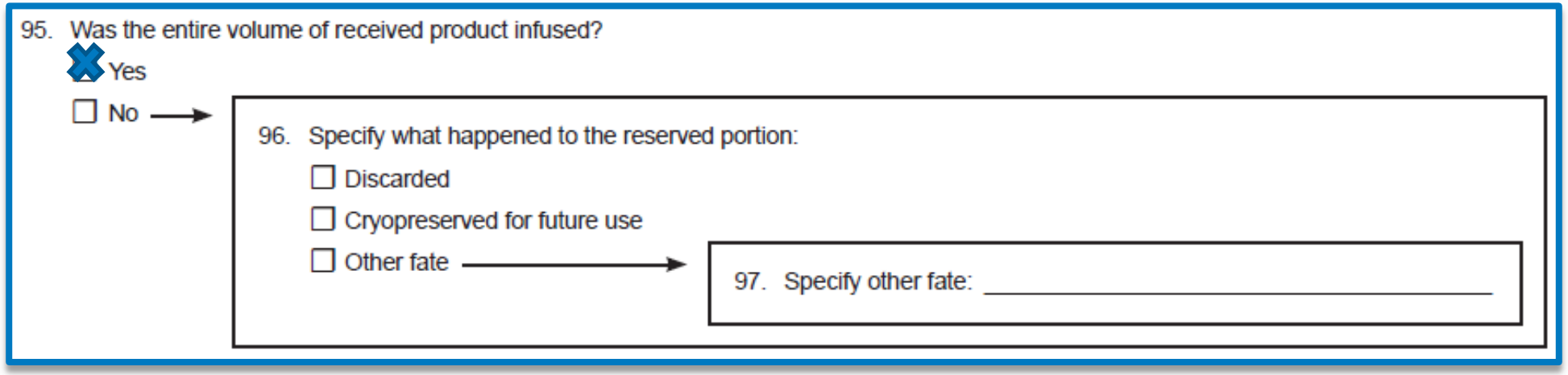
☒ Cryopreserved for future use

☐ Other fate →

97. Specify other fate: _____

Product Infusion Example

Example 2: A marrow product was collected and has a total volume of 1600 mls. The product was buffy coat enriched leaving a volume of 230 mls. The entire buffy coat enriched product was infused. In this case, **Yes** should be reported in question 95.


95. Was the entire volume of received product infused?

☒ Yes

☐ No →

96. Specify what happened to the reserved portion:

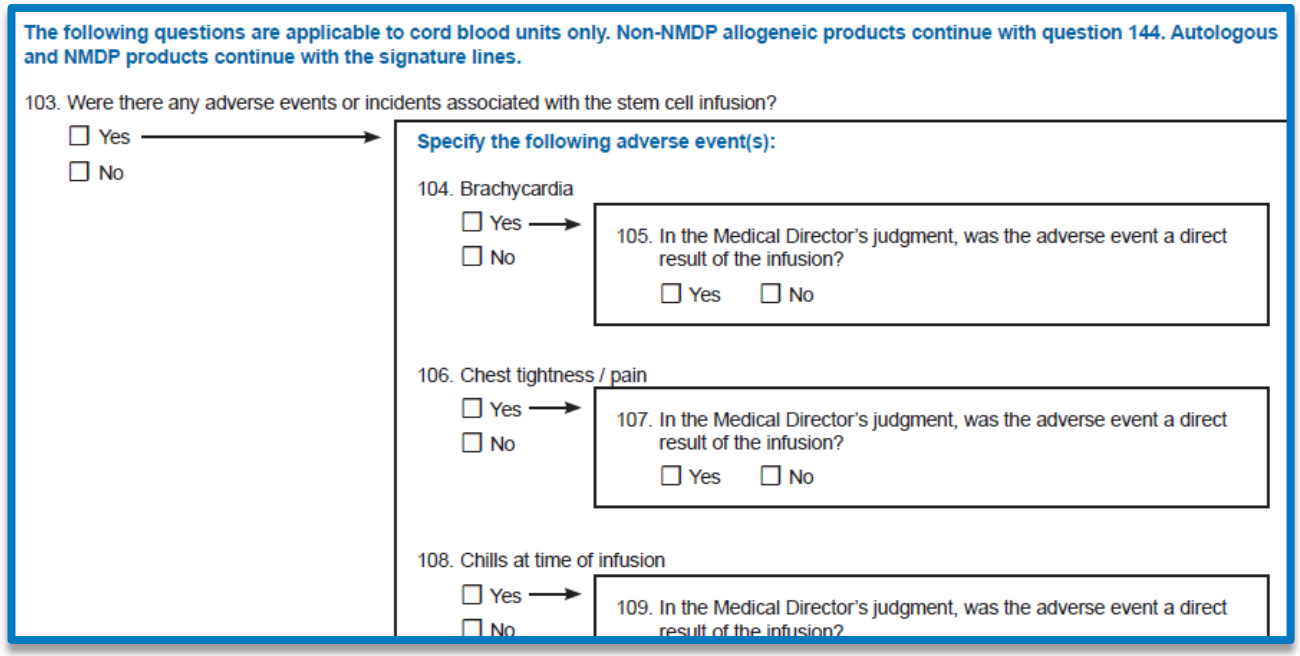
☐ Discarded

☐ Cryopreserved for future use

☐ Other fate →

97. Specify other fate: _____

Adverse Events (CBUs only)



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

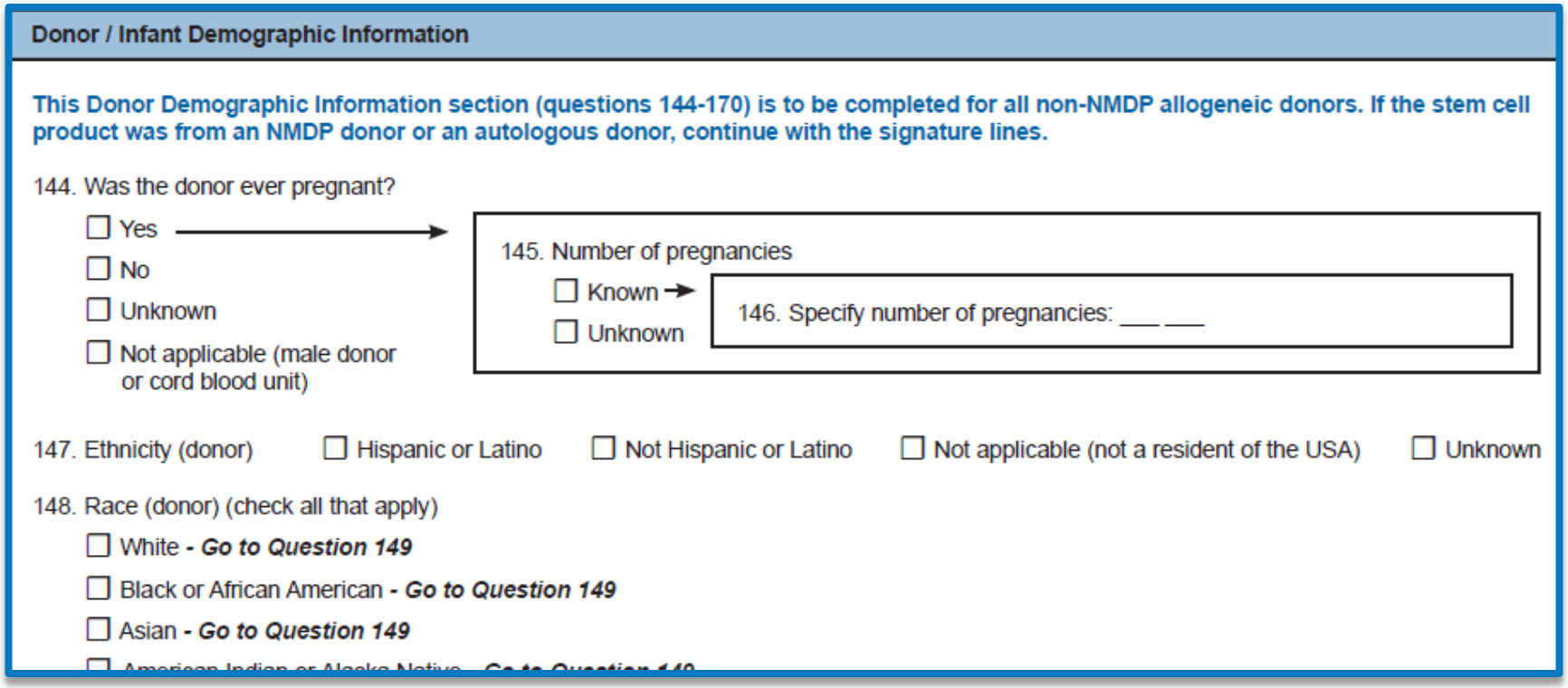
106. Chest tightness / pain
- ☐ Yes → 107. In the Medical Director's judgment, was the adverse event a direct result of the infusion? ☐ Yes ☐ No
- ☐ No

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

Report all adverse events, regardless of grade or severity, occurring during CBU infusion or fevers within 24 hours of infusion.

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Donor/Infant Demographics (Q144-170)



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 → 145. Number of pregnancies
  - ☐ Known → 146. Specify number of pregnancies: ___ ___
  - ☐ Unknown
- ☐ No
- ☐ Unknown
- ☐ Not applicable (male donor or cord blood unit)

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***

The Donor/Infant Demographics section must be completed for non-NMDP allogeneic donors or CBUs, including cooperative registry donors.

Questions