Instructions for Hematopoietic Stem Cell Transplant (HCT) Infusion (Form 2006 – Revision 4)

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Hematopoietic Stem Cell (HCT) Infusion Form.

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

TABLE OF CONTENTS

Hematopoietic Cell Transplant (HCT) Infusion Form

All recipients on the **Comprehensive Report Form track** must complete the Form 2006. Recipients on the **Transplant Essential Data track** must complete the Form 2006 for the following product types:

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

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

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

The Form 2006 is designed to capture product- and infusion-specific information for all products given to a recipient as part of a Hematopoietic Stem Cell Transplant (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. Two different products from the same donor (for example, PBSC and bone marrow), require two 2006 forms; one for each product.

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 O – How to Distinguish Infusion Types and Appendix P – Definition of Product.

Key Fields

Accuracy of the Key Fields is essential for ensuring that:

- Data are being reported for the correct recipient.
- Outcomes data accurately reflects appropriate transplant type and product for each transplant center.
- Data are being shared with the correct donor center, cord blood bank, cooperative registry, or other agency.

The Key Fields precede the form body and are automatically populated in the FormsNet3^{SM} application based on information provided on the CRID Assignment Form 2804. If errors are noted in the key fields, correct Form 2804 and then review it for accuracy. After Form 2804 has been corrected, verify data has been updated on all completed forms. If the data has not been updated automatically, centers will need to reprocess the completed forms to correct the key field data. If errors are noted in key fields for second or subsequent transplants, contact your CRC to make any necessary corrections to the transplant or product type. Transplant and product type will not be automatically populated on product or donor specific forms (Forms 2004, 2005, and 2006) and will need to be manually reported.

Donor/Cord Blood Unit Identification

Question 1: Specify Donor:
Indicate the donor type for this product.

An **autologous** product has cells collected from the recipient for his/her own use.

> If the product was autologous (marrow, PBSC, other product), select "autologous" and continue with question 16.
>
> If the product was an autologous cord blood unit, select "autologous cord blood unit" and continue with question 5.

An **unrelated donor (allogeneic, unrelated)** is a donor who shares no known ancestry with the recipient. Include adoptive parents/children or stepparents/children. Distinguish if the product in an NMDP product or a non-NMDP product. Examples of non-NMDP donor registries include, but are not limited to: St. Louis Cord Blood Bank, Anthony Nolan, and StemCyte International Cord Blood Center.

> If the product was an NMDP unrelated cord blood unit, select "NMDP unrelated cord blood unit" and continue with question 2.
>
> If the product was from an NMDP unrelated donor (marrow, PBSC, other product), select "NMDP unrelated donor" and continue with question 3.
>
> If the product was from a non-NMDP unrelated donor and was facilitated through another registry, select "non-NMDP unrelated donor" and continue with question 4.
>
> If the product was a non-NMDP cord blood unit, select "non-NMDP cord blood unit" and continue with question 5.

A **related donor (allogeneic or syngeneic, related)** is a blood-related relative. This includes monozygotic (identical twins), non-monozygotic (dizygotic, fraternal, non-identical) twins, siblings, parents, aunts, uncles, children, cousins, half-siblings, etc.

> If the product was from a related donor (marrow, PBSC, other product), select "related donor" and continue with question 10.
>
> If the product was a related cord blood unit, select "related cord blood unit" and continue with question 5.

Question 2: NMDP Cord Blood Unit ID:
Report the NMDP Cord Blood Unit ID. This information is included on the product label, the product insert accompanying the product, and within the NMDP search/product

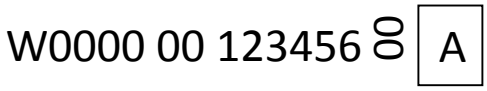
documentation. The ID is always numeric and begins with “9” (e.g., 9000-0000-0). If the product ID does not begin with a “9,” the product may not be an NMDP cord blood unit and the source of the product should be double-checked. Continue with question 15.

Question 3: NMDP Donor ID:
Report the NMDP Donor ID (e.g., 0000-0000-0). This ID is unique for each donor and is assigned by the NMDP. This information is included on the product label, the product insert accompanying the product, and within the NMDP search/product documentation. Continue with question 15.

Question 4: Non-NMDP unrelated donor ID: *(not applicable for related donor)*
Report the non-NMDP unrelated donor ID. Do not complete this field if the recipient has an NMDP donor, a related donor, or a cord blood donor. This ID is often located on the product label, the product insert accompanying the product, and the registry-specific search/product documentation. Continue with question 8.

Question 5: Non-NMDP cord blood unit ID: *(include related and autologous CBUs)*
Report the non-NMDP cord blood unit ID. Examples of non-NMDP donor registries include, but are not limited to: St. Louis Cord Blood Bank and StemCyte International Cord Blood Center. This ID is often located on the product label, the paperwork accompanying the product, and registry specific search/product documentation. Enter the non-NMDP cord blood ID. Note that some cord blood banks can ship their units either through the NMDP or directly to the transplant center. Carefully review the accompanying documentation to determine which is appropriate for your unit. You may wish to consult with your center's Transplant Coordinator, as he or she will have insight as to how the product was acquired.

Question 6: Is the CBU ID also the ISBT DIN number?
Report “yes” if the non-NMDP CBU ID is the same as the International Society of Blood Transfusion (ISBT) Donation Identification Number (DIN) and continue with question 8. If the product has an ISBT label on it, the ISBT DIN number is in the upper left-hand corner and consists of a letter followed by 12 numbers, two numbers on the end, and a letter in a box. Example below:



Please find additional information regarding the ISBT DIN numbers and traceability at http://www.iccbba.org/docs/public/introduction_traceability.pdf. For example, you may see a barcode with an alphanumeric string below it.

If the CBU ID is not the same as the ISBT DIN number, select “no” and continue with question 7.

Question 7: Specify the ISBT DIN number:
If you answered “yes” to question 6, report the ISBT DIN number using the letter, 12 digits, 2 numbers on end, and the letter in the box.

If you answered “no” to question 6 (the product does not have an ISBT DIN number), leave this field blank, override the error, and continue with question 8.

Question 8: Registry or UCB Bank ID:
Specify the registry used to obtain the adult donor or umbilical cord blood unit. The Bone Marrow Donors Worldwide (BMDW) codes have been adopted to avoid submitting the entire name and address of the donor registry.

The registry code for NMDP donors is USA1 and for NMDP cord units is U1CB.

Some common banks that do not list with BMDW have been added to the FormsNet list for version 4, including St Louis Cord Blood Bank (SLCBB) and Viacord (VIAC).

If the donor was found through DKMS, report the registry that facilitated the HCT. Some registries may be listed more than once with BMDW (once for marrow/PBSC products and differently for cord blood products). Ensure that the appropriate code for the product was selected, because distribution of data is dependent on the code.

If the registry code cannot be determined using the BMDW website, select “other registry” and continue to question 9.

Question 9: Specify Other Registry or UCB Bank:
If the BMDW website does not list a match code for the adult donor registry or cord blood bank, provide the registry’s official name in the “Specify other registry” field.

Please ensure that the registry you are entering under “other” is not already listed in the pull-down list for question 8. Entries such as NMDP adult donors, NMDP cords, and New York Cord Bank each have their own entries above.

Questions 10 & 11: Date of Birth (donor/infant):
Report if the donor’s/infant’s date of birth is “known” or “unknown” for question 10. If the donor’s/infant’s date of birth is known, report the date of birth (YYYY-MM-DD) in question 11. If the donor’s/infant’s date of birth is unknown, continue with question 12.

Questions 12 & 13: Age (donor/infant):
Report if the donor’s/infant’s age is “known” or “unknown” for question 12. If the donor’s/infant’s age is known, report the donor’s/infant’s age at the time of product collection in question 13. Report the age in months if the recipient is less than 1 year old, otherwise report the age in years. If the donor’s/infant’s age at collection is unknown, continue with question 14.

Question 14: Sex (donor/infant):
Indicate the donor’s biological sex as “male” or “female.” For cord blood units, report the infant's sex.

Question 15: Was the product derived from an NMDP adult donor, NMDP cord blood unit, or non-NMDP cord blood unit?
If the source of the product was an NMDP adult donor, NMDP cord blood unit, or non-NMDP cord blood unit, select "yes" and continue with question 43. If the product does not meet those criteria, select "no" and continue with question 16 in the Pre-Collection Therapy section.

Pre-Collection Therapy

Question 16: Did the donor receive therapy, prior to any stem cell harvest, to enhance the product collection for this HCT?
Stem cells do not typically circulate in the blood stream. Therefore, in order to increase the quantity of cells for collection, an agent is frequently given to the allogeneic donor or autologous donor-recipient. 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 donor (including autologous donor-recipients) received therapy (such as growth factors, mobilizing agents, chemotherapy, etc.), select "yes" and continue with question 17.

If the donor did not receive therapy to enhance the stem cell product, select "no" and continue with question 28.

Question 17: 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

If the donor or autologous donor-recipient received growth factors prior to the stem cell harvest to enhance the stem cell product select "yes" and continue with question 18.

If the donor or autologous donor-recipient did not receive growth factor(s), select "no" and continue with question 24.

Questions 18-23: Specify therapy(s)
Report if any of the following products were given. Select "yes" or "no" for each question.

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

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

GM-CSF (granulocyte macrophage-colony stimulating factor, **sargramostim**, **Leukine®**)

Plerixafor (Mozobil®)

If the growth or mobilizing factor that was given is not included in the above list, select "yes" for question 22 and specify the generic name for the growth or mobilizing factor in question 23.

Question 24: Systemic therapy (chemotherapy) *(autologous only)*
Indicate if the autologous donor-recipient received systemic therapy prior to the stem cell harvest to enhance the stem cell product. Although the intended purpose of this therapy may not be to treat the recipient's disease, occasionally there is a disease response. Therefore, also record this therapy on the Pre-HCT Disease Specific Form (Forms 20xx) as a line of therapy, if applicable.

Systemic therapies used to enhance the stem cell product may include cyclophosphamide or ICE chemotherapy (Ifosfamide, carboplatin, and etoposide).

If the autologous donor-recipient received systemic therapy prior to the stem cell harvest, select "yes" and continue with question 25. If systemic therapy was not received, select "no" and continue with question 26.

Question 25: Anti-CD20 (rituximab, Rituxan) *(autologous only)*
Indicate if Anti-CD20 monoclonal antibodies (rituximab) were used during the collection of the autologous product. Although the intended purpose of this therapy may not be to treat the recipient's disease, occasionally there is a disease response. Therefore, also record this therapy on the Pre-HCT Disease Specific Form (Forms 20xx) as a line of therapy, if applicable.

An example of systemic therapies using anti-CD20 monoclonal antibodies to enhance stem cell products is R-ICE (rituximab, ifosfamide, carboplatin, and etoposide).

Questions 26-27: Other therapy
If the donor or autologous donor-recipient received any other treatment prior to the stem cell harvest to enhance the stem cell product, select "yes" and specify the treatment administered in question 27.

If the donor or autologous donor-recipient did not receive any other treatment, select "no" and continue with question 28.

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.

Also, if the mobilization method changes (e.g., plerixafor is required starting on Day 3 of collection) this is considered a different product and an additional 2006 form must be completed for the product collected with the new mobilization method.

Question 28: 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. Then the recipient was given plerixafor to enhance the mobilization. Due to the change in mobilization method, 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 mobilization method for which the form is being completed.

Question 29: Was more than one collection required for this HCT?
If more than one day of collection was required for this mobilization event, select "yes" and continue with question 30.

Do not report days of collection for a different product, as each product is reported on a separate 2006 form.

If more than one day of collection was not required, select "no."

Question 30: Specify the number of subsequent days of collection in this episode:
Report the number of collection days for this product *excluding* the first day of collection. For example, if a collection occurred over three days, "2" should be reported for this question. For an HCT that includes multiple products, only report the total number of collection days (excluding the first day) for the product being reported on this form.

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

Question 31: Were anticoagulants added to the product during collection?
If anticoagulants were used **during** collection, select "yes" and continue with question 32. Anticoagulants are typically documented on the product bag label. Anticoagulants are often added to PBSC products.

If anticoagulants were not used during collection, select "no" and continue with question 37.

Questions 32-36: Specify anticoagulant(s):
More than one anticoagulant may be added to a product. Select all the anticoagulants added to the reported product. Do not leave any responses blank.

If an anticoagulant added to the product is not listed on the form, check "yes" for question 35, and specify the anticoagulant's name in question 36.

Question 37: Were anticoagulants added to the product before freezing?
Report any anticoagulants that were added to the product **after collection but prior to cryopreservation**. This does not include anticoagulants that were added during collection and already reported on questions 31-36. Anticoagulants are typically documented on the product bag label. Anticoagulants are often added to PBSC products.

If anticoagulants were added **after collection and prior to freezing**, select "yes" and continue with question 38.

If anticoagulants were not added after collection and prior to freezing, select "no" and continue with question 43.

Questions 38-42: Specify anticoagulant(s)
More than one anticoagulant may be added to a product. Select all the anticoagulants added to the reported product. Do not leave any responses blank.

If an anticoagulant added to the product is not listed on the form, check "yes" for question 41 and specify the anticoagulant's name in question 42.

Product Transport and Receipt

Question 43: Was this product collected off-site and shipped to your facility?
If the product was shipped to the transplant center 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 from an outside facility, or if the product **was** collected on site then shipped off site for laboratory processing, select "no" and continue with question 57. The "no" option usually applies to autologous collections and related donors.

Question 44: Date of receipt of product at your facility:
The intent of this question is to determine the date that the transplant center assumed responsibility for the product from the collection center.
Enter the date your institution became responsible for the product.

If multiple bags of the same product 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 45: 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.worldtimezone.org/.

Questions 46-47: 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 47. It is not necessary to provide the specific temperature of the product during shipment.

If the product is a cord blood unit, continue with question 48. For all other products, continue with question 57.

Question 48: Was there any indication that the environment within the shipper was outside the expected temperature range for this product at any time during shipment? *(Cord blood units only)*
Indicate if there was any indication that the environment within the shipper was outside the expected temperature range for this product at any time during shipment. 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 49: Were the secondary containers (e.g., insulated shipping containers and unit cassette) intact when they arrived at your center? *(Cord blood units only)*
Indicate if the secondary containers were intact upon receipt of the cord blood unit by your center.

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

Question 50: 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 51.

If the cord blood unit was not stored at your center prior to thawing, select “no” and continue with question 54.

Question 51: 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 52: 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 53: Date storage started:
Report the date the cord blood unit was first stored at your center prior to thawing.

NOTE: Questions 54 and 55
The values reported for questions 54 and 55 are from documentation supplied by the cord blood bank. Report the absolute number of cells, not per mL or per kg.

Question 54: 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 55-56: 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 56. 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 57.

Product Processing / Manipulation

Question 57: Was a fresh product received (e.g., not frozen)? *(NMDP products only)*
The intent of this question is to determine if the product shipped to the transplant center was ever cryopreserved. Indicate "yes" if the product was received fresh (and never cryopreserved) and continue with question 58. If the product was frozen, select "no" and continue with question 59. If the product was a cord blood unit, select "not applicable (cord blood unit)" and continue with question 59.

Question 58: Was the entire fresh product cryopreserved at your facility prior to infusion? *(NMDP products only)*
Indicate if the fresh NMDP product that arrived at your center was cryopreserved prior to infusion. If the **entire** fresh product was cryopreserved prior to infusion, select "yes" and continue with question 59.

Select "no" if the product was not cryopreserved prior to infusion. Also select "no" in situations where the product is split and the fresh product will be infused without ever having been cryopreserved, even if the remaining portions are cryopreserved for future use.

Question 59: 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 60.

If the product was never cryopreserved, select "no" and continue with question 71.

Question 60: 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 64.

If the entire product was not thawed, select "no" and continue with question 61.

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

Question 61: Was only a compartment of the bag thawed? *(cord blood units only)*
Large product bags (units, fraction) are often comprised of several compartments (chambers). The compartments can be removed from the larger bag and thawed individually.

Indicate if compartment(s) from within the larger product bag was(were) thawed.

Question 62: Were there multiple product bags?
Indicate if the product consisted of multiple product bags. If "yes," go to question 63. If "no," go to question 64.

Question 63: Specify number of bags thawed:
Of the total number of product bags, indicate the number of bags thawed. This number should be less than the total number of bags cryopreserved.

Question 64: Date thawing process initiated:
Report the date the thawing process began.

Question 65: 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.worldtimezone.org/.

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 66: Time product ready for infusion or expansion (24-hour clock):
Report the time the thawed product was ready for infusion or expansion. This time is frequently when 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.worldtimezone.org/.

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

Question 67: Was the primary container (e.g., cord blood unit bag) intact upon thawing?
Indicate if the primary container was intact upon thawing. The primary container refers to the product bag, not the shipping container.

If the cord blood unit primary container was not intact upon thawing, a product complaint form (Form 3010) must be completed.

Questions 68-69: What method was used to thaw the product?
Report the thawing method used to thaw the product. If a method other than “waterbath” or “electric warmer” was used, select “other method” and specify the method in question 69.

Question 70: Did any adverse events, 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.

Question 71: 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.” **Do not report cryopreservation (including plasma removal as part of cryopreservation) as a method of manipulation; cryopreservation of the product(s) is reported in questions 57-58, if applicable.**

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.” For an autologous product, continue with question 109. For an allogeneic product, continue with question 158.

Question 72: Specify portion manipulated:
Indicate the portion of the product that was manipulated. If the entire product was manipulated, select "entire product" and continue with question 73. If a portion of the product was removed and manipulated, select "portion of product" and continue with question 73.

If multiple portions of the product were manipulated in different ways, select "portion of product" to indicate that the manipulation was not performed on the entire product. All of the manipulations for each portion of the product should be reported in this section.

Questions 73-95: Specify all methods used to manipulate the product:
Indicate the method(s) of stem cell manipulation. Answer each question as "yes" or "no" and do not leave any responses blank.

Note: Steps in Manipulation
If the manipulation consists of several steps, individual steps do not need to be reported as separate manipulations. For example, washing that is part of CD34+ expansion does not need to be reported as a separate manipulation. Similarly, T-cell depletion that is part of expansion does not need to be reported.

In the cases above, if T-cell depletion and/or washing are done as stand-alone manipulations, they should be reported.

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

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

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

B cell reduced: B cell reduction is performed to reduce/remove the quantity of B cells in the product. [1]

CD8 reduced: CD8 reduction is performed to reduce/remove the population of CD8 cells in the product.[1] The removal of CD8 cells may mitigate the risk of GVHD.

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

Plasma reduction may be done in order to minimize the risks associated with ABO mismatched products or to prevent volume overload. Previous versions of the Form 2006 made a distinction between plasma removal

and volume reduction; for the purpose of this form, both volume reduction and plasma removal should be reported here.

Plasma reduction/removal that is part of the cryopreservation process should not be reported as manipulation.

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

Cultured (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.

PUVA treated: Treatment with psoralen and ultraviolet light (PUVA).[1]

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.

CD133 enriched: CD133 enrichment identifies and selects stem cells that have a CD133 marker on the cell surface.
Monocyte enriched: Monocyte enrichment identifies and selects monocytes.

Mononuclear cells enriched: Mononuclear cell enrichment identifies and selects mononuclear cells.

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.

If a method of manipulation was performed on the product, but is not listed above, select "yes" for question 94 and specify the method in question 95. 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.

Question 96: Were antibodies used during product manipulation?
If antibodies were used during product manipulation, select "yes" and continue with question 97. If antibodies were not used, select "no" and continue with question 109.

Questions 97-108: Specify antibodies:
Specify the antibodies used for product manipulation. Do not leave any responses blank. If antibodies were used during product manipulation, but are not listed above, select "yes" for question 107 and specify in question 108.

Autologous Products Only

The following section refers to autologous products only, including autologous cord blood. If this is not an autologous HCT, continue with the Product Analysis section at question 158.

Question 109: Were tumor cells detected in the recipient or autologous product prior to HCT?
Indicate if tumor cells (e.g., plasma cells in a myeloma patient, lymphoma cells, or breast cancer cells) were detected in the circulating blood stream or bone marrow within the period between the last systemic therapy and collection, or if tumor cells were present in the product. If tumor cells were detected, select "yes" and continue with question 110. If no tumor cells were found in the circulating blood cells, bone marrow (between last systemic therapy and collection), or product (before purging), select "no" and continue with question 136.

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

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

Questions 110-135: Specify tumor cell detection method used and site(s) of tumor cells:
For each method of tumor cell detection, indicate "yes" if tumor cells were detected. If yes, continue with the subsequent questions regarding site(s) of tumor cells. If no tumor cells were located, continue with the next detection method. Do not leave any responses blank.

> **Routine histopathology** includes a review of histological and morphological findings in the circulating blood, bone marrow, or autologous product.
>
> **Polymerase chain reaction (PCR)** is a molecular method used to detect known molecular abnormalities using markers for specific diseases.

Other molecular techniques include gene expression profiling techniques such as microarray. Specify the method used in question 119.

Immunohistochemistry is a technique used to evaluate surface markers on cellular material. Flow cytometry is an example of immunohistochemistry.

Cell culture technique is a technique used to detect malignant cell proliferation in cell culture medium.

Other techniques should be reported if the method used to detect tumor cells is not one listed above. Specify the technique in question 132.

If tumor cells were detected using one of the methods listed above, specify the site(s) of detection. Select “yes” if the site was tested and tumor cells were detected. Select “no” if the site was tested and tumor cells were not detected. Select “not done” if the site was not tested for tumor cells.

Circulating blood cells are evaluated after peripheral blood collection.

Bone marrow may be tested to detect tumor cells in the interval between the most recent systemic treatment and the stem cell collection.

Collected cells are in the product that will be used for transplant. Detection of disease in the collected cells should be reported prior to removing malignant cells (purging).

Question 136: Was the product treated to remove malignant cells (purged)?
This type of negative selection manipulation removes malignant cells from the collected product.

If the product was purged, select “yes” and continue with question 137. If the product did not have malignant cells to remove and/or was not purged, select “no” and continue with question 158.

Questions 137-150: Specify method(s) used:
Specify all methods used to purge the product. Answer each question as “yes” or “no,” being sure not to leave any question blank.

Monoclonal antibody: a negative selection method in which antibodies destroy malignant T- or B-cells.

4-hydroperoxycyclophosphamide (4HC) and **Mafosfamide:** a negative selection method in which derivatives of cyclophosphamide destroy malignant cells.

Elutriation: a method in which cells are separated based on size, potentially allowing malignant cells to be separated from non-malignant cells.

Immunomagnetic Column: a selection method in which monoclonal antibodies and magnetic beads attach to targeted cells, allowing for the separation of malignant and non-malignant cells using a magnet.

Toxin: a negative selection method in which a toxin or toxin-derivative may be combined with a monoclonal antibody to destroy malignant cells.

CD34 selection (other than preparation of mononuclear fraction): a positive selection method in which only CD34 cells for transplant are identified and collected. Select this option if this method was used to separate malignant cells from cells for transplant. Do not select this option if the product was CD34 selected for other reasons.

Deeg, H. Joachim, and H. Klingemann. *A guide to bone marrow transplantation*. 2nd rev. and enl. ed. Berlin: Springer-Verlag, 1992. Print.

Keng, Peter C., Philip Rubin, Louis S. Constine, Christopher Frantz, Nasser Nakissa, and Philip Gregory. "Characterization Of The Biophysical Properties Of Human Tumor And Bone Marrow Cells As A Preliminary Step To The Use Of Centrifugal Elutriation In Autologous Bone Marrow Transplantation." *International Journal of Radiation OncologyBiologyPhysics* 10.10 (1984): 1913-1922.

Peters WP, Hamm C, Baynes RD. Autologous Bone Marrow and Stem Cell Transplantation. In: Bast RC Jr, Kufe DW, Pollock RE, et al., editors. Holland-Frei Cancer Medicine. 5th edition. Hamilton (ON): BC Decker; 2000. Chapter 67. Available from: http://www.ncbi.nlm.nih.gov/books/NBK20890/

Questions 151-157: Specify if tumor cells were detected in the graft after purging by each method used:

For each of the detection methods listed (and described above in questions 110-135), indicate whether tumor cells were detected in the product after the purging was completed. Answer each question as “yes” or “no,” being sure not to leave any question blank.

Product Analysis (All Products)

NOTE: Product Analysis

The **“at infusion”** timepoint is a critical timepoint and should reflect the values of the infused product (i.e., what was given to the patient). As long as the values specific to the volume of product infused are known, the analysis at this timepoint is the only analysis required by the CIBMTR. All other timepoints are not required. However, for NMDP products, reporting analysis for the “product arrival” timepoint is recommended for quality assurance purposes. Additionally, for **cord blood products**, the “post-thaw” timepoint is the most indicative of the quality of the product. If there are sufficient cells to obtain a post-thaw/pre-wash sample, it is recommended to report this analysis as well.

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

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

Question 158: Specify the timepoint in the product preparation phase that the product was analyzed:
Indicate the timepoint at which product analysis was reported. A maximum of four timepoints may be reported. Each timepoint can only be reported once.

> **Product arrival**: Assessment of *fresh product* at the transplant facility. This may include arrival of fresh product from an apheresis or collection center, or product collected from an autologous or related donor at your site.
>
> **Pre-cryopreservation:** Assessment of *fresh product* prior to cryopreservation ***at your center***.
>
> **Post-thaw:** Assessment after the product has been thawed, but prior to any post-thaw manipulation, including washing the cells to remove cryoprotectant.
>
> **At infusion:** *Must be reported if values specific to the volume of product infused are known.* If the product was manipulated after thawing, report the post-manipulation analysis under the "at infusion" timepoint.

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

The "at infusion" timepoint should only report the values for the actual product volume infused. Therefore, if analysis was performed on the entire product but only a portion of the product was infused, the "at infusion" values reported should represent only the portion of product infused. If product analysis values of the entire product are known and the values specific to only the volume of product infused cannot be determined, then the "at infusion" may be reported using the known volume (and additional details including viability, culture results, CFU assessment results, etc.), but the cell counts may be reported as "not done." An additional timepoint such as "pre-cryopreservation" or "post-thaw" should be reported if the product was analyzed at your center.

> **Example 1 – entire product infused:** The entire product is analyzed at arrival and does not undergo any manipulation, cryopreservation, or additional analyses. The entire product volume is infused. The values from the product analysis should be reported for the "at infusion" timepoint.
>
> **Example 2 – portion of product infused:** The entire product is analyzed prior to infusion and the values from this analysis are reflective of the entire product.

Only a portion of this product is infused. The counts specific to the volume of product infused are proportional to the volume infused and can be calculated. The results of the analysis performed on the entire product should be reported for the appropriate timepoint (e.g., product arrival, pre-cryopreservation, or post-thaw).

If the product arrives at your center (or is collected at your center), is tested, and the cryopreserved, report these values as "at arrival." If the product arrives, and is tested several times, and then cryopreserved, report the first testing results as "at arrival" and the last test results prior to cryopreservation as "pre-cryopreservation." If the product is thawed, but not retested prior to infusion, you can report the values prior to cryopreservation as "at infusion." If a viability assessment is completed, ensure that it is reported accurately for the at infusion time point.

Question 159: Date of product analysis:
Report the date of the product analysis for each timepoint reported. In situations where the product is being collected at your center and the "product arrival" timepoint is being used, report the first date of collection as the date of product analysis if the collection spans multiple days.

Question 160: Total volume of product plus additives:
Enter the total volume of the product plus additives in the bag(s) for each timepoint. Report the volume in either milliliters (mL) or grams (g).

Questions 161-176: Report the total number of cells (not cells per kilogram) not corrected for viability.
For each of the cell types, report "done" if the cell type was quantified at the specified timepoint. Report the absolute number of the cells, not cells per kg.

Total nucleated cells (TNC): the total nucleated cell count includes nucleated red and nucleated white blood cells. *See note below*

Nucleated white blood cells: (also known as leukocytes) the nucleated cell count includes the neutrophils, eosinophils, basophils, lymphocytes, and monocytes. *See note below*

Mononuclear cells: the total mononuclear cell count includes lymphocytes and monocytes.

Nucleated red blood cells: (also known as normoblasts) the total count of red blood cells containing a nucleus. *See note below*

CD34+ cells: the total count of cells with CD34+ markers on the surface.

CD3+ cells: the total count of cells with CD3+ markers on the surface.

CD3+CD4+ cells: the total count of cells with CD3+CD4+ markers on the surface. The lab report may display this value as "CD4+."

CD3+CD8+ cells: the total count of cells with CD3+CD8+ markers on the surface. The lab report may display this value as "CD8+"

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 17.96×10^6/mL, the product volume is 390 mL, and the nRBCs per 100 WBCs is 12.8 (using the formula above when considering cells/mL):

$$\frac{(17.96\ x\ 10^6) \times (390\ mL) \times (12.8 + 100)}{100} = 79x10^8\ uncorrected\ TNC$$

If the cell type was not quantified at that specific timepoint, report "not done" and continue with the next cell type.

Questions 177-178: Viability of cells:
If the viability of the cells was quantified, select "done" and report the percentage of viable cells in question 178. If your center's laboratory assay only measures viable cells, report the number of viable cells in questions 161-176 along with a viability number of 100% in question 178. If the assay measures all cells and then checks viability, report the total number and report the percent of cells that are viable.

Questions 179-180: Method of testing cell viability:
Indicate the method of testing viability

> **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 both methods of viability testing are performed, report 7-AAD results.

If the cell viability was tested using a different method, select "other method" and specify the method in question 180.

Question 181: 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 182. If no CFU assessments were performed, continue with question 187.

Question 182: Was there growth?
If CFUs were assessed after thawing, indicate whether growth was detected.

Questions 183-184: 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 184. Report the total CFU as documented on the laboratory report. Do not report CFU per dish, per bag, or per kg.

Questions 185-186: 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 186. Report the total BFU-E as documented in the laboratory report. Do not report BFU per dish, per bag, or per kg.

Question 187: Were cultures performed before infusion to test the product(s) for bacterial or fungal infection? *(complete for all cell products)*
If cultures were performed, select "yes" and continue with question 188.

If cultures were not performed, select "no" and continue with question 196.

Questions 188-195: Specify results and 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 cultures were performed on the product, indicate the results as "positive," "negative," or "unknown."

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

Product Infusion

Questions 196: 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.

If this Form 2006 is completed for additional cells not intended to produce engraftment, (i.e., question 198 was reported as "no") report the date the additional cells were infused. However, the Key Field "Date of this HCT" must be reported as date of the actual HCT (clinical day 0) intended to produce engraftment.

Question 197: Was more than one product infused? (e.g., marrow and PBSC, PBSC and cord blood, two different cords, etc.)
Indicate if more than one product was infused as part of this transplant event. Previous transplants should not be reported here. Multiple bags from the same collection are not considered different products and should not be reported here. If "yes," continue with question 198. If "no," continue with question 199.

Question 198: Was the product described on this insert intended to produce hematopoietic engraftment?
If an infusion of additional cells (not intended to produce engraftment) was given prior to the actual HCT (i.e., clinical day 0), the cells must be reported as a product on the Pre-TED Form 2400 and on a separate Form 2006. If the additional cells were infused after the actual HCT, for **any reason** other than those pertaining to the original HCT graft,

they should be reported as a DCI on the appropriate follow-up form. Reporting the additional cells (given pre-HCT and not intended to produce engraftment) on the Form 2006 is the only mechanism the CIBMTR has in place to collect this data and ensure that the quality assurance data is reported to cord blood banks, if applicable.

If the product reported on this form was intended to produce engraftment, select “yes.” If the product was not intended for engraftment, select “no.”

Question 199: Date infusion started:
Report the date the product was infused. If multiple bags from the same product were infused, report the start date of the first bag.
If **multiple products** were infused, enter the initiation date of **the product for which this form is being completed**.

Question 200: 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.worldtimezone.org/.

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

Question 201: 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 202: 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.worldtimezone.org/.

Question 203: Total volume of product plus additives intended for infusion:
Report the total volume of the infused product, including any additives.

In most cases, this value will be the same as the "total volume of product" (question 143/164) for the "at infusion" timepoint (question 158).

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

> **Example 1 – with manipulation:** If a single product consisted of two collections and the products were pooled prior to any manipulation (e.g., CD34+ selection), the pooled volume prior to manipulation would be reported in question 160 only. The final infused product volume post manipulation would be reported in question 204.
>
> **Example 2 – without manipulation:** If a single product consisted of two collections and the products were pooled and infused without any manipulation, the total volume would be reported in question 160 and question 204. These volumes should be the same unless there were additives post pooling.

Question 204: Was the entire volume of 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.

Questions 205-206: 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.

Questions 207-208: 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, select "other route of infusion" and specify the infusion route in question 208.

NOTE:
The following questions refer to all stem cell products except for autologous marrow or autologous PBSC products. If this HCT used an autologous marrow or autologous PBSC product, continue with the signature lines at the end of the form.

Question 209: Were there any adverse events or incidents associated with the stem cell infusion?
Indicate whether any adverse events or incidents occurred as a result of the stem cell infusion. **Report all adverse events regardless of the grade or severity.**

If an adverse event occurred, select “yes” and continue with question 210. If an adverse event did not occur, select “no” and continue with question 250.

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 210-249: 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 245. 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 247-248.

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.

Donor/Infant Demographic Information

The Donor Demographic Information section (questions 250-270) is to be completed for all non-NMDP allogeneic donors. If the stem cell product was from an NMDP donor or an autologous donor, continue with the signature lines at the end of the form.

Question 250: Was the donor ever pregnant?
If the donor has ever been pregnant, select “yes” and continue with question 251.

If the donor has never been pregnant, select “no” and continue with question 253.

If there is no documentation regarding whether or not the donor has ever been pregnant, select “unknown” and continue with question 253.
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 253.

Questions 251-252: Number of pregnancies
Indicate if the number of pregnancies is known or unknown. If "known," specify the total number of pregnancies in question 252.

If the total number of pregnancies is not known, select "unknown" and continue with question 253.

Question 253: Specify blood type:
Report the donor's blood type.

Question 254: Specify Rh factor:
Report the donor's Rh factor as "negative" or "positive."

Question 255: Did this donor have a central line placed?
If the donor had a central line placed during the donation process, select "yes" and continue with question 256.
If the donor did not have a central line, select "no" and continue with question 258.

If the product is a cord blood unit or marrow, select "not applicable (cord blood unit or marrow product)" and continue with question 258.

Questions 256-257: Specify the site of the central line placement:
Indicate the location of the donor's central line. If "other site" is selected, complete question 257 to specify the location of central line placement.

Question 258: Donor's ethnicity:
Indicate the donor's ethnicity. For more information regarding ethnicity, see Appendix I.

Questions 259-260: 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.

Copy questions 259-260 to report more than one race.

Questions 261-263: What is the biological relationship of the donor to the recipient?
From the perspective of the recipient, indicate the biological relationship of the donor. If the recipient and donor are not biologically related, select "unrelated" and continue with question 264. If the recipient and donor are related, but the relationship is not best characterized by one of the options for question 261, select "other biological relative" and specify in question 262. If the biological relationship is not listed among the options, select "other biological relative" and specify the biological relationship in question 263 (i.e., maternal grandmother).

Question 264: Was the donor/product tested for potentially transplantable genetic diseases?
If the donor and/or product were tested for genetic disease, select "yes" and continue with question 265. If the donor and/or product were not tested, or if there is no documentation of genetic testing, select "no" or "unknown," respectively, and continue with question 272 for related donors or the signature lines at the end of the form for all other donor types.

Questions 265-271: Specify disease(s) tested:
For each of the diseases listed, indicate whether testing was done. Indicate "yes" or "no" and specify the results in the following question. Do not leave any responses blank. If the donor was tested for a potentially transplantable disease, but it was not listed in questions 265-268, select "yes" for "other disease" and specify the disease and the results in questions 270-271.

NOTE:
The following questions (268-281) apply only to allogeneic related donors. If the stem cell product was from an autologous donor, non-NMDP unrelated donor, NMDP donor, or was a cord blood unit, then continue with the signature lines at the end of the form.

Question 272: Was the donor hospitalized (inpatient) during or after the collection?
Indicate if the donor was hospitalized during or after the collection for any reason.

Questions 273-274: Did the donor experience any life-threatening complications during or after the collection?
Examples of life-threatening complications include, but are not limited to the following:

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

If the donor experienced life-threatening complications during or after the collection, select "yes" and specify the complication(s) in question 274.

If the donor did not experience life-threatening complications during or after the collection, select "no" and continue with question 275.

Question 275: 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 any blood products as a result of the collection, select "yes" and continue with question 276. If the recipient did not receive blood transfusions as a result of the collection, select "no" and continue with question 280.

Questions 276-277: Was the blood transfusion product autologous?
If the recipient received transfusions of their own blood that had been previously collected and stored, even once, indicate "yes" and specify the number of units received in question 277.

If the recipient received no autologous blood transfusions, indicate "no" and continue with question 278.

Questions 278-279: Was the blood transfusion product allogeneic (homologous)?
If the recipient received blood transfusions (excluding autologous blood product), indicate "yes" and specify the number of units received in question 279.

If the recipient did not receive any blood transfusions (excluding autologous products), indicate "no" and continue with question 280.

Questions 280-281: 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 281. If the donor did not die as a result of the collection, select "no" and continue with question 282.

Questions 282-283: Did the recipient submit a research sample to the NMDP/CIBMTR repository? *(Related donors only)*
There are a select number of transplant centers participating in the Related Specimen Repository. If your center is one of the participating centers, and the recipient provided a research sample, select "yes" and provide the recipient ID in question 283. The ID number is located on the bar code that is attached to the sample tube.

If the recipient did not provide a research sample, select "no" and continue with question 284.

Questions 284-285: Did the donor submit a research sample to the NMDP/CIBMTR repository? *(Related donors only)*
If the donor provided a research sample, select "yes" and provide the donor ID in question 285.

If the donor did not provide a research sample, 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.

Manual Change History

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
2.1	11/21/2013	Modify	The formulas in the explanatory text for questions 161-176 did not publish correctly in version 2.0 and were updated
2.1	11/21/2013	Add	Added "(Revision 4)" to title of document
2.2	03/28/2014	Modify	Question 207 – modified text to read: *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. ~~and i~~ Intraperitoneal refers to infusion within the peritoneal cavity. If the route of infusion is not one of the above options, select "other route of infusion" and specify the infusion route in question 208.*
2.3	09/24/2014	Add	Question 71 – added the following text: *If any part of the product was manipulated in any way prior to infusion at the transplant center, select "yes."* ***Do not report cryopreservation (including plasma removal as part of cryopreservation) as a method of manipulation; cryopreservation of the product(s) is reported questions 57-58, if applicable.*** *If the product was shipped to your facility, do not report manipulation of the product performed at the collection center.*

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
2.3	09/24/2014	Add	Questions 73-95 – added the following text: ***Note: Steps in Manipulation*** *If the manipulation consists of several steps, individual steps do not need to be reported as separate manipulations. For example, washing that is part of CD34+ expansion does not need to be reported as a separate manipulation. Similarly, T-cell depletion that is part of expansion does not need to be reported.* *In the cases above, if T-cell depletion and/or washing are done as stand-alone manipulations, they should be reported.* … ***Plasma reduced (removal):*** *Plasma reduction is performed to remove plasma via sedimentation or centrifugation.*[1] *Plasma reduction may be done in order to minimize the risks associated with ABO mismatched products or to prevent volume overload. Previous versions of the Form 2006 made a distinction between plasma removal and volume reduction; for the purpose of this form, both volume reduction and plasma removal should be reported here.* *Plasma reduction/removal that is part of the cryopreservation process should not be reported as manipulation.* ...
2.4	01/15/2015	Modify	Modified the explanatory text in question 66: *Report the time the thawed product was ready for infusion or expansion. This time is frequently when 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.worldtimezone.org/.*

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
2.4	01/15/2015	Add	Added additional explanatory text to question 158: *If the product arrives at your center (or is collected at your center), is tested, and the cryopreserved, report these values as "at arrival." If the product arrives, and is tested several times, and then cryopreserved, report the first testing results as "at arrival" and the last test results prior to cryopreservation as "pre-cryopreservation." If the product is thawed, but not retested prior to infusion, you can report the values prior to cryopreservation as "at infusion." If a viability assessment is completed, ensure that it is reported accurately for the at infusion time point.*
2.4	01/15/2015	Add	Added an informational box to the explanatory text following questions 161-176: ***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.*
2.4	01/15/2015	Add	Added informational text to question 179-180: *If both methods of viability testing are performed, report 7-AAD results.*