2006: Hematopoietic Stem Cell Transplant (HCT) Infusion

Centers must complete the Form 2006 for each product when the recipient is assigned to the **Comprehensive Report Form track**. Centers must also complete the Form 2006 for the following product types when the recipient is assigned to the **Transplant Essential Data track**:

- NMDP donor products
- NMDP and non-NMDP cord blood units
- Any product co-infused with a cord blood unit

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, Center Type and Data Collection Forms.

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

If more than one type of HCT product is infused, ***each product type*** must be analyzed and reported on a ***separate*** form. For example, the scenarios below require two 2006 forms, one for each product:

- Two different products from the same donor (i.e., PBSC and bone marrow)
- A co-infusion of two products (i.e., haplo donor PBSC and CBU)

However, a series of collections from the same donor that uses the same collection method and mobilization cycle, even if the collections are performed on different days, **should be considered a single product**.

For more information see Appendix D and Appendix E.

Manual Updates:

Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please click here or reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/ Remove/ Modify	Description
6/21/ 2021	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	The Product Processing as Part of Cryopreservation red box above question 33 was updated: ***Product Processing as Part of Cryopreservation****: Product processing performed as part of the cryopreservation process should not be reported as a separate process. For example, plasma reduction / removal or buffy coat enrichment performed as part of the cryopreservation process should not be reported as product processing.*
6/21/ 2021	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	The blue box above question 58 was added: ***Viability Testing****: When reporting the viability, it is important to consider the sample source used for viability testing. If viability is performed on the entire product, report the viability for the Total Nucleated Cells (TNC) and not the individual cell types (i.e., CD34+, CD3+). However, if viability was performed only on select cell types (i.e., viability was performed on both the CD34+ and CD3+ cells), then report the viability for both CD34+ and CD3+. Similarly, if a product is CD34+ selected and viability is performed on the product post-manipulation, the viability should only be reported for CD34+ cells.*
5/5/ 2021	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	The following instructions were added for buffy coat enriched for question question 33: ***Buffy coat enriched****: Buffy coat enrichment is performed to reduce/remove mature erythrocytes and plasma. Buffy coat enrichment performed as part of the cryopreservation process should not be reported as product processing.*
5/5/ 2021	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	Red warning box added above question 33: ***Product Processing as Part of Cryopreservation****: Product processing performed as part of the cryopreservation process should not be reported as a separate process. For example, plasma reduction / removal performed as part of the cryopreservation process should not be reported as product processing.*
3/9/ 2021	2006: Hematopoietic Stem Cell Transplant (HCT)	Add	Product Processing blue note box added above question 33: ***Product Processing****: Wash and dilution, both which generally apply to cord blood units, are now included as processing options, though they may not be classified as such by laboratories. If dilution is performed as part of washing, dilution should not need be reported. Only report the primary procedure. See*

	Infusion		*the Steps in Manipulation note box below.*
3/8/2021	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	The following information was added to question 153: *It should be noted for cord blood unit transplants that almost all units are screened, or the infant is screened, for potentially transplantable genetic diseases. This may be documented as a 'hemoglobin screen,' which evaluates for sickle cell and/or thalassemia, both of which are hemoglobinopathies.*
3/8/2021	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	Instructions on how to report the date of product analysis, depending on if the the product was analyzed multiple times and examples 1 – 3 were added to question 42.
3/8/2021	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	Added the following statement to question 41: *The At Infusion timepoint should include values reflective of the product infused regardless of when the analysis occurred. Since all products are analyzed prior to cryopreservation, the At Infusion timepoint would be applicable for these cell counts. Depending on the product type and your center's practice, viability may be assessed closer to the time of infusion.*
3/8/2021	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	Example 1 added to questions 2-3: *Example 1: The donor was mobilized with Granix (tbo-Filgrastim) prior to the start of collection. Since this is a biologic medical product that is highly similar to Neupogen, this would be captured under G-CSF.*
12/22/2020	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	The blue note box in question 31 was updated: *In the new revision of the HCT Infusion (2006) Form, product processing and manipulation have been separated into two categories for reporting purposes.* *Product Processing: Captures changes made to the original product that does not affect the physical properties of the product* *Product Manipulation: Captures changes made to the original product affecting the physical properties of the product ~~with the intent to provide additional GVHD prophylaxis~~*
8/21/2020	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	Updated the following note box (above Q159) to clarify the intent of Q159-170: *The following questions (~~160~~ 159 -170) apply only to non-NMDP 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 at the end of the form.*
6/3/	2006:	Added	Provided clarification to questions 1, 4, and 5 that these questions are only

2020	Hematopoietic Stem Cell Transplant (HCT) Infusion		enabled for PBSC and bone marrow products from non-NMDP donors.
5/19/2020	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	For question 13, specified that a constant temperature is usually found in ***cord blood*** **shipping containers**.
4/6/2020	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	In section Q144-170: Donor/Infant Demographic Information, moved question 147 to question 159.
3/23/2020	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	Added guidance to questions 46 – 47, 58-59, 64-65, 70-71, and 76-77 regarding scenarios where center's laboratory assay only measures viable cells.
2/27/2020	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	Updated the text for questions 163-165 as indicated below (removed text is struck out and added text is in red): *If the ~~recipient~~ donor did not give autologous blood transfusion units, select "no" and continue with question 166.*
1/24/2020	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	Version 4 of the 2006: Hematopoietic Stem Cell Transplant (HCT) Infusion section of the Forms Instruction Manual released. Version 4 corresponds to revision 5 of the Form 2006.

Last modified: May 06, 2022

Q1-3: Pre-Collection Therapy

This section of the HCT Infusion (2006) form captures pre-collection therapy information regarding the donor's mobilization or priming; this section of the form is not completed for cord blood units or products from NMDP donors.

Question 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*)

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. The purpose of the agent is to move the stem cells from the bone marrow into the peripheral blood where the cells can be collected by apheresis. This practice is often referred to as mobilization or priming. Occasionally, a donor may be primed using a growth factor prior to collection of bone marrow.

If the Allogeneic donor received therapy (such as growth factors, mobilizing agents, etc.), select "yes" and continue with question 2.

If the Allogeneic donor did not receive therapy to enhance the stem cell product, select "no" and continue with question 4.

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

Questions 2-3: Specify growth and mobilizing factor(s)

Examples of growth and mobilizing 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

Report if any of the following growth or mobilizing factors were given. Check all that apply.

G-CSF (granulocyte-colony stimulating factor, **filgrastim**, **Neupogen®**)

Pegylated G-CSF (**pegfilgrastim**, **Neulasta®**)

Plerixafor (**Mozobil®**)

If a growth or mobilizing factor was given is not included in the above list, select “other growth or mobilizing factor(s)” for question 2 and specify the generic name for the growth or mobilizing factor in question 3.

Example 1: The donor was mobilized with Granix (tbo-Filgrastim) prior to the start of collection. Since this is a biologic medical product that is highly similar to Neupogen, this would be captured under G-CSF.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q2-3	3/8/ 2021	Add	Example 1 added: *Example 1: The donor was mobilized with Granix (tbo-Filgrastim) prior to the start of collection. Since this is a biologic medical product that is highly similar to Neupogen, this would be captured under G-CSF.*	Not applicable

Last modified: May 05, 2021

Q4-7: Product Collection

NOTE: Multiple collections versus multiple products
This form collects information for a single product. PBSC collected from a single mobilization event (a mobilization event is the planned administration of growth factors or systemic therapy designed to enhance stem cell collection), even when collected over several days, is considered one product.
Multiple products are collected when, for example, the donor requires another mobilization to collect a product at a later date. The collection from the second mobilization event is considered a different product and should be reported on an additional 2006 form.

Question 4: Date of first collection for this mobilization:

Report the date the stem cell collection was performed. If a 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. The collected cell counts were poor and no further collections were attempted. One week later the donor was re-mobilized with G-CSF and a second PBSC collection was performed. Due to the recipient having two mobilization events, this is considered two separate products, and two Form 2006s should be submitted. The date of product collection should be the first day of collection of the mobilization event for which the form is being completed.

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

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

If anticoagulants or other agents were added to the product between collection and infusion, select “yes” and continue with question 6. Anticoagulants are typically documented on the product bag label. Anticoagulants are often added to PBSC products.

If anticoagulants or other agents were not added to the product between collection and infusion, select “no” and continue with question 8.

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

Questions 6-7: Specify anticoagulant(s): (check all that apply)

Report if any of the following anticoagulants were added to the reported product. Check all that apply.

Acid citrate dextrose (ACD, ACD-A)

Citrate phosphate dextrose (CPD, CPD-A)

Ethylenediaminetetraacetic acid (EDTA)

Heparin

If an anticoagulant added to the product is not listed on the form, check “other” for question 6, and specify the anticoagulant’s name in question 7.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Dec 22, 2020

Q8-21: Product Transport and Receipt

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

If the product was shipped to the transplant center or contracted lab from an off-site collection center, select “yes.” In general, the “yes” option will 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 not** shipped to the transplant center or contracted lab from an outside facility, or if the product **was** collected onsite then shipped off-site for laboratory processing, select “no” and continue with question 22. The “no” option usually applies to autologous collections and related donors.

> **NOTE: Contracted Labs**
> In scenarios where a contracted lab does the actual collection, please indicate “yes” for question 8 and complete questions 9-14 for when the product arrives at the transplant center.
> In scenarios where a contracted lab is used to process the product, the word “facility” can be substituted with “contracted lab” in questions 8 and 9.

Question 9: Date of receipt of product at your facility:

The intent of this question is to determine the date 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 arrived 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 10: Time of receipt of product (24-hour clock):

Enter the exact time your institution or off-site laboratory received and became responsible for the product. Report the time using a 24-hour clock and indicate if daylight savings time or standard time was in effect. If the location of your institution or off-site laboratory does not observe daylight savings time, report the time as standard time. For more information about daylight savings time schedules, go to http://www.timeanddate.com/time/dst/.

Questions 11-12: Specify the shipping environment of the product(s):

Indicate the shipping environment of the product. If the recipient’s product was shipped in a way other than

described on the list, select “other shipping environment” and specify the shipping environment in question 12. It is not necessary to provide the specific temperature of the product during shipment.

Question 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?

Indicate if there was any indication the environment within the shipper was outside the expected temperature range for this product at any time during shipment. For cord blood unit shipping containers, the temperature of the shipper is generally constant and tracked using a data-logger. Mishandling of the product shipper or spikes in temperature could impact the integrity of the product.

If there was any indication that the environment within the shipper was outside the expected temperature range upon arrival at your center, a product complaint form (Form 3010) must be completed.

Question 14: 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 product by your center.

If the secondary containers were not intact upon arrival, a product complaint form (Form 3010) must be completed.

If the product is a cord blood unit, continue with question 15. For all other products, continue with question 22.

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

If the cord blood unit was stored at your center prior to thawing, select “yes” and continue with question 16.

If the cord blood unit was not stored at your center prior to thawing, select “no” and continue with question 19.

Question 16: 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 17: 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 18: Date storage started:

Report the date the cord blood unit was first stored at your center prior to thawing.

NOTE: Questions 19 – 21
The values reported for questions 19 – 21 are from information provided for the unit by the cord blood bank. Report the absolute number of cells, not per mL or per kg.

Question 19: Total Nucleated cells: (Cord blood units only)

Report the total nucleated cells for the cord blood product. This information is available within the documentation received with the product shipment and from the search documentation performed to select the product. These values are from the Cord Blood Bank and should not represent post-thaw values assessed at your center's lab.

Questions 20-21: CD34+ cells: (Cord blood units only)

Indicate if the cord blood bank quantified CD34+ cells in the product. If the CD34+ cells were quantified, select "done" and report the total CD34+ cells for the cord blood product in question 21. This information is available within the documentation received with the product shipment and from the search documentation performed to select the product. These values are from the Cord Blood Bank and should not represent post-thaw values assessed at your center's lab.

If the CD34+ cells were not quantified by the cord blood bank, report "not done" and continue with question 22.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Dec 22, 2020

Q22-40: Product Processing / Manipulation

Question 22: Was the product thawed from a cryopreserved state prior to infusion?

If any portion of the product was thawed prior to this infusion, select “yes” and continue with question 23.

If the product was never cryopreserved, select “no” and continue with question 32.

Question 23: 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, the product could be stored in a 500mL bag with five 100mL cryopreserved compartments, or it could be stored in multiple separate product bags that have been cryopreserved.

If the entire product (all compartments or all product bags) was thawed, select “yes” and continue with question 26.

If the entire product was not thawed, select “no” and continue with question 24.

If this infusion is using “leftover” cells from a previous infusion, the “leftover” portion is now considered the entire product. Therefore, if all the “leftover” cells were thawed, select “yes.” If a portion of the “leftover” cells were not used and remain frozen, select “no.”

Question 24: Specify the percent of the product that was thawed? (Cord blood units only)

Indicate the percent of the product that was thawed. If the exact percent is not listed, specify the percent of the product that was thawed in question 25.

Question 26: Date thawing process initiated:

Report the date the thawing process began.

Question 27: Time at initiation of thaw (24-hour clock):

Report the time the product thaw began. Report the time using a 24-hour clock and indicate if daylight savings time or standard time was in effect. If the location of your institution or off-site laboratory does not observe daylight savings time, report the time as standard time. For more information about daylight savings time schedules, go to http://www.timeanddate.com/time/dst/.

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 28: Time of thaw completion (24-hour clock):

Report the time the product thaw is completed. Show the time using a 24-hour clock and indicate if daylight savings time or standard time was in effect. If the location of your institution or off-site laboratory does not

observe daylight savings time, report the time as standard time. For more information about daylight savings time schedules, go to http://www.timeanddate.com/time/dst/.

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 26. The exact time should be documented within the patient record or the stem cell laboratory processing record.

Question 29: What method was used to thaw the product?

Report the thawing method used to thaw the product. If a method other than “water bath” or “electric warmer” was used, select “other method” and specify the method in question 30.

Question 31: Did any incidents, or product complaints occur while preparing or thawing the product?

Indicate if any incidents occurred regarding the product during the thawing process.

If any product complaints were found while preparing or thawing the product, a product complaint form (Form 3010) must be completed. Possible complaints include, but are not limited to: broken bags, a clot in the product, or missing documentation used to identify the product.

Product Processing and Manipulation
In the new revision of the HCT Infusion (2006) Form, product processing and manipulation have been separated into two categories for reporting purposes.
Product Processing: Captures changes made to the original product that does not affect the physical properties of the product (e.g. plasma reduction, RBC reduction, wash)
Product Manipulation: Captures changes made to the original product affecting the physical properties of the product (e.g. ex-vivo T-cell depletion or CD34 selection)

Question 32: Was the product processed prior to infusion?

If any part of the product was processed in any way prior to infusion at the transplant center, select “yes.”

If the product was shipped to your facility, do not report processing of the product performed at the collection center.

If the product was not processed, select “no” and continue with question 34.

Product Processing
Wash and dilution, both which generally apply to cord blood units, are now included as processing options, though they may not be classified as such by laboratories. If dilution is performed as part of washing, dilution should not be reported as a product processing. Only report the primary procedure. See the Steps in Manipulation note box below.

Product Processing as Part of Cryopreservation
Product processing performed as part of the cryopreservation process should not be reported as a separate process. For example, plasma reduction / removal or buffy coat enrichment performed as part of the cryopreservation process should not be reported as product processing.

Question 33: Specify processing: (check all that apply)

Indicate the method(s) of stem cell processing.

Buffy coat enriched: Buffy coat enrichment is performed to reduce/remove mature erythrocytes and plasma.[1]

Buffy coat enrichment performed as part of the cryopreservation process should not be reported as product processing.

Diluted: Dilution is performed to reduce the cell concentration.[1]

Plasma reduced: Plasma reduction is performed to remove plasma via sedimentation or centrifugation.[1]

Plasma reduction / removal performed as part of the cryopreservation process should not be reported as product processing.

RBC reduced: RBC reduction is performed to reduce/remove mature erythrocytes from the product.[1]

Washed: Washing is performed to remove cryoprotectant (such as DMSO) from the product.[1]

[1]ISTB 128. Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions. ICCBBA ST-002. Version. 4.9. March 2012.

Question 34: Was the product manipulated prior to infusion?

If any part of the product was manipulated in any way prior to infusion at the transplant center, select “yes” and go to question 35.

If the product was shipped to your facility, do not report manipulation of the product performed at the collection center.

If the product was not manipulated, select “no” and continue with question 41.

Questions 35: Specify manipulations performed: (check all that apply)

Indicate the method(s) of stem cell manipulation. It is not necessary to report antibody used as part of CD34+ enrichment using the CliniMacs, Isolex, or Miltenyi devices.

If the product manipulation is ex-vivo expansion, genetic manipulation or CD34 enriched, continue to question 41.

If the product is ex-vivo T-cell depleted, continue to question 36.

> **Note: Steps in Manipulation**
> If the manipulation consists of several steps, individual steps do not need to be reported as separate manipulations. For example, T-cell depletion that is part of expansion does not need to be reported. In the case above, if T-cell depletion is done as a stand-alone manipulation, this should then be reported.

Ex-vivo expansion: Ex-vivo expansion is a method of culturing cells to "activate, expand, or promote development of a specified cell population in the presence of specific additive(s)." (ISBT, 2012)[1]

Genetic manipulation (gene transfer/transduction): Gene manipulation refers to any method used to modify the genes in the product cells. Gene transduction refers to the transfer of genes from one cell to another. Using genetic manipulation is still in the "research" stage.

CD34 enriched (CD34+ selection): CD34+ selection is a manipulation method also known as "positive selection." This method identifies and selects stem cells that have a CD34+ marker on the cell surface.

Ex-vivo T-cell depletion: T-cell depletion removes some or all of the T cells in an effort to minimize GVHD. Methods of T-cell depletion include antibody affinity column, antibody-coated plates, antibody-coated plates and soybean lectin, antibody + toxin, immunomagnetic beads, CD34 affinity column plus sheep red blood cell resetting, and T-cell receptor alpha / beta depletion.

If a method of manipulation was performed on the product, but is not listed above, select "other manipulation" for question 35 and specify the method in question 40. Do not report cryopreservation (or processing used in the cryopreservation process) as manipulation.

[1]ISTB 128. *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*. ICCBBA ST-002. Version. 4.9. March 2012.

Questions 36-37: Specify antibodies used: (check all that apply)

Specify the antibodies used for ex-vivo T-cell depletion. If antibodies were used during product manipulation, but are not listed above, select "other antibody" for question 36 and specify in question 37.

Questions 38-39: Specify T-cell depletion method:

Indicate the T-cell depletion method used during product manipulation. If the method used during manipulation is not listed above, select "other method" for question 38 and specify in question 39.

Question 40: Specify other cell manipulation:

If a method of manipulation was performed on the product, but is not captured above, specify the method in question 40. Do not report cryopreservation (or processing used in the cryopreservation process) as manipulation.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q33	6/21/ 2021	Modify	The Product Processing as Part of Cryopreservation red box above question 33 was updated: ***Product Processing as Part of Cryopreservation****: Product processing performed as part of the cryopreservation process should not be reported as a separate process. For example, plasma reduction / removal or buffy coat enrichment performed as part of the cryopreservation process should not be reported as product processing.*	Added for clarification
Q33	5/5/ 2021	Add	The following instructions were added for buffy coat enriched for question 33: ***Buffy coat enriched****: Buffy coat enrichment is performed to reduce/remove mature erythrocytes and plasma. Product processing performed as part of the cryopreservation process should not be reported as a separate process. For example, plasma reduction / removal or buffy coat enrichment performed as part of the cryopreservation process should not be reported as product processing.*	Added for clarification
Q33	5/5/ 2021	Add	Product Processing as Part of Cryopreservation red warning box added above question 33: ***Processing as Part of Cryopreservation*** *Product processing performed as part of the cryopreservation process should not be reported as a separate process. For example, plasma reduction / removal performed as part of the cryopreservation process should not be reported as product processing.*	Added for clarification
Q33	3/9/ 2021	Add	Product Processing blue note box added above question 33: ***Product Processing****: Wash and dilution, both which generally apply to cord blood units, are now included as processing options, though they may not be classified as such by laboratories. If dilution is performed as part of washing, dilution should not need be reported. Only report the primary procedure. See the Steps in Manipulation note box below.*	Added for clarification

Last modified: Jun 21, 2021

Q41-93: Product Analysis (All Products)

> **NOTE: Product Analysis Timepoints**
> Prior revisions of the HCT Product and Infusion (2006) Form (Revisions 1-4) have asked for product analysis values at multiple timepoints. In the new revision of the form, only the “At Infusion” timepoint is required for all product types, except cord blood units (CBUs). For CBUs, both the “At Infusion” and “At Arrival” timepoints are required.

Question 41: Specify the timepoint in the product preparation phase that the product was analyzed:

For all products, the “at infusion” timepoint must be reported. The “at infusion” timepoint should only report the values for the actual product volume infused.

The **At Infusion** timepoint should include values reflective of the product infused regardless of when the analysis occurred. Since all products are analyzed prior to cryopreservation, the **At Infusion** timepoint would be applicable for these cell counts. Depending on the product type and your center’s practice, viability may be assessed closer to the time of infusion.

For cord blood units, both a “product arrival” and an “at infusion” timepoint must be reported.

Cord Blood Units: Centers are reminded to only report product testing performed by their laboratory. Product testing performed by the cord blood bank is captured in the **Product Transport and Receipt** section of this form and should not be reported in the **Product Analysis** section. If the transplant center only tests for viability, report the timepoint, date of analysis, product volume, and viability.

Question 42: Date of product analysis:

Report the date the product was analyzed. For the “At Infusion” timepoint, if the product was analyzed multiple times after arriving at the transplant center, report the latest date the product was analyzed with the associated cell counts prior to infusion. **The date of product analysis is not necessarily the date of the product infusion.**

If a product is analyzed multiple times prior to product infusion, the type of product will determine which analysis to report for the At Infusion timepoint. See below for more information:

Fresh product: If an unmanipulated, fresh product was analyzed multiple times prior to infusion, the most recent complete analysis should be reported for the At Infusion timepoint.

Example 1: Upon receiving a fresh product, the transplant center completes a TNC, CD34, and viability analysis. The product was not manipulated but prior to infusion, a small sample was collected to analyze the viability. The analysis performed upon receiving the fresh product should be reported for the **At Infusion** timepoint.

Cryopreserved product: If a cryopreserved product is infused, 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, only 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 adjusted for the volume infused. In the rare scenario where a complete analysis performed post-thaw, this analysis should be reported for the **At Infusion** timepoint; however, this is unlikely as there is usually not enough product to perform a complete analysis post-thaw.

Example 2: Upon collecting an autologous PBSC product, the transplant center completes a TNC, CD34, and viability analysis. The product is separated into three bags and cryopreserved. Two of the three bags were thawed, the TNC and viability were analyzed, and the product was infused. The analysis performed upon collecting the product, adjusted for the two bags infused (the sum of volume and cell counts) should be reported for the **At Infusion** timepoint.

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

Example 3: Upon receiving a PBSC product, the transplant center completes a TNC, CD34, and viability analysis and then RBC reduced the product. After processing, the CD34 and viability are analyzed. 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.

Question 43: Total volume of product plus additives:

Enter the total volume of the product plus additives in the bag(s) for the timepoint. Report the volume in either milliliters (mL) or grams (g). For the “at infusion” timepoint, the total volume should be the actual volume given to the recipient.

Question 44-45: Report the total nucleated cells (TNC) (Includes nucleated red and nucleated white cells)

Report “done” if the TNC count was quantified at the specified timepoint. Report the absolute number of the cells, not cells per kg. If “done”, go to question 45. If the TNC was “not done,” go to questions 50.

> **NOTE:** Since total nucleated cells consist of both nucleated red and white blood cells, it is possible to calculate a missing value if the two other values are present on lab reports. Centers do not need to calculate and report these lab values if they don’t appear on the laboratory paperwork.

Occasionally, cell differential results may be “corrected” in order to remove cells such as nRBCs. The CIBMTR would like to have uncorrected data submitted in these fields. Some labs report corrected cell counts, others report uncorrected cells counts. Some even report both. If your lab report does not clearly indicate whether the TNC is corrected or uncorrected, ask someone in the lab to help you determine which is correct. This will most likely be the same every time, so you would not need to check for each patient. If this information is not clearly indicated on the lab report, please ensure this is somewhere in your center SOPs. If the only value available to you is the corrected TNC, you may calculate the uncorrected TNC with

the formula below. Please be sure to carefully check your math and the units reported to ensure that the information on the form is correct. To determine the uncorrected TNC count, use the following formula (Adapted from *Essential Laboratory Mathematics* by CW Johnson, DL Timmons, PE Hall (2003), pg 175.):

If the corrected WBC is in cells/mL:

$$\frac{(corrected\ WBC\ per\ mL) \times (volume\ of\ product) \times ((nRBCs\ per\ 100\ WBCs) + 100)}{100} = total\ uncorrected\ TNC$$

If the corrected WBC is in cells/kg:

$$\frac{(corrected\ WBC\ per\ kg) \times (recipient\ kg) \times ((nRBCs\ per\ 100\ WBCs) + 100)}{100} = total\ uncorrected\ TNC$$

If the corrected WBC is an absolute cell count:

$$\frac{(total\ corrected\ WBC) \times ((nRBCs\ per\ 100\ WBCs) + 100)}{100} = total\ uncorrected\ TNC$$

For example, if the corrected WBC is 17.96×106/mL, the product volume is 390 mL, and the nRBCs per 100 WBCs is 12.8 (using the formula above when considering cells/mL):

Questions 46-47: Viability of total nucleated cells:

If the viability of the total nucleated cells was quantified, select “done” and report the percentage of viable cells in question 47. If the viability was “not done” or “unknown” go to question 50. If your center’s laboratory assay only measures viable cells, report the number of viable cells in question 45, select “done” for question 46, and report a viability of 100% in question 47.

Questions 48-49: Method of testing cell viability:

Indicate the method of testing viability.

Flow cytometry based: 7-AAD (7-aminoactinomycin D) and Propidium iodide are compounds that can stain dead cells but will not cross the membrane of living cells. Cytometric techniques are used to calculate the percentage of viable cells in a sample.

Trypan Blue is a technique where the dead cells become stained when in contact with the compound, but living cells remain impermeable to the dye. Cells are counted under a microscope to determine the percentage of viable cells in a sample.

If the cell viability was tested using a different method, select “other method” and specify the method in question 49.

Questions 50-51: Report the nucleated white blood cells:

Report “done” if the nucleated white blood cells (also known as leukocytes) were quantified at the specified timepoint. Report the absolute number of the cells, not cells per kg. If “done,” go to question 51. If the nucleated white blood cell count was “not done,” go to questions 52.

Questions 52-53: Report the mononuclear cells:

The total mononuclear cell count includes lymphocytes and monocytes. Report “done” if the mononuclear cells were quantified at the specified timepoint. Report the absolute number of the cells, not cells per kg. If “done,” go to question 53. If the mononuclear cell count was “not done,” go to questions 54.

Questions 54-55: Report the nucleated red blood cells:

Report “done” if the nucleated red blood cells (also known as normoblasts) were quantified at the specified timepoint. Report the absolute number of the cells, not cells per kg. If “done,” go to question 55. If the nucleated red blood cell count was “not done,” go to questions 56.

Questions 56-57: Report the CD34+ cells:

Report “done” if the CD34+ cells were quantified at the specified timepoint. Report the absolute number of the cells, not cells per kg. If “done,” go to question 57. If the CD34+ cell count was “not done,” go to questions 62.

Viability Testing
When reporting the viability, it is important to consider the sample source used for viability testing. If viability is performed on the entire product, report the viability for the Total Nucleated Cells (TNC) and not the individual cell types (i.e., CD34+, CD3+). However, if viability was performed only on select cell types (i.e., viability was performed on both the CD34+ and CD3+ cells), then report the viability for both CD34+ and CD3+. Similarly, if a product is CD34+ selected and viability is performed on the product post-manipulation, the viability should only be reported for CD34+ cells.

Questions 58-59: Viability of CD34+ cells:

If the viability of the CD34+ cells was quantified, select “done” and report the percentage of viable cells in question 59. If the viability was “not done” or “unknown” go to question 62. If your center’s laboratory assay only measures CD34+ viable cells, report the number of viable CD34+ cells in question 57, select “done” for question 58, and report a viability of 100% in question 59.

Questions 60-61: Method of testing cell viability:

Indicate the method of testing viability.

Flow cytometry based: 7-AAD (7-aminoactinomycin D) and Propidium iodide are compounds that can stain dead cells but will not cross the membrane of living cells. Cytometric techniques are used to calculate the percentage of viable cells in a sample.

Trypan Blue is a technique where the dead cells become stained when in contact with the compound, but living cells remain impermeable to the dye. Cells are counted under a microscope to determine the percentage of viable cells in a sample.

If the cell viability was tested using a different method, select “other method” and specify the method in question 61.

Questions 62-63: Report the CD3+ cells:

Report “done” if the CD3+ cells were quantified at the specified timepoint. Report the absolute number of the cells, not cells per kg. If “done,” go to question 63. If the CD3+ cell count was “not done,” go to questions 68.

Questions 64-65: Viability of CD3+ cells:

If the viability of the CD3+ cells was quantified, select “done” and report the percentage of viable cells in question 65. If the viability was “not done” or “unknown” go to question 68. If your center’s laboratory assay only measures CD3+ viable cells, report the number of viable CD3+ cells in question 63, select “done” for question 64, and report a viability of 100% in question 65.

Questions 66-67: Method of testing cell viability:

Indicate the method of testing viability.

Flow cytometry based: 7-AAD (7-aminoactinomycin D) and Propidium iodide are compounds that can stain dead cells but will not cross the membrane of living cells. Cytometric techniques are used to calculate the percentage of viable cells in a sample.

Trypan Blue is a technique where the dead cells become stained when in contact with the compound, but living cells remain impermeable to the dye. Cells are counted under a microscope to determine the percentage of viable cells in a sample.

If the cell viability was tested using a different method, select “other method” and specify the method in question 67.

Questions 68-69: Report the CD3+CD4+ cells:

Report “done” if the CD3+CD4+ cells were quantified at the specified timepoint. Report the absolute number of the cells, not cells per kg. If “done,” go to question 69. If the CD3+CD4+ cell count was “not done,” go to questions 74.

Questions 70-71: Viability of CD3+CD4+ cells:

If the viability of the CD3+CD4+ cells was quantified, select “done” and report the percentage of viable cells in question 71. If the viability was “not done” or “unknown” go to question 74. If your center’s laboratory assay only measures CD3+CD4+ viable cells, report the number of CD3+CD4+ viable cells in question 69, select “done” for question 70, and report a viability of 100% in question 71.

Questions 72-73: Method of testing cell viability:

Indicate the method of testing viability.

Flow cytometry based: 7-AAD (7-aminoactinomycin D) and Propidium iodide are compounds that can stain dead cells but will not cross the membrane of living cells. Cytometric techniques are used to calculate the percentage of viable cells in a sample.

Trypan Blue is a technique where the dead cells become stained when in contact with the compound, but living cells remain impermeable to the dye. Cells are counted under a microscope to determine the percentage of viable cells in a sample.

If the cell viability was tested using a different method, select “other method” and specify the method in question 73.

Questions 74-75: Report the CD3+CD8+ cells:

Report “done” if the CD3+CD8+ cells were quantified at the specified timepoint. Report the absolute number of the cells, not cells per kg. If “done,” go to question 75. If the CD3+CD8+ cell count was “not done,” go to questions 80.

Questions 76-77: Viability of CD3+CD8+ cells:

If the viability of the CD3+CD8+ cells was quantified, select “done” and report the percentage of viable cells in question 77. If the viability was “not done” or “unknown” go to question 80. If your center’s laboratory assay only measures CD3+CD8+ viable cells, report the number of CD3+CD8+ viable cells in question 75, select “done” for question 76, and report a viability of 100% in question 77.

Questions 78-79: Method of testing cell viability:

Indicate the method of testing viability.

Flow cytometry based: 7-AAD (7-aminoactinomycin D) and Propidium iodide are compounds that can stain dead cells but will not cross the membrane of living cells. Cytometric techniques are used to calculate the percentage of viable cells in a sample.

Trypan Blue is a technique where the dead cells become stained when in contact with the compound, but living cells remain impermeable to the dye. Cells are counted under a microscope to determine the percentage of viable cells in a sample.

If the cell viability was tested using a different method, select “other method” and specify the method in question 79.

NOTE: Method of testing cell viability (questions 48, 60, 66, 72, 78):
For each cell type above, if both flow cytometry based and Trypan Blue methods of viability testing are performed, report flow cytometry-based results.

Question 80: Were the colony-forming units (CFU) assessed after thawing? (cord blood units only)

CFUs have been shown to be a predictor of engraftment. Indicate whether CFUs were assessed after thawing. If the CFUs were assessed, continue with question 81. If no CFU assessments were performed, continue with question 88.

Question 81: Was there growth?

If CFUs were assessed after thawing, indicate whether growth was detected.

Questions 82-83: Total CFU-GM

Indicate if the total CFU-GM (granulocyte/macrophages) was quantified. If the CFU-GM was quantified, report “done” and continue with question 83. Report the total CFU as documented on the laboratory report. Do not report CFU per dish, per bag, or per kg.

Questions 84-85: Total CFU-GEMM

Indicate if the total CFU-GEMM (granulocyte/erythrocyte/monocyte/megakaryocytes) was quantified. If the CFU-GEMM was quantified, report “done” and continue with question 85. Report the total CFU as documented on the laboratory report. Do not report CFU per dish, per bag, or per kg.

Questions 86-87: Total BFU-E

Indicate if the total BFU-E (burst forming unit – erythroid) was assessed. BFU-E indicates the presence of erythroid precursor cells. If the BFU – E was quantified, report “done” and continue with question 87. Report the total BFU-E as documented in the laboratory report. Do not report BFU per dish, per bag, or per kg.

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

If positive cultures were obtained, select “yes” and continue with question 89.

If positive cultures were not obtained, select “no” and continue with question 94.

If cultures are pending, select “pending” and continue with question 94. If these results are reported as “pending” transplant centers will be asked to update this field once the culture results are available.

If culture results are unknown, select “unknown” and continue with question 94.

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.

Questions 89-93: Specify organism code(s)

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 uninfected product will be reported on a separate Form 2006).

If the results were positive, select the isolated organism(s) using the pull down options in FormsNet3.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q41	3/8/ 2021	Add	The following statement was added to Q41: *The At Infusion timepoint should include values reflective of the product infused regardless of when the analysis occurred. Since all products are analyzed prior to cryopreservation, the At Infusion timepoint would be applicable for these cell counts. Depending on the product type and your center's practice, viability may be assessed closer to the time of infusion.*	Added for clarification
Q42	3/8/ 2021	Add	The following instructions and examples were added: *The date of product analysis is not necessarily the date of the product infusion.* *If a product is analyzed multiple times prior to product infusion, the type of product will determine which analysis to report for the At Infusion timepoint. See below for more information: Fresh product: If an unmanipulated, fresh product was analyzed multiple times prior to infusion, the most recent complete analysis should be reported for the At Infusion timepoint.* *Example 1: Upon receiving a fresh product, the transplant center completes a TNC, CD34, and viability analysis. The product was not manipulated but prior to infusion, a small sample was collected to analyze the viability. The analysis performed upon receiving the fresh product should be reported for the At Infusion timepoint.* *Cryopreserved product: If a cryopreserved product is infused, 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, only 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 adjusted for the volume infused. In the rare scenario where a complete analysis performed post-thaw, this analysis should be reported for the At Infusion timepoint; however, this is*	Added for clarification

			unlikely as there is usually not enough product to perform a complete analysis post-thaw. Example 2: Upon collecting an autologous PBSC product, the transplant center completes a TNC, CD34, and viability analysis. The product is separated into three bags and cryopreserved. Two of the three bags were thawed, the TNC and viability were analyzed, and the product was infused. The analysis performed upon collecting the product, adjusted for the two bags infused (the sum of volume and cell counts) should be reported for the At Infusion timepoint. Processed product: Report the last analysis performed prior to product infusion for the At Infusion timepoint. Example 3: Upon receiving a PBSC product, the transplant center completes a TNC, CD34, and viability analysis and then RBC reduced the product. After processing, the CD34 and viability are analyzed. 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.	
Q58	6/21/ 2021	Add	The blue box above question 58 was added: ***Viability Testing**: When reporting the viability, it is important to consider the sample source used for viability testing. If viability is performed on the entire product, report the viability for the Total Nucleated Cells (TNC) and not the individual cell types (i.e., CD34+, CD3+). However, if viability was performed only on select cell types (i.e., viability was performed on both the CD34+ and CD3+ cells), then report the viability for both CD34+ and CD3+. Similarly, if a product is CD34+ selected and viability is performed on the product post-manipulation, the viability should only be reported for CD34+ cells.*	Added for clarification

Last modified: Jun 21, 2021

Q94-143: Product Infusion

Question 94: Date of this product infusion:

Report the date this product was infused. If the product was infused over multiple days, report the first date of infusion.

Question 95: Was the entire volume of received product infused?

Indicate “yes” if the entire volume of the product received was infused and continue to question 98. Indicate “no” if only a portion of the product received was infused and continue to question 96.

See the infusion reporting examples below for further clarification:

Infusion Reporting Examples:

A. 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 that was received was not infused, “no” should be reported in question 95.
B. A bone marrow product is collected and arrives at the transplant center in two bags and both bags of the fresh product are infused. As the entire volume of the received product was infused, “yes” should be reported in question 95.

Questions 96-97: Specify what happened to the reserved portion:

Report if the product was “discarded,” “cryopreserved for future use,” or “other fate.” If “other fate” is selected, report the outcome of this product in question 97.

Question 98: Time product infusion initiated (24-hour clock):

Report the start time of the infusion. If multiple bags were infused, report the start time of the infusion of the first bag. Show the time using a 24-hour clock and indicate if daylight savings time or standard time was in effect. If the location of your institution does not observe daylight savings time, report the time as standard time. For more information about daylight savings time schedules, go to http://www.timeanddate.com/time/dst/.

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

Question 99: Date infusion stopped:

Report the date the infusion was completed. If multiple bags of the same product were infused, report the stop date of the last bag.

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

Question 100: 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**.

Enter the completion time of the infused product using a 24-hour clock and indicate if daylight savings time or standard time was in effect. If the location of your institution does not observe daylight savings time, report the time as standard time. For more information about daylight savings time schedules, go to http://www.timeanddate.com/time/dst/.

Questions 101-102: Specify the route of product infusion:

Report the route by which the product was infused. Intravenous refers to infusion into the veins – examples include infusion via central line or via catheter. Intramedullary refers to infusion into the marrow cavity within a bone, such as directly into the left or right iliac crest. Intraperitoneal refers to infusion within the peritoneal cavity. If the route of infusion is not one of the above options (including intraperitoneal), select “other route of infusion” and specify the infusion route in question 102.

> **NOTE:** The following questions are applicable to cord blood units only. If this HCT used a non-NMDP allogeneic product, continue with question 144. Autologous and NMDP products continue with the signature lines at the end of the form.

Question 103: 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 using a cord blood product. **Report all adverse events regardless of the grade or severity**.

If an adverse event occurred, select “yes” and continue with question 104. If an adverse event did not occur, select “no” and continue with question 144.

A serious adverse event is defined as an event which:

- led to death,
- was considered life-threatening,
- required prolongation of hospitalization,
- led to persistent or significant disability/incapacity,
- or led to a congenital anomaly/birth defect.

If any of the above happened, an Adverse Event Form (Form 3001) must also be completed. **Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.** Please review Adverse Event reporting at the CIBMTR website: http://www.cibmtr.org/

DataManagement/TrainingReference/Pages/AdverseEvents.aspx.

Questions 104-143: Specify the following adverse event(s)

Indicate “yes” or “no” for each adverse event listed. Do not leave any responses blank. If the recipient experienced an expected (in the physician’s opinion) adverse event that was not listed, specify the other expected adverse event in question 138. If the recipient experienced an unexpected adverse event (i.e., not one of the options listed above, or an “other expected AE”), specify the unexpected adverse event in questions 141-143.

For each adverse event that occurred, indicate if the medical director believes the adverse event(s) to be directly related to the infusion of the product.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Dec 22, 2020

Q144-170: Donor/Infant Demographic Information

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

Question 144: Was the donor ever pregnant?

If the donor has ever been pregnant, select “yes” and continue with question 145.

If the donor has never been pregnant, select “no” and continue with question 147.

If there is no documentation regarding whether or not the donor has ever been pregnant, select “unknown” and continue with question 147.

If the product is a cord blood unit or was from a male donor, select “Not Applicable (male donor or cord blood unit)” and continue with question 147.

Questions 145-146: Number of pregnancies

Indicate if the number of pregnancies is known or unknown. If “known,” specify the total number of pregnancies in question 146.

If the total number of pregnancies is not known, select “unknown” and continue with question 147.

Question 147: Donor’s ethnicity:

Indicate the donor’s ethnicity. For more information regarding ethnicity, see Appendix I.

Questions 148-149: Donor’s race and detail: (*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 150: Was the donor a carrier for potentially transferable genetic diseases?

If the donor was a carrier for a potentially transplantable genetic disease, select “yes” and continue with question 152. If the donor was not tested, or if there is no documentation of genetic testing, select “no” and continue with question 154.

Questions 151-152: Specify potentially transferable genetic disease:

Indicate the potentially transplantable genetic disease the donor was a carrier for. If the donor was a carrier for a potentially transplantable disease, but the disease was not listed in question 152, select “other

disease" and specify the disease in questions 153.

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

If the donor and/or product were tested for other transferable genetic or clonal abnormalities, select "yes" and continue with question 155. If this is a related donor and/or the donor/product were not tested, or if there is no documentation of genetic testing, select "no" or "unknown," respectively, and continue with question 160 for related donors or the signature lines at the end of the form for all other donor types.

It should be noted for cord blood unit transplants that almost all units are screened, or the infant is screened, for potentially transplantable genetic diseases. This may be documented as a 'hemoglobin screen,' which evaluates for sickle cell and/or thalassemia, both of which are hemoglobinopathies.

Questions 154-158: Specify disease(s) tested:

For each of the genetic or clonal abnormalities listed, indicate whether the disease testing was done. Indicate "yes" or "no" and specify the method of testing in the following question. Do not leave any responses blank. If the donor was tested for a potentially transferable genetic or clonal abnormality, but it was not listed in questions 155-157, select "yes" for "other transferable genetic or clonal abnormality" and specify the abnormality in question 159.

> ! **NOTE:** The following questions (159-170) apply only to non-NMDP 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 at the end of the form.

Question 159: Did this donor have a central line placed? (non-NMDP PBSC donors only)

This question only applies to non-NMDP PBSC donors. If the donor had a central line placed during the donation process, select "yes" and continue with question 160. If the donor did not have a central line, select "no" and continue with question 160.

Question 160: Was the donor hospitalized (inpatient) during or after the collection?

Indicate "Yes" if the donor was hospitalized for complications during or after the collection. Indicate "No" if the donor was not hospitalized as an inpatient or if the donor was admitted to an observation unit and discharged in less than 24 hours.

Questions 161-162: 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

Many of these criteria are outlined by the Common Terminology Criteria for Adverse Events (CTCAE) and would be reported as a Grade 4 or higher adverse event. For more information on CTCAE complications that can be reported, see the published criteria at: https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm.

If the donor experienced life-threatening complications during or after the collection, select “yes” and specify the complication(s) in question 162.

If the donor did not experience life-threatening complications during or after the collection, select “no” and continue with question 163.

Questions 163-165: Did the allogeneic donor give one or more autologous transfusion units?

If the allogeneic donor gave one or more autologous transfusion units, select “yes” and specify the date of collection of the first unit and total number of units collected in questions 164-165. If the donor did not give autologous blood transfusion units, select “no” and continue with question 166.

Questions 166-168: Did the donor receive blood transfusions as a result of the collection?

Indicate if the donor received blood transfusions as a result of the collection. If the donor received transfusions of their own blood that had been previously collected and stored, even once, indicate “autologous transfusions” and specify the number of units received in question 167.

If the donor received blood transfusions (excluding autologous blood product), indicate “allogeneic transfusions” and specify the number of units received in question 168.

If the recipient did not receive blood transfusions as a result of the collection, select “no” and continue with question 169.

Questions 169-170: Did the donor die as a result of the collection?

If the donor died as a result of the collection, select “yes” and specify the cause of death in question 170. If the donor did not die as a result of the collection, select “no” and continue with the signature lines.

Signature Lines:

The FormsNet3^{SM} application will automatically populate the signature data fields, including name and email address of person completing the form and date upon submission of the form.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)

Q153	3/8/ 2021	Add	The following instructions were added: *It should be noted for cord blood unit transplants that almost all units are screened, or the infant is screened, for potentially transplantable genetic diseases. This may be documented as a 'hemoglobin screen,' which evaluates for sickle cell and/or thalassemia, both of which are hemoglobinopathies.*	Added for clarification

Last modified: Mar 08, 2021