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 products 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
7/26/ 2024	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	Product Analysis Timepoints red warning box modified above Q41: *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, an additional ~~both the "At Infusion" and~~ "At Arrival" timepoint-s- should be reported if the CBU was analyzed prior to the product wash. ~~are required.~~*
7/26/ 2024	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	Instruction for reporting timepoints for CBUs updated: *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.~~ an "At Arrival" timepoint should be reported if the center performed an analysis prior to the CBU wash. An "At Infusion" timepoint must be reported and should reflect the product analysis performed post wash.*
7/26/ 2024	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	Orca Bio Products and Donor Information blue box added above Q34
7/26/ 2024	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Remove	Omidubicel and Orca T Products blue box updated above Q34 and 35 to clarify these instructions are only applicable for Omidubicel
3/8/	2006:	Add	Omidubicel and Orca-T Products blue box added above Q35: ***Omidubicel***

2024	Hematopoietic Stem Cell Transplant (HCT) Infusion		***and Orca-T Products*** *If the product is Omidubicel, select* ***Ex vivo*** *expansion for the first product and* ***Other manipulation*** *for the second product – specify the manipulation as 'Negative fraction.' If the product is Orca-T, report the manipulation as* ***CD34 enriched****.*
3/8/ 2024	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Add	Omidubicel and Orca-T Products blue box added above Q34: ***Omidubicel and Orca-T Products*** *If the product is Omidubicel or Orca-T, select* ***Yes*** *the product was manipulated.*
9/23/ 2022	2006: Hematopoietic Stem Cell Transplant (HCT) Infusion	Modify	Version 5 of the 2006: Hematopoietic Stem Cell Transplant (HCT) Infusion section of the Forms Instruction Manual released. Version 5 corresponds to revision 6 of the Form 2006.

Last modified: Jul 29, 2024

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.), report **Yes**.

If the Allogeneic donor did not receive therapy to enhance the stem cell product, report **No**.

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)** and specify the generic name for the growth or mobilizing factor.

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)
.	.	.	.	.

Last modified: Sep 23, 2022

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, report **Yes**. Anticoagulants are often added to PBSC products and are typically documented on the product bag label.

If anticoagulants or other agents were not added to the product between collection and infusion, report **No**.

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**, and specify the anticoagulant's name.

Section Updates:

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

Last modified: Sep 23, 2022

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**. The “no” option usually applies to autologous collections and related donors.

> **Contracted Labs**
> In scenarios where a contracted lab does the actual collection, please indicate **Yes** for *Was this product collected off-site and shipped to your facility* and complete *Date of recipient of product at your facility, Time of receipt of product, Specify the shipping environment of the product(s), Was there any indication that the environment within the shipper was outside the expected temperature range for this product at any time during shipment*, and *Were the secondary containers (e.g., insulated shipping containers and unit cassette) intact when they arrived at your center* questions 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 *Was this product collected off-site and shipped to your facility* and *Date of receipt of product at your facility* questions.

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.

- **Room Temperature**: Shipping environment where controlled cooling is not required.
- **Cooled**: Shipping environment below ambient temperatures (e.g., 59° F – 77° F) but above freezing (e.g., 32° F>). Examples include shipments utilizing refrigerated gel packs (Re-FREEZ-R-BRIX, etc.).
- **Frozen (cryopreserved)**: Shipping environment where liquid components are maintained in a solid state. Examples include shipments utilizing dry ice, Crēdo coolers, or other thermo-insulated containers.

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. 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 was *not* a CBU, continue with the Product Processing / Manipulation section.

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

Indicate **Yes** or **No** if the cord blood unit was stored at your center prior to thawing.

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.

> **Total nucleated cells (Cord blood units only) and CD34+ cells (Cord blood units only)**
> The values reported for *Total nucleated cells (Cord blood units only)* and *CD34+ cells (Cord blood units only)* 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**.

Section Updates:

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

Last modified: Sep 23, 2022

Q22-40: Product Processing / Manipulation

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

Indicate if any portion of the product was thawed prior to this infusion. If the product was never cryopreserved, select **No**.

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**.

If the entire product was not thawed, select **No**.

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

Indicate the percentage of the product that was thawed. If the exact percentage is not listed, select **Other percent** and specify the percentage of the product that was thawed.

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 thaw start date above. 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 method used to thaw the product. Only report the method of thawing the product. If a method other than **Water bath** or **Electric warmer** was used to thaw the product, select **Other method** and specify the method

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
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 32: Was the product processed prior to infusion?

Product processing includes changes made to the original product that does not affect the physical properties of the product (i.e., plasma reduction, RBC reduction, was).

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.

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.

Orca Bio Products and Processing / Manipulation
Refer to the Orca Bio Reporting Guide, located on the CIBMTR Portal, to determine how to report processing and manipulation for Orca Bio products.

Omidubicel Products
If the product is Omidubicel, select **Yes** the product was manipulated.

Question 34: Was the product manipulated prior to infusion?

Product manipulation includes changes made to the original product affecting the physical properties of the product (i.e., ex-vivo T-cell depletion or CD34 selection).

If any part of the product was manipulated in any way prior to infusion at the transplant center, select **Yes**.

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

Omidubicel Products
If the product is Omidubicel, select **Ex vivo expansion** for the first product and **Other manipulation** for the second product – specify the manipulation as 'Negative fraction.'

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

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

If the product is **Ex-vivo T-cell depleted**, specify the antibodies used.

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** and specify the method. 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.

- **Anti-CD3**: Agent / antibody that binds to CD3 surface proteins on T-cells.
- **Anti-CD4**: Agent / antibody that binds to CD4 surface proteins on T-cells.
- **Anti-CD8**: Agent / antibody that binds to CD8 surface proteins on T-cells.
- **Anti-CD19**: Agent / antibody that binds to CD19 surface proteins on T-cells.
- **Anti-CD45RA**: Agent / antibody that binds to CD45 surface proteins on T-cells. Examples of monoclonal antibodies used in T-cell depletion include OX33.
- **α/β Antibody**: Agent / antibody that binds to TCRs on peripheral blood CD3+ T cells. Examples of monoclonal antibodies used in T-cell depletion include IP26 and T10B9
- **Anti-CD52**: Agent / antibody that binds to CD52 surface proteins on T-cells.

If antibodies were used during ex-vivo T-cell depletion but not listed above, select **Other antibody** and specify the other antibody.

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

Indicate the T-cell depletion method used during product manipulation.

- **Antibody affinity column**: A separation process used to purify a solution or mixture into distinct components.
- **Immunomagnetic beads**: Uniform polymer particles coated in a polystyrene casing that provides a hydrophobic surface to facilitate physical absorption of molecules, such as antibodies (e.g., Clinimacs©)

If the method used during t-cell depletion is not listed above, select **Other method** and specify the method.

Question 40: Specify other cell manipulation:

If a method of manipulation was performed on the product, but is not captured above, specify the method. 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)
Q34	7/26/ 2024	Add	Orca Bio Products and Processing / Manipulation added above Q34: ***Orca Bio Products and Processing / Manipulation****: Refer to the Orca Bio Reporting Guide, located on the CIBMTR Portal, to determine how to report processing and manipulation for Orca Bio products.*	Orca Bio Reporting Guide is now available
Q34	7/26/ 2024	Delete	Omidubicel and Orca-T Products blue box updated above Q34 to clarify the instruction is only applicable for Omidubicel: ***Omidubicel ~~and Orca-T~~ Products*** *If the product is Omidubicel ~~or Orca-T~~, select **Yes** the product was manipulated.*	Removed as Orca Bio Reporting Guide is now available
Q34	3/8/ 2024	Add	Omidubicel and Orca-T Products blue box added above Q34: ***Omidubicel and Orca-T Products*** *If the product is Omidubicel or Orca-T, select **Yes** the product was manipulated.*	Added for product specific information
Q35	7/26/ 2024	Delete	Omidubicel and Orca-T Products blue box updated above Q35 to clarify the instruction is only applicable for Omidubicel: ***Omidubicel ~~and Orca-T~~ Products*** *If the product is Omidubicel, select **Ex vivo** expansion for the first product and **Other manipulation** for the second product – specify the manipulation*	Removed as Orca Bio Reporting Guide is

			*as 'Negative fraction.' ~~If the product is Orca-T, report the manipulation as **CD34 enriched**~~.*	now available
Q35	3/8/ 2024	Add	Omidubicel and Orca-T Products blue box added above Q35: ***Omidubicel and Orca-T Products** If the product is Omidubicel, select **Ex vivo** expansion for the first product and **Other manipulation** for the second product – specify the manipulation as 'Negative fraction.' If the product is Orca-T, report the manipulation as **CD34 enriched**.*	Added for product specific information

Last modified: Jul 29, 2024

Q41-91: Product Analysis (All Products)

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. For CBUs, an additional “At Arrival” timepoint should be reported if the CBU was analyzed prior to the product wash.

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, an “At Arrival” timepoint should be reported if the center performed an analysis prior to the CBU wash. An “At Infusion” timepoint must be reported and should reflect the product analysis performed post wash.

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. Report **Not done** if the TNC count was not quantified at the specified timepoint.

> **Nucleated Red and White Blood Cells:** 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:

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

If the corrected WBC is in cells/kg:

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

If the corrected WBC is an absolute cell count:

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

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. If the viability was not assessed, or if it is unknown whether viability was tested, report **Not done** or **Unknown**, respectively.

If your center's laboratory assay only measures viable cells, report the number of viable cells in *Total nucleated cells*, select **Done** for this question, and report the viability as 100%.

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.

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 the nucleated white blood cell count was not assessed, report **Not done**.

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 the mononuclear cell count was not assessed, report **Not done**.

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 the nucleated red blood cell count was not assessed, report **Not done**.

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 the CD34+ cell count was not assessed, report **Not done**.

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.

Cell viability
If both flow cytometry based and Trypan Blue methods of viability testing are performed, report the flow cytometry-based results.

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. If the viability was not assessed, or if it is unknown whether viability testing was performed, report **Not done** or Unknown, respectively.

If your center's laboratory assay only measures CD34+ viable cells, report the number of viable CD34+ cells in *Total number of CD34+ cells*, select **Done** for this question, and report the viability as 100%.

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 the CD3+ cell count was not assessed, report **Not done**.

> **Cell viability**
> If both flow cytometry based and Trypan Blue methods of viability testing are performed, report the flow cytometry-based results.

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. If the viability was not assessed, or if it is unknown whether viability was assessed, report **Not done** or **Unknown**, respectively.

If your center’s laboratory assay only measures CD3+ viable cells, report the number of viable CD3+ cells in *Total number of CD3+ cells*, select **Done** this question, and specify the viability as 100%.

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.

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 the CD3+CD4+ cell count was not assessed, report **Not done**.

Cell viability
If both flow cytometry based and Trypan Blue methods of viability testing are performed, report the flow cytometry-based results.

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. If the viability was not assessed, or if it is unknown whether viability was assessed, report **Not done** or Unknown, respectively.

If your center's laboratory assay only measures CD3+CD4+ viable cells, report the number of CD3+CD4+ viable cells in the *Total number of CD3+CD4 cells*, select Done for this question, and report the viability as 100%.

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.

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 the CD3+CD8+ cell count was not assessed, report **Not done**.

Cell viability
If both flow cytometry based and Trypan Blue methods of viability testing are performed, report the flow cytometry-based results.

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. If the viability was not assessed, or if it is unknown whether viability was assessed, report **Not done** or **Unknown**, respectively.

If your center's laboratory assay only measures CD3+CD8+ viable cells, report the number of CD3+CD8+

viable cells in *Total number of CD3+CD8+ cells*, select **Done** for this question, and report the viability as 100%.

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.

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.

Question 81: Was there growth?

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

Questions 82 – 85: Indicate which assessments were carried out (check all that apply)

Select which CFU was assessed after thawing, select all that apply.

If the total CFU-GM (granulocyte / macrophages) was quantified, select **Total CFU-GM** and report the total CFU-GM as documented on the laboratory report.

If the total CFU-GEMM (granulocyte / erythrocyte / monocyte / megakaryocytes) was quantified, select **Total CFU-GEMM** and report the total CFU-GEMM as documented on the laboratory report.

If the total BFU-E (burst forming unit – erythroid) was quantified, select **Total BFU-E** and report the total BFU-E as documented on the laboratory report.

Do not report CFU per dish, per bag, or per kg.

Question 86: 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**.

If positive cultures were not obtained, select **No**.

If cultures are pending, select **Pending**. 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 unavailable, or if it is unknown whether culture assessments were performed, select **Unknown**.

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.

Organism Codes
The codes for “other organism, specify” (codes 198, 209, 219, and 259) should rarely be needed; check with the microbiology lab or HCT physician before using them.

Questions 87-91: 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^{SM}.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q41	7/26/ 2024	Modify	Product Analysis Timepoints red warning box modified above Q41: *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, an additional ~~both the “At Infusion” and~~ “At Arrival” timepoint-s- should be reported if the CBU was analyzed prior to the product wash. ~~are required.~~*	Updated for clarification for scenarios where two separate analyses are not performed prior to wash and after

Q41	7/26/ 2024	Modify	Instruction for reporting timepoints for CBUs updated: *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.~~ an "At Arrival" timepoint should be reported if the center performed an analysis prior to the CBU wash. An "At Infusion" timepoint must be reported and should reflect the product analysis performed post wash.*	Updated for clarification for scenarios where two separate analyses are not performed prior to wash and after

Last modified: Jul 29, 2024

Q92-141: Product Infusion

Question 92: 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 93: Was the entire volume of received product infused?

Indicate **Yes** if the entire volume of the product received was infused. Indicate **No** if only a portion of the product received was infused.

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 for *Was the entire volume of the received product infused?*.
- **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 for *Was the entire volume of the received product infused?*

Questions 94-95: 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, also report the outcome of this product.

Question 96: 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 97: 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 98: 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 99-100: 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 (DL catheter, central venous catheter).
- **Intramedullary (Intraosseous)**: Refers to infusion into the marrow cavity within a bone, such as directly into the left or right iliac crest.

If the route of infusion is not one of the above options (including intraperitoneal), select **Other route of infusion** and specify the infusion route.

> ! The following questions are applicable to cord blood units only. If this HCT used a non-NMDP allogeneic product, continue with the Donor / Infant Demographic Information section. Autologous and NMDP products continue with the signature lines at the end of the form.

Question 101: 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**. If an adverse event did not occur, select **No**.

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 in the Data Management Guide.

Questions 102-141: 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, select **Yes** for *Other expected adverse event* and specify. If the recipient experienced an unexpected adverse event (i.e., not one of the options listed above, or an "other expected AE"), select **Yes** for *Other unexpected adverse event* and specify the unexpected adverse event.

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.

Flushing / facial flushing and cough should **not** be reported as an adverse event; however, abdominal pain may be reported (expected or unexpected).

Section Updates:

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

Last modified: Feb 15, 2023

Q142-168: 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 142: Was the donor ever pregnant?

If the donor has ever been pregnant, select **Yes**. If the donor has never been pregnant, select **No**. If there is no documentation regarding whether or not the donor has ever been pregnant, select **Unknown**.

If the product is a cord blood unit, or was from a male donor, select **Not Applicable (male donor or cord blood unit)**.

Questions 143-144: Number of pregnancies

Indicate if the number of pregnancies is **Known** or **Unknown**. If **Known**, specify the total number of pregnancies.

If the total number of pregnancies is not documented or cannot be determined, report *Unknow*n.

Question 145: Donor's ethnicity

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

Questions 146-147: 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 148: Was the donor a carrier for potentially transferable genetic diseases?

If the donor was a carrier for a potentially transplantable genetic disease, select **Yes**. If the donor was not tested, or if there is no documentation of genetic testing, select **No**.

Questions 149-150: Specify potentially transferable genetic disease

Indicate the potentially transplantable genetic disease for which the donor is a carrier. If the donor was a carrier for a potentially transplantable disease, but the disease was not listed, select **Other disease** and specify. Only genetic diseases that are transferable (from donor to recipient) should be reported. Chagas and WNV (West Nile Virus) should not be reported as a potentially transferable genetic disease as they are examples of infections and not a genetic disease.

Submit a ticket through CIBMTR Center support regarding questions about transferable genetic diseases.

Question 151: 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**. 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 the signature lines.

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 disease and / or thalassemia, both of which are considered hemoglobinopathies.

Questions 152-155: 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, select **Yes** for *Other transferable genetic or clonal abnormality* and specify.

> ! The remaining questions 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 157: Did this donor have a central line placed? (non-NMDP PBSC donors only)

This question only applies to non-NMDP PBSC donors. Indicate if the donor had a central line placed during the donation process.

Question 158: Was the donor hospitalized (inpatient) during or after the collection?

Indicate if the donor was hospitalized for complications during or after the collection. 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, report **No**.

Questions 159 – 160: 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).

If the donor did not experience life-threatening complications during or after the collection, select **No**.

Questions 161-163: 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. If the donor did not give autologous blood transfusion units, select **No**.

Questions 164-166: 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.

If the donor received blood transfusions (excluding autologous blood product), indicate **Allogeneic transfusions** and specify the number of units received.

If the recipient did not receive blood transfusions as a result of the collection, select **No**.

Questions 167-168: Did the donor die as a result of the collection?

Indicate if the donor died as a result of the collection. If **Yes**, specify the cause of death. 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)
.	.	.	.	.

Last modified: Sep 23, 2022