CIBMTR® CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Instructions for Hematopoietic Stem Cell Transplant (HSCT) Infusion Form 2006

E-mail comments regarding the content of the CIBMTR Forms Instruction Manual to: CIBMTRFormsManualComments@nmdp.org. Comments will be considered for future manual updates and revisions. For questions that require an immediate response, contact your transplant center's CIBMTR liaison.

All transplant centers (TED-only and Comprehensive Report Form) must complete the Form 2006 for the following product types:

- NMDP donor products
- NMDP and non-NMDP cord blood units

However, if the above criteria **are not** met, but the recipient is assigned to the Comprehensive Report Form track, the Form 2006 is required.

Additionally, all transplant centers (TED-only and Comprehensive Report Form) participating in the Related Sample Repository must complete the Form 2006 for all non-NMDP donor products when a research sample is collected.

For more information see General Instructions, section 3 – Center Type and Data Collection Forms.

The Form 2006 is designed to capture product- and infusion-specific information for all products given to a recipient as part of a Hematopoietic Stem Cell Transplant (HSCT). **This includes cells given prior to the HSCT for reasons other than engraftment**. In addition to its research purposes, this information is used for quality assurance measures, both by the NMDP and the Cord Blood Banks.

If more than one type of HSCT product is infused, each product type must be analyzed and reported on separate forms. A series of collections should be considered a **single product** when they are from the same donor and use the same collection method and mobilization cycle, even if the collections are performed on different days.

For guidance reporting data for specific infusion scenarios such as single fresh product vs. single frozen product, and multiple fresh products vs. multiple frozen products, see attachments 1-4 at the end of this document.

For more information see Appendix O – How to Distinguish Infusion Types and Appendix P – Definition of Product.

Key Fields

Accuracy of the Key Fields is essential for ensuring that:

- Data are being reported for the correct recipient.
- Transplant centers have access to their data.
- Data are being shared with the correct donor center, cord blood bank, cooperative registry, or other agency.

If more than one product is infused, the Key Fields should represent the single product for which the form is being completed.

For instructions regarding the completion of the Key Fields, see Appendix K. Key fields include all fields listed in the *Center Identification* and *Recipient Identification* boxes.

Pre-Collection Therapy

NOTE: Questions 1 – 19 vs. Questions 20 – 295

Questions 1-19 refer to the time period up to and including the *collection process,* and should be answered from the perspective of the *collection or apheresis center.* Questions 20-295 refer to the time period between *collection and infusion*, and should be answered from the perspective of the *transplant center.*

If your transplant center functioned as both the collection/apheresis center and transplant center for the product for which this form is being completed, answer all questions on this form as indicated above.

If your transplant center functioned as only the receiving transplant center for the product for which this form is being completed, answer questions 1-19 based on the documentation received from the collection center, and question 20-295 from the perspective of your center.

Question 1: Did the donor receive treatment, prior to any stem cell harvest, to enhance the product collection for this HSCT?

Stem cells do not typically circulate in the blood stream. Therefore, in order to increase the quantity of cells for collection, an agent is frequently given to the allogeneic donor or autologous recipient. The purpose of the agent is to move the stem cells from the bone marrow into the peripheral blood. This practice is often referred to as *mobilization* or *priming*.

For autologous and non-NMDP donors:
If the donor received an agent such as chemotherapy or growth factors, or the autologous recipient received an agent to enhance the stem cell product, check "yes."

If the donor did not receive therapy to enhance the stem cell product, check "no" and continue with question 11.

For NMDP adult donors and cord blood units (NMDP and non-NMDP):
Check "NMDP donor" or "cord blood unit" and continue with question 20. Do not skip directly to question 20 without answering this question.

Question 2: Chemotherapy – *Autologous only*
Indicate if the autologous recipient received chemotherapy prior to the stem cell harvest to enhance the stem cell product. Although the intended purpose of this therapy may not be to treat the recipient's disease, occasionally there is a disease response. Therefore, also record this therapy in the Disease Specific Form as a line of therapy.

Question 3: Anti-CD20 (rituximab, Rituxan) – *Autologous only*
Indicate if the autologous recipient received anti-CD20 prior to the stem cell harvest. Although the intended purpose of this therapy may not be to treat the recipient's disease, occasionally there is a disease response. Therefore, also record this therapy in the Disease Specific Form as a line of therapy.

Question 4: Growth factor(s)
A growth factor is a substance that affects an organism's growth. Examples of growth factors include but are not limited to the following:

- Epidermal growth factor (EGF)
- Erythropoietin (EPO)
- Fibroblast growth factor (FGF)
- Granulocyte-colony stimulating factor (G -CSF)
- Granulocyte-macrophage colony stimulating factor (GM-CSF)
- Growth differentiation factor-9 (GDF9)
- Hepatocyte growth factor (HGF)
- Insulin-like growth factor (IGF)
- Platelet-derived growth factor (PDGF)
- Thrombopoietin (TPO)
- Transforming growth factor alpha(TGF-α)
- Transforming growth factor beta (TGF-β)

If the donor/autologous recipient received growth factors prior to the stem cell harvest to enhance the stem cell product check "yes" and continue with question 5.

If the donor/autologous recipient did not receive growth factor(s), check "no."

Question 5: G-CSF
Indicate if the donor/autologous recipient received G-CSF (filgrastim, Neupogen) prior to the stem cell harvest to enhance the stem cell product.

Question 6: GM-CSF
Indicate if the donor/autologous recipient received GM-CSF (sargramostim, Leukine) prior to the stem cell harvest to enhance the stem cell product.

Question 7: Other (growth factor)
If the donor/autologous recipient received a growth factor such as AMD3100 (plerixafor, Mozobil) prior to the stem cell harvest, check "yes" and continue with question 8. For **autologous** recipients only, chemotherapy drugs should not be reported in the Other (growth factor) category; instead, report any chemotherapy drugs given to enhance the stem cell product in question 2.

If the donor/autologous recipient did not receive any other growth factor, check "no" and continue with question 9.

Question 8: Specify (growth factor)
Specify the other growth factor(s) given to the donor/autologous recipient.

Question 9: Other treatment
If the donor/autologous recipient received any other treatment prior to the stem cell harvest to enhance the stem cell product, check "yes."

If the donor/autologous recipient did not receive any other treatment, check "no" and continue with question 11.

Question 10: Specify (other treatment)
Specify the other treatment administered to the donor/autologous recipient.

Product Collection

Question 11: Date of product collection
Report the date the stem cell collection was performed. If a single collection event occurred over multiple days, enter the date the collection started (i.e. Day 1).

> **Example 1:** An autologous recipient was mobilized with G-CSF and underwent a two-day PBSC collection. Since the collection and mobilization methods remained the same over the duration of the collection, this collection is considered one product. Report the collection start date as the date of product collection.

> **Example 2:** An autologous recipient was mobilized with G-CSF and underwent a two-day PBSC collection. Then, the recipient received

> Plerixafor to enhance the mobilization. Due to the change in mobilization methods, two separate Form 2006s should be submitted, and the date of product collection should be reported for the product for which the form is being completed.

Question 12: Was more than one collection required for this HSCT?
If more than one collection was required, check "yes" and continue with question 13.

If more than one collection was not required, check "no."

Question 13: Specify the number of subsequent days of collection in this episode
Report the number of collection days for this product *excluding* the first day of collection. For example, if a collection occurred over three days, "2" should be reported for this question. For an HSCT that includes multiple products, report the total number of collection days (excluding the first day) for which the form is being completed.

Complete a separate Form 2006 for each subsequent mobilization cycle. A separate Form 2006 does not need to be filled out for each collection from the same mobilization cycle.

Question 14: Were anticoagulants added to the product during collection?
Report any anticoagulants that were added to the product prior to shipment or cryopreservation. Anticoagulants are typically documented on the product bag label. Additionally, anticoagulants are added to most PBSC products.

If anticoagulants were used **during or after** the collection (prior to shipping), check "yes."

If anticoagulants were not used, check "no" and continue with question 20.

Question 14 and question 191 (Did the volume of infused product include any added agents?) differ in regards to the timeframe to which each question refers. Question 14 is intended to cover the time period between collection and processing, prior to shipment and/or cryopreservation, at the collection center or receiving transplant center. Question 191 is intended to capture agents added to the product after its arrival at the receiving transplant center.

> **Example:** A fresh product is received at your transplant center. The stem cell processing laboratory adds an anticoagulant and then cryopreserves the entire product. Report "no" for question 14, and "yes" for question 191.

Question 15-19: Specify anticoagulants
More than one anticoagulant may be added to a product. Select all the anticoagulants added to the reported product.

If "other" is chosen, specify the other anticoagulant.

Product Transport and Receipt

NOTE: Questions 1-19 vs. Questions 20-295
Questions 20-295 refer to the time period between *collection and infusion*, and should be answered from the perspective of the *transplant center.* Questions 1-19 refer to the time period up to and including the *collection process,* and should be answered from the perspective of the *collection/apheresis center.*

If your transplant center functioned as both the collection/apheresis and transplant center for the product for which this form is being completed, answer all questions on this form using the timeframes specified above.

If your transplant center functioned as only the receiving transplant center for the product for which this form is being completed, answer questions 1-19 based on the documentation received from the collection/apheresis center, and question 20-295 from the perspective of your center.

Question 20: Was this product collected off-site and shipped to your facility?
In general, the "yes" option should be used for unrelated donors. However, there may be circumstances where the donor resides in the same geographic location as the recipient and the collection occurred at the same facility as the transplant; in this case, the "no" option should be used.

If the product was shipped to the transplant center from an off-site collection center, check "yes."

If the product **was not** shipped to the transplant center from an outside facility, or if the product **was** collected on-site then shipped off-site for laboratory processing, check "no" and continue with question 31. In general, the "no" option should be used for autologous collections and related donors.

Question 21: Date of receipt of product at your facility
The intent of this question is to determine the date that the transplant center assumed responsibility for the product from the collection center.

Enter the date your institution became responsible for the product.

If multiple bags of the same product arrive on different days, report the date the first bag arrived at your facility.

If a contract laboratory processes the product prior to arrival at the transplant facility, report the date the product arrived at the contract laboratory.

Question 22: Time of receipt of product (24-hour clock)
Enter the time the product was received at your institution or off-site laboratory as measured using a 24-hour clock. This time should reflect the moment your center became responsible for the product. In addition, indicate whether the date was during daylight savings time or standard time. If your institution or the off-site laboratory that received the product uses standard time year round, then standard time should be reported even if the date falls within daylight savings.

For more information about daylight savings time schedules, go to http://www.worldtimezone.org/.

Questions 23-24: Specify the shipping environment of the product(s)
Indicate the shipping environment of the product. If "frozen gel pack" or "room temperature per transplant center request" is selected, continue with question 31. If "frozen cord blood unit(s)" is selected, continue with question 25. If "other temperature" is selected, continue with question 24 and specify the other shipping environment.

Question 25: *Cord blood product only* – Were the secondary containers (e.g., insulated shipping containers and unit cassette) intact when they arrived at your center?
Indicate if the secondary containers were intact upon receipt of the cord blood unit by your center.

If the cord blood unit was obtained through the NMDP, and the secondary containers **were not** intact upon arrival, the NMDP Search Coordinating Unit must be contacted.

Question 26: *Cord blood product only* – Was the cord blood unit completely frozen when it arrived at your center?
Indicate if the cord blood unit was completely frozen upon receipt of the unit by your center.

If the cord blood unit was obtained through the NMDP, and the product **was not** completely frozen upon arrival, the NMDP Search Coordinating Unit must be contacted.

Question 27: *Cord blood product only* – Was the cord blood unit stored at your center prior to thawing?
If the cord blood unit was stored at your center prior to thawing, check "yes."

If the cord blood unit was not stored at your center prior to thawing, check "no" and continue with question 31.

Question 28: Specify the storage method used for the cord blood unit
Indicate the storage method used for the cord blood unit. The storage method is generally standard and should be documented within the laboratory at your center. Note: *liquid nitrogen* is also known as *liquid phase.*

Question 29: Temperature during storage
Indicate the storage temperature used for the cord blood unit. The storage temperature is generally standard and should be documented within the laboratory at your center.

Question 30: Date storage started
Report the date the cord blood unit was first stored prior to thawing.

Product Processing/Manipulation

Question 31: Was a fresh product received, then cryopreserved at your facility prior to infusion?
The intent of this question is to determine if the product **shipped** to the transplant center was ever cryopreserved.

This question should be answered from the perspective of the receiving transplant center. If your center functioned as both the *collection/apheresis* center and the *transplant* center, then answer this question as "no" (even if the product was cryopreserved) because the product was not shipped (i.e. *received*) to your institution.

If the product was shipped to your center and the **entire** fresh product was cyropreserved prior to infusion, check "yes."

Check "no" if:

- The product (allogeneic or autologous) was shipped to your center, but was not cryopreserved prior to infusion.
- A portion of the product was infused and the remainder was cryopreserved. The outcome for any portion of the product that was not infused will be reported in questions 200-201.

If the product is a cord blood unit (i.e., the product is shipped frozen), check "not applicable, cord blood unit."

Question 32: Was the product thawed from a cryopreserved state prior to infusion?
If **any portion** of the product was thawed prior to infusion, select "yes."

If the product was never cryopreserved, select "no."

> **Example:** The recipient received two bags of autologous cells that were cryopreserved from a collection one year ago. The cells were collected and transplanted at the same facility. Question 31 should be answered "no," as the cells were not **shipped** to the transplant center. Question 32 should be answered "yes."

Question 33: Was the entire product thawed?
A product may have been collected as a single product bag and then cryopreserved and stored in compartments. For example, a 500mL bag may have five 100mL cryopreserved compartments. Or, the product could be stored in multiple cryopreserved bags (not compartmentalized from one product bag).

If the entire product (all compartments or all product bags) was thawed, check "yes" and continue with question 37.

If the entire product was not thawed, check "no."

If this infusion is using "left-over" cells from a previous infusion, the "left-over" portion is now considered the *entire product*. Therefore, if **all** of the "left-over" cells were thawed, check "yes." If a portion of the "left-over" cells were not used and remain frozen, check "no."

Question 34: Was a compartment of the bag thawed?
Large product bags (units, fraction) are often comprised of several compartments (chambers). The compartments can be removed from the larger bag and thawed individually.

Indicate if a compartment(s) of the larger product bag was thawed.

Question 35: Were there multiple product bags?
Indicate if the entire product consisted of multiple product bags.

Question 36: Specify number of bags thawed
Of the total number of product bags, indicate the number of bags thawed. This number should be less than the total number of bags collected.

Question 37: Date thawing process initiated
Report the date the thawing process began.

NOTE: Questions 38-39 – Thaw initiation and completion time
The CIBMTR recognizes that documentation of thaw initiation and completion times vary by institution. For example, one center may document the time the product was placed in and removed from the water bath, whereas another center may document the time as the water bath thaw and wash process. Follow your institution's process for reporting the initiation and completion times.

Question 38: Time at initiation of thaw (24-hour clock)
Report the time the product thaw begins.

If multiple bags of the same product are thawed, report the time the first bag begins thawing. The exact time should be documented within the patient record or the stem cell laboratory processing record.

Question 39: Time at completion of thaw (24-hour clock)
Report the time the product thaw is complete.

If multiple bags of the same product are thawed, report the time the last bag was finished thawing, even if the date is not the same as the date reported in question 37. The exact time should be documented within the patient record or the stem cell laboratory processing record.

Question 40: Was the primary container (e.g., cord blood unit bag) intact upon thawing?
Indicate if the primary container was intact upon thawing. The primary container refers to the product bag, not the shipping container.

If the cord blood unit was obtained through the NMDP, and the primary container **was not** intact upon arrival, the NMDP Search Coordinating Unit must be contacted.

Question 41: What method was used to thaw the product?
Report the thawing method used to thaw the product.

Question 42: Specify other thaw method
Specify the other method used to thaw the product.

Question 43: Did any adverse events or incidents occur while thawing the product?
Indicate if any adverse events or incidents occurred regarding the product during the thawing process.

Question 44: Was the product manipulated prior to infusion?
If any part of the product was manipulated in any way prior to infusion, check "yes." **Do not report cryopreservation as a method of manipulation.**

If the product was not manipulated, check "no." For autologous product, continue with question 92. For allogeneic products, continue with question 141.

Question 45: Specify portion manipulated
If all of the cells were manipulated using the same method, select "entire product." If some of the cells were manipulated, or if all of the cells were manipulated using different methods, select "portion of product."

NOTE: Questions 46-72 Specify all methods used to manipulate the product.
Report all methods used to manipulate the product at the transplant facility (i.e. if the product was shipped to your facility, do not report manipulation of the product performed at the collection center).

All bags from one mobilization cycle are considered a single product; report all manipulation methods used on any part of the single product.

Do not report methods of manipulation performed as part of another procedure (e.g., T-cell depletion as part of expansion).

Question 50 – Plasma Removal vs. Question 56 – Volume Reduction
The difference between question 50 (plasma removal for ABO incompatibility) and question 56 (volume reduction as manipulation method) is that question 50 should be used only if the product was ABO incompatible and therefore plasma reduced. Whereas, question 56 should be selected when a product is volume reduced to result in a smaller product.

If "yes" is reported for both question 50 and 56, the product must be plasma reduced for ABO incompatibility and then further reduced to reduce the total product volume.

Question 46: ABO incompatibility (RBC depletion)
RBC or plasma depletion is often used in cases where there is ABO incompatibility between donor and recipient. Incompatibility can cause hemolysis and delayed red blood cell recovery.

This option should be used for **allogeneic** products only**;** report RBC depletion of **autologous** products as "volume reduction" under question 56.

Indicate if the product was manipulated for ABO incompatibility.

Questions 47-53: Specify method
Indicate the method(s) used for ABO incompatibility manipulation. If "other" is selected, specify the method in question 53.

Question 54: Ex-vivo expansion
Ex-vivo expansion is a type of manipulation where the cells have been maintained ex vivo (cultured) to activate, expand or promote development of a specified cell population in the presence of specified additive(s). The most common method of ex vivo expansion uses hematopoietic growth factors. Ex-vivo expansion is most commonly used with cord blood transplants.

Indicate if ex-vivo expansion was used on the product. Do not report T-cell depletion separately if it was done as a part of this procedure.

Question 55: Genetic manipulation (gene transfer/transduction)
Genetic manipulation is a promising area of research, and hematopoietic stem cells are promising target cells for gene therapy due to their differentiation and expansion abilities.

Indicate if genetic manipulation was used on the product.

Question 56: Volume reduction
The purpose of volume reduction is specifically to reduce the volume in order to prevent volume overload.

Indicate if volume reduction was used to manipulate the product.

Question 57: CD34+ selection
CD34+ selection is manipulation method also known as "positive selection." This method collects stem cells that have a CD34+ marker on the surface cell, and is commonly done with a CliniMACS/CliniMax or Isolex machine.

Indicate if CD34+ selection was used.

Questions 58-59: Specify manufacturer of CD34+ selection machine
Indicate the type of machine used for CD34+ selection. If "other" is selected, specify the manufacturer in question 59.

NOTE: CD34 Affinity Column Plus Sheep Red Blood Cell Rosetting
CD34 affinity column plus sheep red blood cell rosetting combines 2 methods (positive and negative selection) to achieve a greater degree of T-cell depletion. Sheep erythrocytes adhere spontaneously to human T-cells forming rosettes. The rosettes are then isolated from the rest of the product using Ficoll-Hypaque gradient centrifugation.

Questions 60-70: T-cell depletion
This method of negative selection manipulation is most commonly used for allogeneic HSCT, as it removes some or all of the T-cells to minimize GVHD. The removed T-cells may be infused at a later date (i.e., DLI). Methods of T-cell depletion may include the use of antibodies.

Indicate if the product was T-cell depleted and the method used. If "yes" is selected for questions 61-66, indicate the specific antibodies used for T-cell depletion in questions 73-91.

Questions 71-72: Other manipulation, specify
Indicate if the product was manipulated using any other method, and specify the manipulation type.

Examples include but are not limited to the following:
- Preparation of T-regulatory cells
- B-cell reduction
- Buffy coat enrichment
- CD133 enrichment
- Monocyte enrichment
- Mononuclear cell enrichment
- PUV treatment

Cryopreservation is NOT considered a method of manipulation. Do not include cryopreservation or freeze media in the "other" category.

Question 73: Were antibodies used during product manipulation?
If antibodies were used during product manipulation, select "yes." If antibodies were not used, select "no" and continue with question 92.

Questions 74-91: Specify Antibodies
Specify the antibodies used for product manipulation. Do not leave any responses blank.

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.

Question 92: Were tumor cells detected in the recipient or autologous product prior to HSCT?
Indicate if tumor cells (e.g. plasma cells in a myeloma patient, lymphoma cells, or breast cancer cells) were detected in the circulating blood stream within the period between the last systemic therapy and collection, or if tumor cells were present in the product. If no tumor cells were found in the product, continue with question 141.

Do not report the presence of *tumor markers* (e.g. SPEP, IFE and free light), as they do not necessarily indicate the presence of a tumor.

Do not report the presence of a tumor (i.e. solid tumor) in the recipient prior to HSCT on this form; the disease status of the recipient is recorded on the recipient forms.

Questions 93-118: Specify tumor cell detection method used, and site(s) of tumor cells:
For each of the detection methods listed, indicate whether tumor cells were detected. If "yes," specify the site where the cells were detected.

Question 119: Was the product treated to remove malignant cells (purged) *(autologous product only)*
This type of negative selection manipulation removes malignant cells from the collected product.

If the product was purged, check "yes" and continue with question 120. If the product was not purged, check "no" and continue with question 141.

Questions 120-133: Specify method(s) used
Specify all methods used to purge the product.

Questions 134-140: Specify if tumor cells were detected in the graft after purging by each method used
For each of the detection methods listed, indicate whether tumor cells were detected in the graft.

Product Analysis (Complete for All Products)

NOTE: Product Analysis

The **"at infusion"** timepoint is a critical timepoint and should reflect the values of the infused product (i.e. what was given to the patient). As long as the values specific to the volume of product infused are known, the analysis at this timepoint is the only analysis required by the CIBMTR. All other timepoints are not required. However, for NMDP products, reporting analysis for the "product arrival" timepoint is recommended for quality assurance purposes.

Report the product analysis results for each timepoint that testing was performed.

If the product is contained in **multiple bags**, or is a combination of **multiple products** infused together, add the cell counts from each bag/product to get the total cell count. To calculate the percent viability, average the viability of all bags/products.

Questions 141 & 162: Specify the timepoint in the product preparation phase that the product was analyzed

Indicate the timepoint at which product analysis is reported. A maximum of five timepoints may be reported. Each timepoint may only be reported once.

If the product is analyzed upon arrival at the receiving transplant center, and the product is not manipulated or cryopreserved prior to infusion and no additional analyses are performed, then the timepoint of analysis should be reported as "at infusion" instead of "product arrival."

The "at infusion" timepoint should only be reflective of the values specific to the actual product volume infused. Therefore, if analysis was performed on the entire product but only a portion of the product was infused, the "at infusion" values reported should represent the values of only the portion of product infused. If the product analysis values of the entire product are known and the values specific to only the volume of product infused cannot be determined, then the "at infusion" product analysis timepoint values should not be reported.

> **Example 1 – entire product infused:** The entire product is analyzed at arrival and does not undergo any manipulation, cryopreservation or additional analyses. The entire product volume is infused. The values from the product analysis should be reported for the "at infusion" timepoint because they reflect the values of the product infused.

Example 2 – portion of product infused: The entire product is analyzed prior to infusion and the values from this analysis are reflective of the entire product. Only a portion of this product is infused. The counts specific to the volume of product infused are unknown. In this case, the "at infusion" product analysis timepoint should be left blank. The results of the analysis performed on the entire product should be reported for the appropriate timepoint (e.g. product arrival, post-processing / manipulation, post-thaw, or post-manipulation).

- **Product arrival**: Receipt of *fresh product* at the transplant facility. Analysis may consist of TNC and volume, sterility and/or phenotype.
- **Post-processing, pre-cryopreservation/manipulation:** Assessment of *fresh product* at time of cryopreservation or prior to manipulation.
- **Post-thaw:** After the product has been thawed, but prior to any post-thaw manipulation. Analysis may consist of TNC and volume, and/or phenotype. Report post-thaw values if not the same as "at infusion" values.
- **Post-manipulation:** For fresh products. Report post-manipulation values if not the same as "at infusion" values.
- **At infusion:** *Must be reported if values specific to the volume of product infused are known.* If direct thaw, without counts or flow analysis, may be the same as "Post-processing, pre-cryopreservation/manipulation." If this is the case, only report the values once under the "at infusion" timepoint. If the product was manipulated after thawing, report the analysis under the "at infusion" timepoint.

Questions 142 & 163: Date of product analysis
Report the date of the product analysis for each timepoint reported.

Questions 143 & 164: Total volume of product
Enter the total volume of the product in the bag(s) for each timepoint. Report the volume in either milliliters (mL) or grams (g).

NOTE: Reporting Cell Counts
Report the absolute values (total cells, not cells per mL). If a laboratory reports cells per mL, multiply by volume in mL to get total cells. The exponent fields provided on the form are intended to reduce errors resulting from shifting the decimal. Report the data as it appears on the laboratory report.

Lab Conversion Examples:

NC	Nucleated Cell Count	(cells x 10^6/ml)		150.0 x 10^6/ml
Volume	ml or gm	---		250ml
TNC	Total Nucleated Cells	(NC)(Vol)		37500 x 10^6
MNC	Mononucleated Cells	(TNC)(% lymph + % mono)		35625 x 10^6
		% lymphs = 80% = 0.80	% monos = 15% = 0.15	
		(37500 x 10^6)(0.95)		
Nucleated RBC	Nucleated Red Blood Cells	(TNC)(% Nucleated RBC)		1850 x 10^6
		% Nucleated RBC = 5% = 0.05		
		(37500 x 10^6)(0.05)		
CDxx	Immunophenotyping	(TNC)(% Region Analyzed)(CDxx)		19960.3 x 10^6
		% Region Analyzed = 75.50% = .755	%CDxx = 70.50% = .705	
		(37500 x 10^6)(.755)(.705)		

Questions 144-150 & 165-171
For each of the cell counts listed, report the value as documented on the laboratory report. If the product is contained in **multiple bags**, add the cell counts from each bag to get the total cell count.

Questions 151 &172: Viability of cells
Enter the percentage of viable cells. If your center's laboratory assay only measures viable cells, report the number of viable cells in question 144-150 along with a viability number of 100% in question 151. If the assay measures all cells and then checks viability, report the total number and report the percent of cells that are viable.

If the product is contained in **multiple bags**, report the average viability of all bags.

Questions 152 &173: Method of testing cell viability
Indicate the cell viability testing method used.

Questions 153 &174: Specify other method
Specify the other method used for viability testing.

Questions 154 & 175: Were the colony-forming units (CFU) assessed after thawing *(cord blood product only)*?
CFUs have been shown to be a predictor of engraftment. Indicate whether CFUs were assessed after thawing.

Questions 155 &176: Was there growth?
If CFUs were assessed after thawing, indicate whether growth was detected.

Questions 156 &177: Total colonies per product
Report the total number of colonies detected per product. Report the total CFU as documented on the laboratory report. Do not report CFU per dish, per bag or per Kg.

To determine the **total # of CFU in the product**, divide the total number of cells in the cord blood product by the number of cells plated. Then, multiply the result by the average number of CFU.

Example:

	5×10^8 TNC	Total number of cells in cord blood product
÷	10,000/plate or 1×10^4 TNC	Number of cells plated
=	5×10^4	
x	100†	Average number of CFUs
=	$5x10^6$	Total number of CFU in product
† Plate 1: 95, Plate 2: 105, Plate 3: 100; 95 + 105 + 100 = 300 ÷ 3 = 100 average of three plates		

Questions 157 &178: Total CFU-GM
Report the total CFU-GM. The “GM” stands for “granulocytes and monocytes.”

Questions 158 & 179: Were cultures performed before the infusion to test the product(s) for bacterial or fungal infection? *(complete for all cell products)*
If cultures were performed, check “yes” and continue with question 159 and/or 180.

If cultures were not performed, check “no” and continue with question162 and/or 183.

Questions 159 & 180: Specify results
If a **single product** was split into multiple bags and one or more bags are contaminated, then all bags should be considered contaminated for the purposes of reporting data to the CIBMTR.

If **multiple products** are infused, and only one product is contaminated, then report the infection on the Form 2006 for the product that was contaminated (i.e. the un-infected product will be reported on a separate Form 2006).

If cultures were performed prior to infusion, indicate the results as "positive," "negative," or "unknown."

Questions 160 & 181: Specify organism code(s)
From the list provided on page 9 of the paper form, or from the drop-down box in the FormsNet2™ application, indicate the organisms detected.

Questions 161 & 182: If code 198, 209, 219, or 259, specify organism
Specify the "other" organisms detected.

Product Infusion

Question 183: Was more than one product infused? (e.g., marrow and PBSC, PBSC and cord blood, two different cords, etc.)
Indicate if more than one product was infused. Multiple bags from the same collection are not considered different products, and should not be reported here.

Question 184: Was the product infusion described on this insert intended to produce hematopoietic engraftment?
If an infusion of additional cells (not intended to produce engraftment) was given prior to the actual HSCT (i.e. clinical day 0), the cells must be reported as a product on the Pre-TED Form 2400 and on a separate Form 2006. If the additional cells were infused after the actual HSCT, for **any reason** other than those pertaining to the original HSCT graft, they should be reported as a DCI on the appropriate follow-up form. Reporting the additional cells (given pre-HSCT and not intended to produce engraftment) on the Form 2006 is the only mechanism the CIBMTR has in place to collect this data and ensure that the quality assurance data is reported to cord blood banks, if applicable.

If the product reported on this form was intended to produce engraftment, check "yes." If the product was not intended for engraftment, check "no."

Question 185: Date of this product infusion
Report the date the infusion of this product. If the product was infused over multiple days, see the "note" box below.

If this Form 2006 is completed for additional cells not intended to produce engraftment, (i.e. question 184 was reported as "no") report the date the additional cells were infused. However, the Key Field "Date of this HSCT" must be reported as date of the actual HSCT (clinical day 0) intended to produce engraftment.

NOTE: Questions 186-187 - Products infused over multiple days
If the product, for which this form is being completed, was infused over **multiple days**, report the date the infusion was started and the initiation time and completion time as documented in the recipient's medical record (i.e. transfusion record).

Example: Infusion began January 1, 2009 at 11:30 p.m. and was completed January 2, 2009 at 1:00 a.m.
Question 185: 01/01/2009
Question 186: 23:30, standard time
Question 187: 01:00, standard time

Question 186: Time product infusion initiated (24-hour clock)
Report the start time of the infusion. If multiple bags are infused, report the start time of the infusion of the product. Additionally, indicate whether the infusion start time was during daylight savings time, or standard time. For more information about daylight savings time schedules, go to http://www.worldtimezone.org/.

If **multiple products** were infused, enter the initiation time of **the product for which this form is being completed**.

If it takes longer than 24 hours to infuse the product, the start time should still be reported as instructed.

Question 187: Time product infusion completed (24-hour clock)
If **multiple bags** of the same product were infused, report the completion time of the last bag.

If **multiple products** were infused, enter the completion time of **the product for which this form is being completed**.

If the total infusion time was greater than 24 hours, the completed time should still be reported as instructed.

Enter the completion time of the infused product and indicate whether the time reflects daylight savings or standard time. For more information about daylight savings time and schedules, go to http://www.worldtimezone.org/.

Question 188: Total volume of product plus additives infused
Report the total volume of the infused product, including any additives.

In most cases, this value will be the same as the "total volume of product" (question 143/164) for the "at infusion" timepoint (question 141/162). If the entire product is not infused, the answer to question 199 should be "no."

The total volume reported may be from pooled products. If products are pooled prior to infusion, report the total volume of the pooled product that was infused. It is important to be aware that the timing of the pool determines how the data is reported. See the examples below.

> **Example 1 – with manipulation:** If a single product consisted of two collections and the products were pooled prior to any manipulation (e.g. CD34+ selection), the pooled volume prior to manipulation would be reported in question 143/164 only. The final infused product volume post manipulation would be reported in question 188.
>
> **Example 2 – without manipulation:** If a single product consisted of two collections and the products were pooled and infused without any manipulation, the total volume would be reported in question 143/164 and question 188. These volumes should be the same unless there were additives post pooling.

Questions 189-190: Specify the route of product infusion
Indicate the route of product infusion. For many years, the only route has been IV. If not documented otherwise, IV can be assumed to be the method used.

Question 191: Did the volume of infused product include any added agents?
Report any agents that were added to the product after thawing and/or after receipt of the product at the transplant center.

If the volume of the infused product included added agents, check "yes" and continue with question 192.

If the volume of the infused product did not include added agents, check "no" and continue with question 199.

The difference between this question and question 14 (Were anticoagulants added to the product during collection?) is that this question is intended to capture agents added to the product after the arrival of the product at the receiving transplant center. Whereas, the intention of question 14 is to cover the time period between collection and processing, prior to cryopreservation or shipment of the product.

Example: A fresh product is received at your transplant center. The stem cell processing laboratory adds an anticoagulant and then cryopreserves the entire product. Report "no" for question 14, and "yes" for question 191.

Question 192-198: Specify agent(s) added
Specify all agents added to the product.

Include products that do not fall under the specified categories in the "other, specify" category. One example of an agent reported under "other, specify" would be the additive Normosol. Do not include agents used for cryopreservation in this "other, specify" field.

Question 199: Was the entire volume of product infused?
Indicate if the entire volume of the product was infused.

Questions 200-201: Specify what happened to the reserved portion
Report the outcome for any portion of the product that was not infused.

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 the signature lines at question 296.

Question 202: Were there any adverse events or incidents associated with the stem cell infusion?
Indicate whether any adverse events or incidents occurred as a result of the stem cell infusion. **Report all adverse events regardless of the grade or severity.**

If an adverse event occurred, check "yes" and continue with question 203. If an adverse event did not occur, check "no" and continue with question 266.

Questions 203-261: Specify the following adverse event(s)?
Indicate whether or not the listed adverse events were associated with the stem cell infusion. If an event occurred, answer the "required medical intervention" and "resolved" questions associated with that event. If an event did not occur, do not complete the associated questions.

Question 262: In the Medical Director's judgment, was the adverse event a direct result of the infusion?
Indicate if the Medical Director believes the adverse event(s) to be directly related to the infusion of the product.

Questions 263-265: Specify the most likely cause of the adverse event
From the options provided, indicate the most likely cause of the adverse event.

Donor Demographic Information

This Donor Demographic Information section (questions 266-281) is to be completed for all non-NMDP allogeneic donors. If the stem cell product was from an NMDP donor or an autologous marrow or PBSC donor, continue with the signature lines at question 296.

The following information regarding the demographics of the donor is important for donor safety outcomes. The CIBMTR and NMDP are public health authorities, and are authorized by law to collect information necessary to fulfill the legislated mandate to collect data needed to assess both recipient and donor outcomes.

If IRB decision prohibits reporting of any of the requested information, a donor consent form should be created to permit release of this information.

If any of the requested information is unavailable, indicate the answer as "unknown" if given as an option, or leave the field blank and either override the error in FormsNet2™, or write in "unknown" on the paper version of the form.

NOTE: Cord Blood Units
For questions 267-281 (excluding question 269), if the product is a cord blood unit, the term "donor" refers to the infant, not the mother.

Question 266: *Female donor only* – Was the donor ever pregnant?
If the donor has ever been pregnant, check "yes" and continue with question 267.

If the donor has never been pregnant, check "no."

If there is no documentation regarding whether or not the donor has ever been pregnant, check "unknown."

If the product is a cord blood unit, check "not applicable/cord blood unit"

Question 267: Specify number of pregnancies
Report the total number of pregnancies of the donor.

Question 268: Donor's blood type and Rh factor
Report the blood type and Rh factor of the donor.

Question 269: Did this donor have a central line placed?
If the donor had a central line placed during the donation process, check "yes" and continue with question 270.

If the donor did not have a central line, check "no."

If the product is a cord blood unit or marrow, check "not applicable, cord blood unit or marrow product."

Questions 270-271: Specify the site of the central line placement
Indicate the location of the donor's central line. If "other site" is selected, complete question 271 specifying the other site location.

Question 272: Donor's ethnicity
Indicate the donor's ethnicity. For more information regarding ethnicity, see Appendix I.

Question 273: Donor's race *(Mark the group(s) in which the donor is a member. Check all that apply.)*
Indicate the race of the donor, marking all that apply. For more information regarding race, see Appendix I.

Question 274: What is the relationship of the donor to the recipient?
Indicate the relationship of the donor to the recipient.

If "other relative" is selected, continue to question 275.

Questions 275-276: Specify the relationship of the donor to the recipient
For the purposes of this manual, the CIBMTR defines the term "relative" as a biologically related individual. From the list provided, select the relationship of the donor to the recipient. If "other relative" is select, specify the relationship.

Question 277: Was the donor/product tested for potentially transplantable genetic diseases?
If the donor and/or product were tested for genetic disease, check "yes." If the donor and/or product were not tested or if there is no documentation of genetic testing, check "no" or "unknown" respectively and continue with question 282.

Questions 278-281: Specify disease(s) tested
For each of the diseases listed, indicate whether testing was done. If "other" is reported as "yes," specify the disease.

The following questions 282-295 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 296.

Question 282: Was the donor hospitalized (inpatient) during or after the collection?
Indicate if the donor was hospitalized during or after the collection for any reason.

Question 283: Did the donor experience any life-threatening complications during or after the collection?
Examples of life-threatening complications include, but are not limited to the following:

- Allergic reaction to filgrastim
- Reaction to anesthesia
- PBSC donors: Low platelet counts (<30,000)
- Marrow donors: Injury to bone, nerve or muscle during collection

If the donor experienced life-threatening complications during or after the collection, check “yes.”

If the donor did not experience life-threatening complications during or after the collection, check “no” and continue with question 285.

Question 284: Specify complications
Specify any life-threatening complications that the donor experienced during or after the collection.

Question 285: Did the donor receive blood transfusions as a result of the collection?
If the donor received blood transfusions as a result of the collection, check “yes” and continue with question 286. If the donor did not receive any transfusions, select “no” and continue with question 290.

Question 286: Was the blood transfusion product autologous?
Indicate if the donor’s blood transfusion product was autologous. Often autologous units are drawn from the donor before donation in case the donor needs to be given blood after the collection.

Question 287: Specify number of units
Specify the number of autologous transfusion units the donor received as a result of collection.

Question 288: Was the blood transfusion product allogeneic (homologous)?
Indicate if the donor’s blood transfusion product was allogeneic.

Question 289: Specify number of units
Specify the number of allogeneic transfusion units the donor received as a result of collection.

Question 290: Did the donor die as a result of the collection?
If the donor died as a result of the collection, check "yes" and continue with question 297. If the donor did not die as a result of the collection, check "no" and continue with question 298.

Question 291: Specify cause of death
Specify the donor's cause of death if the donor died as a result of the collection.

Questions 292-293: *Related donors only* – Did the recipient submit a research sample?
There are seven transplant centers participating in the Related Specimen Repository. If your center is one of the participating centers, and the recipient provided a research sample, check "yes" and provide the recipient ID. The ID number is located on the bar code that is attached to the sample tube.

If the recipient did not provide a research sample, check "no" and continue with question 294.

Questions 294-295: *Related donors only* – Did the donor submit a research sample?
If the donor provided a research sample, check "yes" and provide the donor ID.

If the donor did not provide a research sample, check "no" and continue with question 294.

Attachment 1: Single Product, Received Fresh

Question		Product Handling			
		No manipulation	**Whole Product Manipulated**	**Split Processing (Multiple Bags or 1 bag split into portions, i.e, CD34 selected)**	**Portion Reserved (multiple bags, one or more frozen for later use)**
	(12) More than one collection?	Indicate "YES" if there was	Indicate "YES" if there was	Indicate "YES" if there was	Indicate "YES" if there was
	>(13) Number of other days	If "YES", indicate number of additional days	If "YES", indicate number of additional days	If "YES", indicate number of additional days	If "YES", indicate number of additional days
	(31) Fresh Rec'd, then cryo? Note: Generally applies only to Allo	Not common. Reply YES if frozen on receipt. Note: YES would indicate a protocol deviation for NMDP Products.	Not common. Reply YES if frozen on receipt. Note: YES would indicate a protocol deviation for NMDP Products.	Not common. Reply YES if frozen on receipt. Note: YES would indicate a protocol deviation for NMDP Products.	Not common. Reply YES if frozen on receipt. Reply YES only if portion infused is first frozen. If product for this transplant is infused fresh, and a portion is cryopreserved, then check NO here, and YES in Q199 Note: YES would indicate a protocol deviation for NMDP Products.
	(32) Product Thawed?	NO, unless Q31 is YES	NO, unless Q31 is YES	NO, unless Q31 is YES	NO, unless Q31 is YES
	>(33) Entire Product Thawed?	N/A	N/A	N/A	N/A
	(35) Multiple Bags?	N/A	N/A	N/A	N/A
	>(36) Specify Number	N/A	N/A	N/A	N/A
	(44) Product Manipulated?	NO	YES	YES	Answer as appropriate for the *infused portion.*
	>(45) Portion Manipulated	N/A	ENTIRE	PORTION	PORTION
	>(46-91) Specify Manipulation	N/A	Specify manipulations done	Specify all manipulation done to all parts. Eg: if the component parts are manipulated differently, check all boxes for manipulations applied to ANY part.	Specify manipulations done
	For the analysis sections (Q141-182), combine values from all components of *this product* when reporting.				
	Analysis @ Arrival	Report if available	Report if available	Report if available. Combine values from all components.	Report if available
	Analysis Post Process, Pre-Cryo	Report if different from Arrival	Report if different from Arrival	Report if different from Arrival. Combine values from all components.	Report if different from Arrival
	Analysis Post-Thaw	N/A	N/A	N/A	N/A
	Analysis Post Manipulation	N/A	Report if different from At Infusion.	Report if different from At Infusion. Combine values from all components.	Report if different from at infusion.
	Analysis @ Infusion (Required)	Report all values on the infused product. REQUIRED	Report all values on the infused product. REQUIRED	Report all values on the infused product. Combine values from all components. REQUIRED	Report all values on the infused product. REQUIRED
	(183) >1 Product infused	NO	NO	NO	NO
	(186) Time Infusion Started	Record Start of first bag/portion	Record Start of first bag/portion	Record Start of first bag/portion	Record Start of first bag/portion
	(187) Time Infusion Ended	Record end of last bag/portion	Record end of last bag/portion	Record end of last bag/portion	Record end of last bag/portion
	(199) Entire Vol Infused?				NO
	>(200) Fate of Rest				Specify Fate

Attachment 1, continued: Single Product, Received Fresh

Question		Product Handling		
		All infused	**Portion of one product reserved**	**Pooled prior to analysis**
	(12) More than one collection?*	YES	YES	YES
	>(13) Number of other days	Indicate number of additional days. Complete a 2006 for each product.	Indicate number of additional days. Complete a 2006 for each product.	Indicate number of additional days. Complete a 2006 for each product.
	(31) Fresh Rec'd, then cryo?	Not common. Reply YES if frozen on receipt for *this product*. Note: YES would indicate a protocol deviation for NMDP Products.	Not common. Reply YES if frozen on receipt. Note: YES would indicate a protocol deviation for NMDP Products.	Not common. Reply YES if frozen on receipt. Note: YES would indicate a protocol deviation for NMDP Products.
	(32) Product Thawed?	NO, unless Q31 is YES	NO, unless Q31 is YES	NO, unless Q31 is YES
	>(33) Entire Product Thawed?	N/A	N/A	N/A
	(35) Multiple Bags?	Answer this specific to *this product.*	Answer this specific to *this product.*	Answer this specific to *this product.*
	>(36) Specify Number			
	(44) Product Manipulated?	Indicate if manipulation was done for *this product.*	Indicate if manipulation was done for *this product.*	Indicate if manipulation was done for *this product.*
	>(45) Portion Manipulated	Indicate portion manipulated for *this product*.	Indicate portion manipulated for *this product*.	Indicate portion manipulated for *this product*.
	>(46-91) Specify Manipulation	Specify manipulations done for *this product.*	Specify manipulations done for *this product.*	Specify manipulations done for *this product.*
	For the analysis sections(Q141-182), combine values from all components of *this product* when reporting.			
	Analysis @ Arrival	Report if available. Only report info for *this product.*	Report if available. Only report info for *this product.*	Report if available. Only report info for *this product.*
	Analysis Post Process, Pre-Cryo	Report if different from Arrival. Only report info for *this product.*	Report if different from Arrival. Only report info for *this product.*	Report if different from Arrival. Only report info for *this product.*
	Analysis Post-Thaw	N/A	N/A	N/A
	Analysis Post Manipulation	Report only the values for *this product.* Report if different from At Infusion.	Report only the values for *this product.* Report if different from At Infusion.	Report the pooled counts on the 2006 for *both* products (counts on all forms should be identical). Report if different from At Infusion.
	Analysis @ Infusion (Required)	Report only the values for *this product.*	Report only the values for *this product.*	Report the pooled counts on the 2006 for *both* products (counts on all forms should be identical).
	(183) >1 Product infused	YES	YES	YES
	(186) Time Infusion Started	Record start of first bag/portion for *this product.*	Record start of first bag/portion for *this product.*	Record start of first bag/portion for *the pooled product.*
	(187) Time Infusion Ended	Record end of last bag/portion for *this product.*	Record end of last bag/portion for *this product.*	Record end of last bag/portion for *the pooled product.*
	(199) Entire Vol Infused?	YES	NO for each product where a portion was reserved, YES for the rest	Probably YES
	>(200) Fate of Rest	N/A	Specify Fate	N/A

*Please note, this question refers to the whole HSCT, and not the product, so the answer would need to be YES for all multiple products, because there would have at least been a collection for each product. Q13 should refer to all collections for all products minus 1.

Attachment 2: Single Product – Received Frozen or Remainder from Previous Infusion*

Question		Product Handling			
		No manipulation	**Whole Product Manipulated**	**Split Processing (Multiple Bags or 1 bag split into portions, i.e, CD34 selected)**	**Portion Reserved (multiple bags, one or more frozen for later use)**
	(12) More than one collection?	Indicate "YES" if there was	Indicate "YES" if there was	Indicate "YES" if there was	Indicate "YES" if there was
	>(13) Number of other days	If "YES", indicate number of additional days	If "YES", indicate number of additional days	If "YES", indicate number of additional days	If "YES", indicate number of additional days
	(31) Fresh Rec'd, then cryo?	YES for remainder, NO for products rec'd frozen	YES for remainder, NO for products rec'd frozen	YES for remainder, NO for products rec'd frozen	YES for remainder, NO for products rec'd frozen
	(32) Product Thawed?	YES	YES	YES	YES
	>(33) Entire Product Thawed?	Answer as appropriate. Answer the rest of the questions based on *thawed* portion only if not all thawed.	Answer as appropriate. Answer the rest of the questions based on *thawed* portion only if not all thawed.	Answer as appropriate. Answer the rest of the questions based on *thawed* portion only if not all thawed.	NO-Answer the rest of the questions based on *thawed* portion only if not all thawed.
	(35) Multiple Bags?	N/A	N/A	N/A	N/A
	>(36) Specify Number				
	(44) Product Manipulated? *By your team post-thaw	NO	YES	YES	Answer as appropriate for the *infused product.*
	>(45) Portion Manipulated	N/A	ENTIRE	PORTION	Answer as appropriate for the *infused product.*
	>(46-91) Specify Manipulation	N/A	Specify manipulations done	Specify all manipulation done to all parts. Eg: if the component parts are manipulated differently, check all boxes for manipulations applied to ANY part.	Specify manipulations done
	For the analysis sections(Q141-182), combine values from all components of *this product* when reporting.				
	Analysis @ Arrival	N/A	N/A	N/A	N/A
	Analysis Post Process, Pre-Cryo	Report if done at your site and different from at infusion.	Report if done at your site and different from at infusion.	Report if done at your site and different from at infusion. Combine values from all components.	Report if done at your site and different from at infusion.
	Analysis Post-Thaw	Report if done at your site and different from at infusion.	Report if done at your site and different from at infusion.	Report if done at your site and different from at infusion. Combine values from all components.	Report if done at your site and different from at infusion.
	Analysis Post Manipulation	N/A	Report if different from At Infusion.	Report if different from At Infusion. Combine values from all components.	Report if different from At Infusion.
	Analysis @ Infusion (Required)			Combine values from all components.	
	(183) >1 Product infused	NO	NO	NO	NO
	(186) Time Infusion Started	Record Start of first bag/portion	Record Start of first bag/portion	Record Start of first bag/portion	Record Start of first bag/portion
	(187) Time Infusion Ended	Record end of last bag/portion	Record end of last bag/portion	Record end of last bag/portion	Record end of last bag/portion
	(199) Entire Vol Infused?				NO
	>(200) Fate of Rest				Specify fate

* Treat remainders of a product from a previous infusion as the "whole" product.

Attachment 3: Multiple Products, Received Frozen or Remainder from Previous Infusion*

Question		Product Handling		
		All infused	**Portion of one product reserved**	**Pooled prior to analysis**
	(12) More than one collection?	YES	YES	YES
	>(13) Number of other days	Indicate number of additional days. Complete a 2006 for each product.	Indicate number of additional days. Complete a 2006 for each product.	Indicate number of additional days. Complete a 2006 for each product.
	(31) Fresh Rec'd, then cryo? Note: Generally applies only to allo	YES for remainder, NO for products rec'd frozen	YES for remainder, NO for products rec'd frozen	YES for remainder, NO for products rec'd frozen
	(32) Product Thawed?	YES	YES	YES
	>(33) Entire Product Thawed?	YES	NO--Answer on *thawed* portion only if not all thawed.	YES
	(35) Multiple Bags?	Answer this specific to *this product.*	Answer this specific to *this product.* Answer on *thawed* portion only if not all bags thawed (i.e., read question as "Were there multiple bags *thawed*?")	Answer this specific to *this product.*
	>(36) Specify Number			
	(44) Product Manipulated? *by your team post-thaw	Indicate if manipulation was done to *this product.*	Indicate if manipulation was done to *this product.*	Indicate if manipulation was done to *this product.* If pooled prior to manipulation, the 2006 for each product should reflect the same information.
	>(45) Portion Manipulated	Indicate portion manipulated for *this product.*	Indicate portion manipulated for *this product.*	Indicate portion manipulated for *this product.*
	>(46-91) Specify Manipulation	Specify manipulations done for *this product.*	Specify manipulations done for *this product.*	Specify manipulations done for *this product.*
	For the analysis sections(Q141-182), combine values from all components of *this product* when reporting.			
	Analysis @ Arrival	N/A	N/A	N/A
	Analysis Post Process, Pre-Cryo	Report if done at your site and different from at infusion.	Report if done at your site and different from at infusion.	Report if done at your site and different from at infusion.
	Analysis Post-Thaw	Report if done at your site and different from at infusion.	Report if done at your site and different from at infusion.	Report if done at your site and different from at infusion.
	Analysis Post Manipulation	Report only the values for *this product.* Report if different from At Infusion.	Report only the values for *this product.* Report if different from At Infusion.	Report the pooled counts on the 2006 for *both* products. Report if different from At Infusion.
	Analysis @ Infusion (Required)	Report only the values for *this product.*	Report only the values for *this product.*	Report the pooled counts on the 2006 for *both* products.
	(183) >1 Product infused	YES	YES	YES
	(186) Time Infusion Started	Record start of first bag/portion for *this product.*	Record start of first bag/portion for *this product.*	Record start of first bag/portion for *this product.*
	(187) Time Infusion Ended	Record end of last bag.portion for *this product.*	Record end of last bag.portion for *this product.*	Record end of last bag.portion for *this product.*
	(199) Entire Vol Infused?	YES	NO for all products where a portion was reserved, YES for the rest	
	>(200) Fate of Rest	N/A	Specify Fate	

* Treat remainders of a product from a previous infusion as the "whole" product.