Instructions for Infectious Disease Markers (2004) Form

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Infectious Disease Markers Form.

Infectious Disease Markers

The Infectious Disease Markers (2004) will come due in the following instances:

- Non-NMDP unrelated donor (TED or CRF track)
- Non-NMDP unrelated cord blood (TED or CRF track)
- Related cord blood (TED or CRF track)
- HLA-identical sibling (CRF track or when consented for "Research Sample Repository" on TED track)
- HLA-matched other relative or HLA-mismatched relative (CRF track or when consented for "Research Sample Repository" on TED track)

If the donor or cord blood unit was secured through the NMDP, IDM test results will be reported by the donor center on NMDP Forms 24 and 50 or will be submitted by the cord blood bank through CORD Link®.

Infectious diseases result from pathogens that enter the human body and multiply. Examples of pathogens include viruses, bacteria, fungi, and parasites. Infectious diseases may be transmitted through liquids, food, body fluids, contaminated objects, or airborne particles.

An Infectious Disease Marker (IDM) indicates if an individual currently has, or previously has had, an infectious disease that could be transferred to another person.

- Antibody testing assesses whether an individual's immune system recognizes an antigen presentation, which indicates previous exposure to the pathogen.
- Antigen testing, such as testing for the presence of the Hepatitis B surface antigen, assesses whether the individual has an active infection, where the pathogen is present in the blood. Antigen testing is done because the individual may not yet have developed antibodies against the pathogen at the time of infection.

The purpose of IDM testing is to assess the donor's exposure to infectious diseases and the likelihood of their transmitting a disease to the recipient.

For a glossary of terms used in this section of the manual, see Appendix B: Glossary of Terms.

Links to Sections of Form:
Q1: Donor / Cord Blood Unit Identification
Q2 – 28: Infectious Disease Markers

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.

To review the historical Manual Change History for this form, reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/Remove/Modify	Description
7/25/2025	Infectious Disease Markers (2004)	Add	Version 6 of the 2004: Infectious Disease Markers section of the Forms Instructions Manual released. Version 6 corresponds to revision 7 of the Form 2004.

Q1: Donor / Cord Blood Unit Identification

Question 1: Who is being tested for IDMs?

Indicate whether the **Donor IDM** (for peripheral blood stem cells and / or bone marrow products), **Maternal IDM** (mother of the cord donor), or **Cord blood unit IDM** itself is being tested. Maternal IDMs and cord blood unit IDMs apply only to cord blood products; if both maternal and cord blood IDMs are available, report the results from cord blood unit testing. Cord blood banks send documentation accompanying the cord that will specify IDM results, and the source of the specimen sent for IDM testing; most cord blood banks perform IDM testing on maternal serum due to the limited volume and cell count of cord blood units.

Section Updates

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

Q2 – 29: Infectious Disease Markers

Report the final test results. Final test results could refer to either the initial screening test or the confirmatory test. If a screening test is negative, a confirmatory test might not be done. In this case, use the screening test as the final test result. However, if a screening test is positive, a confirmatory test may be done. In this case, use the confirmatory test as the final test result. If testing is only performed on the harvested product and not on the peripheral blood sample, report those samples accordingly.

Hepatitis B Virus (HBV)

Hepatitis B infection is caused by the hepatitis B virus (HBV). Hepatitis B is spread through infected blood and other body fluids. Signs and symptoms of infection generally occur 60-150 days after exposure and include fever, fatigue, nausea, vomiting, and jaundice (secondary to liver inflammation). Patients with an acute hepatitis B infection generally do not require treatment; approximately 95% of adults who get acute hepatitis B will recover without developing chronic hepatitis B infection. Chronic hepatitis B infection is generally monitored for progression or evidence of liver damage, at which point patients may be treated with antiviral drugs. Chronic hepatitis B infection can lead to liver scarring (cirrhosis) and liver cancer (hepatocellular carcinoma). In the United States, the hepatitis B vaccine is now part of the routine childhood vaccination schedule.

Question 2: HBsAg (hepatitis B surface antigen)

The hepatitis B surface antigen is a protein expressed on the surface of the hepatitis B virus. Its presence in the blood serum indicates acute or active chronic infection. In acutely infected patients, blood will test HBsAg positive within one to nine weeks of exposure to the virus. Patients who do not go on to develop chronic infection will be surface antigen negative by 15 weeks after the onset of symptoms. Chemiluminescent immunoassay (CIA), electrochemiluminescent immunoassay (ECLIA), or enzyme-linked immunosorbent assay (ELISA) are used to test for the presence of hepatitis B surface antigens; research indicates CIA and ECLIA may be more sensitive for detecting low levels of HBsAg[1]. Positive HBsAg results require confirmation with specific antigen neutralization.

Report the laboratory result as **Reactive** (positive) or **Non-reactive** (negative). For any inconclusive or indeterminate results, report **Inconclusive**. If HBsAg testing was not performed, report **Not done**.

[1] Fei CR, Ye AQ, Zhang J. (2011). Evaluation of different methods in determination of low level HBsAg. Zhejiang Da Xue Xue Bao Yi Xue Ban, 40(4):436-439.

Question 3: Date sample for HBsAg collected

Indicate the date the sample for HBsAg was collected for infectious disease marker testing.

Question 4: Anti HBc (hepatitis B core antibody)

The total hepatitis B core antibody refers to both IgG and IgM antibodies produced by the body in response to the presentation of the core antigen by liver cells. Since core antigen is present only in infected liver cells and cannot be detected in the blood of an infected individual, only core antibody is tested, since it circulates in the peripheral blood. After infection, total core antibodies will persist for life. Presence of core antibodies can indicate active and/or prior infection, but hepatitis core antibodies will not be present in individuals with no history of natural infection with HBV. This means that vaccinated individuals will not be anti-HBc positive because vaccination results in the body developing antibodies to the hepatitis B surface antigen. Chemiluminescent immunoassay (CIA), enzyme-linked immunosorbent assay (ELISA), or Elecsys anti-HBc is used to test for the presence of hepatitis B core antibodies. Currently, there is no licensed confirmatory test for anti-HBc in the United States; confirmation of antibody presence is done by performing a second anti-HBc test using a different manufacturer's test kit.[2]

Report the laboratory result as **Reactive** (positive) or **Non-reactive** (negative). For any inconclusive or indeterminate results, report **Inconclusive**. If anti-HBc testing was not performed, report **Not done**.

[2] Centers for Disease Control & Prevention. (2012). CDC Hepatitis B Information for Health Professionals. Retrieved from http://www.cdc.gov/hepatitis/HBV/HBVfaq.htm

Question 5: Date sample for Anti HBc collected

Indicate the date the sample for Anti HBc was collected for infectious disease marker testing.

Question 6: FDA licensed NAAT testing for HBV

Nucleic acid amplification testing (NAAT) is a combination PCR test that detects the presence of viral genes rather than antigens or antibodies. This test allows earlier detection and provides more sensitivity than previously used tests.

Report the laboratory result as **Positive** or **Negative**. For any inconclusive or indeterminate results, report **Inconclusive**. If HBV NAAT testing was not performed, report **Not done**.

If HBV NAAT testing was performed but results are not being reported to the CIBMTR (e.g., donor declines to release results), report **Not done**.

Non-U.S. centers should answer this question, regardless of FDA licensure. If a non-FDA licensed NAAT test was used, report these results under *Other Infectious Disease Marker*.

Question 7: Date sample for FDA licensed NAAT testing for HBV collected

Indicate the date the sample for FDA licensed NAAT testing for HBV was collected for infectious disease marker testing.

Hepatitis C Virus (HCV)

Hepatitis C infection is caused by the hepatitis C virus (HCV). Hepatitis C is generally spread through infected blood. Newly infected individuals are generally asymptomatic, though signs and symptoms of infection, similar to those seen in other viral hepatitis infections, can develop. Since acute hepatitis C infection is generally asymptomatic, it is rarely identified or treated during the acute infection stage. Approximately 15-25% of infected individuals will clear the virus without treatment and will not develop chronic hepatitis C infection. Chronic hepatitis C infection can lead to chronic liver disease and/or scarring of the liver (cirrhosis); chronic HCV is the leading indication for liver transplant in the United States. Currently no approved vaccination for hepatitis C exists.

Question 8: Anti-HCV (hepatitis C antibody)

The total hepatitis C antibody refers to both IgG and IgM antibodies produced by the body in response to the presentation of antigens by the hepatitis C virus. Antibodies can generally be detected as soon as four weeks after exposure and will persist for life. Enzyme-linked immunosorbent assay (ELISA) or chemiluminescent immunoassay (CIA) is used to screen for hepatitis C antibodies; confirmatory testing is done by recombinant immunoblot assay (RIBA). A positive ELISA or CIA result without confirmation by RIBA is considered an indeterminate result, unless HCV RNA is detected in the blood by PCR.

Report the laboratory result as **Reactive** (positive) or **Non-reactive** (negative). For any inconclusive or indeterminate results, report **Inconclusive**. If anti-HCV testing was not performed, report **Not done**.

Question 9: Date sample for Anti-HCV collected

Indicate the date the sample for Anti-HCV was collected for infectious disease marker testing.

Question 10: FDA licensed NAAT testing for HCV

Nucleic acid amplification testing (NAAT) is a combination PCR test that detects the presence of viral genes rather than antigens or antibodies. This test allows earlier detection and provides more sensitivity than previously used tests.

Report the laboratory result as **Positive** or **Negative**. For any inconclusive or indeterminate results, report **Inconclusive**. If HCV NAAT testing was not performed, report **Not done**.

If HCV NAAT testing was performed but results are not being reported to CIBMTR (e.g., donor declines to release results), report **Not done**.

Non-U.S. centers should answer this question, regardless of FDA licensure.

If a non-FDA licensed NAAT test was used, report these results under *Other Infectious Disease Marker*.

Question 11: Date sample for FDA licensed NAAT testing for HCV collected

Indicate the date the sample for FDA licensed NAAT testing for HCV was collected for infectious disease marker testing.

Human Immunodeficiency Virus (HIV)

HIV infection is caused by exposure to one of two viruses, either HIV-1 or HIV-2. HIV-2 is less virulent and has a longer incubation period than HIV-1. Both types of HIV progressively destroy CD4+ cells, which include T-helper cells, monocytes, and their derivatives (macrophages and dendritic cells), and are an important part of the body's immune defense. HIV can lead to acquired immunodeficiency syndrome (AIDS), a condition in which the immune system begins to fail, leading to life-threatening opportunistic infections. Mechanism of HIV transmission is through exposure to blood or other body fluids, or through vertical transmission (maternal-fetal transmission).

Question 12: HIV-1 p24 antigen

The HIV p24 antigen is a viral core protein that is detectable in the blood during acute infection; it is detectable earlier than HIV antibody. The p24 antigen appears approximately two weeks after exposure and will be present in the blood for three to five months. Once antibodies to HIV are detectable in the blood, p24 antigen is usually no longer detectable by immunoassay due to antigen-antibody binding. Enzyme-linked immunosorbent assay (ELISA) is used to test for the presence of p24 antigen; it may be done in conjunction with antibody testing in order to detect the virus in all stages of

infection. Positive p24 antigen results require confirmation with specific antigen neutralization.[3]

Report the laboratory result as **Reactive** (positive) or **Non-reactive** (negative). For any inconclusive or indeterminate results, report **Inconclusive**. If HIV-1 p24 antigen testing was not performed, report **Not done**.

If HIV-1 p24 testing was performed but results are not being reported to CIBMTR (e.g., donor declines to release results, states that cannot report results per state laws, etc.), select **Not reported**.

[3] University of California, San Francisco. (n.d.) HIV InSite Knowledge Base. Retrieved January 15, 2013, from http://hivinsite.ucsf.edu/InSite?page=KB

Question 13: Date sample for HIV-1 p24 antigen collected

Indicate the date the sample for HIV-1 p24 antigen was collected for infectious disease marker testing.

Question 14: FDA licensed NAAT testing for HIV-1

Nucleic acid amplification testing (NAAT) is a combination PCR test that detects the presence of viral genes rather than antigens or antibodies. This test allows earlier detection and provides more sensitivity than previously used tests.

Report the laboratory result as **Positive** or **Negative**. For any inconclusive or indeterminate results, report **Inconclusive**. If HIV-1 NAAT testing was not performed, report **Not done**.

If HIV-1 NAAT testing was performed but results are not being reported to CIBMTR (e.g., donor declines to release results, states that cannot report results per state laws, etc.), report **Not reported**.

Non-U.S. centers should answer this question, regardless of FDA licensure.
If a non-FDA licensed NAAT test was used, report these results under *Other Infectious Disease Marker*.

Question 15: Date sample for FDA licensed NAAT testing for HIV-1 collected

Indicate the date the sample for FDA licensed NAAT testing for HIV-1 was collected for infectious disease marker testing.

Anti-HIV 1 and Anti-HIV 2
Testing for both HIV 1 and HIV 2 is required when reporting the results of anti-HIV1 and anti-HIV 2/ This testing may be performed as separate tests or using a combined assay.

Question 16: Anti-HIV 1 and anti-HIV 2 (antibodies to Human Immunodeficiency Viruses)

The HIV-1 and HIV-2 antibodies are produced by the body in response to the antigens presented by the HIV-1 and HIV-2 viruses, such as p24 (HIV-1) core antigen and p26 (HIV-2) core antigen. Antibodies are not detectable as early during the course of infection as the viral antigens but will persist for the patient's lifetime once developed. Enzyme-linked immunosorbent assay (ELISA) is used to test for the presence of HIV-1 and HIV-2 antibodies. Most laboratories will utilize a combined assay that detects both viral antibodies, but in some cases, they will be done as separate tests. Positive HIV-1 antibody results require confirmation by western blot, which uses gel electrophoresis to detect specific proteins. Currently, there is no licensed confirmatory test for anti HIV-2 in the United States; confirmation of antibody presence is done by performing a second anti HIV-2 test using a different manufacturer's test kit.

Report the laboratory result as **Reactive** (positive) or **Non-reactive** (negative) *only* if the patient was evaluated for antibodies to both HIV-1 and HIV-2. For any inconclusive or indeterminate results, report **Inconclusive**.

If the donor was only assessed for antibodies to one virus, report **Not done**.

If anti-HIV-1 and / or anti-HIV-2 testing was not performed, report **Not done**.

If anti-HIV-1 and anti-HIV-2 testing was performed but results are not being reported to CIBMTR (e.g., donor declines to release results, states that cannot report results per state laws, etc.), report **Not reported**.

Question 17: Date sample for Anti-HIV 1 and anti-HIV 2 collected

Indicate the date the sample for Anti-HIV 1 and anti-HIV 2 was collected for infectious disease marker testing.

Chagas (T. cruzi)

Chagas disease is caused by the parasitic protozoan *Trypanosoma cruzi* (T. cruzi), which is endemic in South America, Central America, and the Caribbean. Chagas is spread through exposure to infected blood, most commonly through an insect vector such as triatomine bugs. It can also be spread through transmission from mother to fetus (also known as "vertical transmission"), blood transfusions, organ transplant, or needlesticks. In acute infection, there are rarely severe symptoms; most cases are asymptomatic or will exhibit generalized, non-specific symptoms. Treatment with anti-parasitic drugs during the acute phase is often curative. Of the individuals who are untreated and enter the chronic phase of infection, only 20-40% will ever have signs and symptoms related to Chagas disease. Symptomatic Chagas disease can affect the nervous, digestive, and cardiac systems and can be very severe, even resulting in death.

Question 18: Chagas testing

Testing for antibodies to T. cruzi is generally done by enzyme-linked immunosorbent assay (ELISA) or chemiluminescent immunoassay (CIA). If active infection is suspected, another evaluation, such as PCR, may be done to confirm and identify the strain of infection. In 2011, the FDA approved a more specific immunoassay that evaluates the donor for antibodies to specific excreted-secreted antigens presented by the T. cruzi pathogen. This assessment is intended to be a supplemental test for individuals who have been repeatedly reactive to the previously approved immunoassays.

Report the laboratory result as **Positive** or **Negative**. For any inconclusive or indeterminate results, report **Inconclusive**. If Chagas testing was not performed, report **Not done**.

Question 19: Date sample for Chagas testing collected

Indicate the date the sample for Chagas testing was collected for infectious disease marker testing.

Herpes Simplex Virus (HSV)

Herpes Simplex Virus includes two viruses, HSV-1 and HSV-2, which are two of the human herpes viruses (Herpesviridae family). Other human herpes viruses include cytomegalovirus (CMV), Epstein-Barr virus (EBV), and varicella zoster virus (VZV). HSV-1 is typically manifested as skin lesions or lesions of the oral mucous membranes; it may also infect the genitalia, but this is less common. HSV-2 is typically manifested as lesions of the external genitalia. Both HSV-1 and HSV-2 are spread through contact with lesions during active infection; HSV-1 can be spread through saliva. After initial infection, the virus will lay dormant in the body and can reoccur. Stress, fatigue, and infection can all cause the virus to be reactivated. According to data from 1999-2004, the seroprevalence of HSV-1 in individuals in the United States between ages 14-49 is estimated at 57.7%, while the seroprevalence of HSV-2 for the same population is estimated at 17.2%.[5]

[5] Xu F, Sternberg MR, Kottiri BJ, et al. (2006). Trends in Herpes Simplex Virus Type 1 and 2 Seroprevalence in the United States. J Am Med Assoc, 296(8).

Question 20: Anti-HSV (Herpes simplex virus antibody)

Testing for antibodies to HSV is typically done by enzyme-linked immunosorbent assay (ELISA), glycoprotein G-specific immunoblot assay, or Western Blot. These immunoassays detect antibodies to both HSV-1 and HSV-2, though the results will specify whether detected antibodies are specific to HSV-1 or HSV-2 (or both). Results may be expressed as quantified antibody titer; in this case, the laboratory or test kit

manufacturer will provide reference ranges to determine if the result is considered positive, indeterminate, or negative.

Report the laboratory result as **Positive** or **Negative**. If *either* HSV-1 or HSV-2 antibodies are detected, report **Positive**. For any inconclusive or indeterminate results, report **Inconclusive**. If anti-HSV testing was not performed, report **Not done**.

Question 21: Date sample for Anti-HSV collected

Indicate the date the sample for Anti-HSV was collected for infectious disease marker testing.

Epstein-Barr Virus (EBV)

Epstein-Barr Virus (EBV) is part of the human herpes virus's family *Herpesviridae*. EBV infection may cause infectious mononucleosis, particularly in young adults. Infectious mononucleosis symptoms include fever, sore throat, lymphadenopathy, and fatigue. After initial infection, the virus will lay dormant in the body and can reoccur; recurrence of EBV is often subclinical. Late events associated with prior EBV infection include Burkitt's lymphoma, post-transplant lymphoproliferative disorder (PTLD), and nasopharyngeal carcinoma.

Question 22: Anti-EBV (Epstein-Barr virus antibody)

Testing for antibodies to EBV is typically done by enzyme-linked immunosorbent assay (ELISA). This immunoassay can be used to detect IgM and/or IgG antibodies to EBV. The presence of IgM antibodies indicates a recent or current infection, usually within the past four to six months. Presence of IgG antibodies indicate a previous infection and confers long-term immune response to the virus. Results may be expressed as quantified antibody titer; in this case, the laboratory or test kit manufacturer will provide reference ranges to determine if the result is considered positive, indeterminate, or negative.

Report the laboratory result as **Positive**, **Negative**, or Inconclusive. A positive IgM or IgG assay is considered a **Positive** (reactive) result. For any inconclusive or indeterminate results, report **Inconclusive**. If anti-EBV testing was not performed, report **Not done**.

Question 23: Date sample for Anti-EBV collected

Indicate the date the sample for Anti-EBV was collected for infectious disease marker testing.

Varicella Zoster Virus (VZV)

Varicella zoster virus (VZV) is one of the human herpes viruses Herpesviridae family). VZV, known as chickenpox with its initial presentation, manifests as pruritic skin

blisters and typically first presents in childhood. After the initial infection, the virus will lay dormant in the body and can reoccur. Recurrence results in herpes zoster, more commonly known as shingles, which manifests as a painful, blistering skin rash.

Question 24: Anti-VZV (Varicella zoster virus antibody)

Testing for antibodies to VZV is generally done by fluorescent-antibody-to-membrane-antigen (FAMA), enzyme-linked immunosorbent assay (ELISA) or chemiluminescent immunoassay (CIA). These immunoassays can be used to detect IgM and/or IgG antibodies to VZV. Presence of IgM antibodies indicate a recent or current infection, usually within the past four to six months. Presence of IgG antibodies indicate a previous infection and confers a long-term immune response to the virus. Results may be expressed as quantified antibody titer; in this case, the laboratory or test kit manufacturer will provide reference ranges to determine if the result is considered positive, indeterminate, or negative.

Report the laboratory result as **Positive** or **Negative**. A positive IgM or IgG assay is considered a **Positive** (reactive) result. For any inconclusive or indeterminate results, report **Inconclusive**.

If anti-VZV testing was not performed, report **Not done**.

Question 25: Date sample for Anti-VZV collected

Indicate the date the sample for Anti-VZV was collected for infectious disease marker testing.

Other positive Infectious Disease Marker

Testing may be done for antibodies to pathogens other than those already listed on this form. If the donor was tested for any other infectious disease markers and had a positive result, report below. Duplicate *Other positive infection disease marker* question to report multiple positive IDM results. Note, results of CMV testing do **not** need to be reported on this form.

Examples of other testing that may be reported as an “other infectious disease marker” include:

- Anti-HBs
- Anti-HBe
- WNV by ELISA
- Lyme disease

Question 26: Other positive infectious disease marker, specify

Indicate if the donor was tested and positive for an IDM other than those already listed on this form; do not report PCR results or negative results. If the donor was tested and

positive for other IDMs, report **Yes**. If the donor was not tested for any other IDMs or was tested and negative for any other IDMs, report **No**.

Reporting Multiple Positive Other IDM Results
Complete *Date sample for other infectious disease markers collected* and *Specify test and method* questions for each other positive IDM identified by adding an additional instance in the FormsNet3^{SM} application.

Question 27: Date sample for other positive infectious disease marker collected

Indicate the date the sample for other positive infectious disease marker was collected for infectious disease marker testing.

Question 28: Specify test and method

Specify the pathogen(s) evaluated, the immunoassay or other test used, and the immunoglobulins measured.

Section Updates

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

Instructions for Confirmation of HLA Typing (2005) Form

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Confirmation of HLA Typing (2005) Form.

Form Name

For transplants using an NMDP donor or cord blood unit, the donor's HLA typing is reported on NMDP Confirmation of Donor HLA Typing (22) Form and the recipient's HLA typing is reported on NMDP Final Recipient HLA Typing (117) Form.

In all other situations, the Confirmation of HLA Typing (2005) Form is used to report HLA typing for both the donor and recipient on the Transplant Essential Data (TED) and comprehensive report form (CRF) tracks. This includes:

- Non-NMDP unrelated donor
- Non-NMDP unrelated cord blood unit
- Related cord blood unit
- HLA matched related donor
- HLA mismatched related donor
- Recipient of any of the donor types listed above
- Match siblings/syngeneic recipients and donors participating in the Related HCT Specimen Repository

A separate Confirmation of HLA Typing (2005) Form should be completed for each non-NMDP donor, recipient, or cord blood unit; however, only the recipient form is required for syngeneic transplants and HLA identical siblings. Typing on the donor / CBU must be reported when meeting any of the descriptions above.

If the recipient is receiving a subsequent HCT from the same donor and HLA Typing Forms have already been completed for the first HCT, the center does not need to complete a second set of HLA Typing Forms for the subsequent infusion. However, if a recipient is receiving a subsequent HCT from a different donor fitting one of the descriptions above, the HLA Typing Form must be completed for the new donor.

The human immune system recognizes and defends against threats from outside the body. An important component of the immune system is the **human leukocyte antigen (HLA)** genes. These genes produce proteins, some of which are expressed on the

surface of cells. These surface proteins allow cells to recognize self from non-self. Cells with matching proteins are recognized as self and passed over. However, when the proteins do not match between cells, one cell is identified as non-self, and an immune reaction is triggered to destroy it.

If the HLA of a donor and a recipient do not match closely, the immune response could result in the recipient's body attacking the transplanted cells (resulting in graft failure), or the transplanted cells attacking the recipient's body (graft-versus-host disease).

HLA genes are divided into three classes. The two classes that are important in matching donors and recipients are class I (HLA-A, B, C) and class II (includes HLA-DR, DQ). All HLA genes are encoded on an area of chromosome six known as the Major Histocompatibility Complex (MHC).

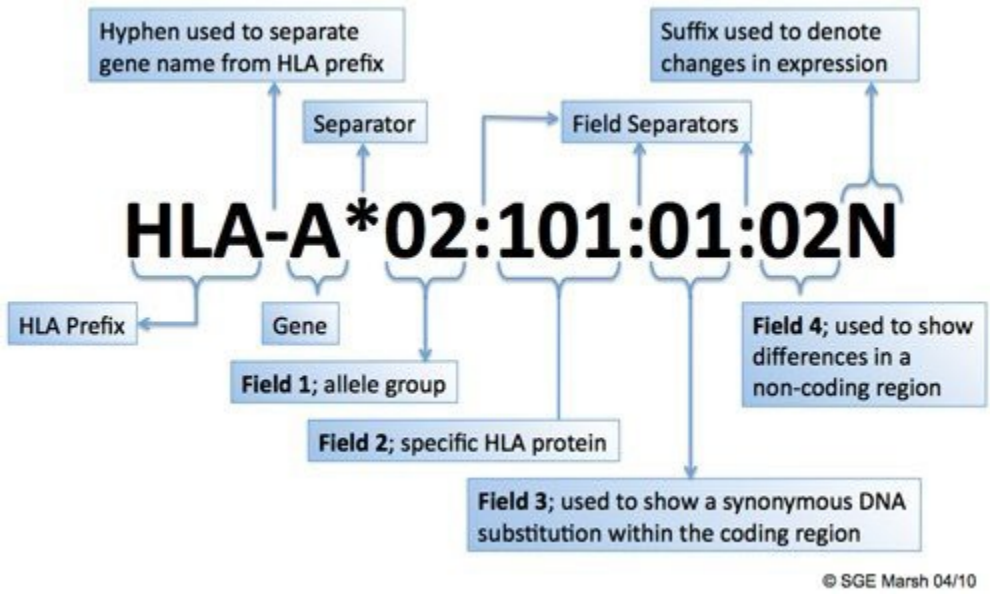
Finding a good donor-recipient HLA match can be difficult because HLA is highly polymorphic, or variable. It can be completely unique to an individual. Since DNA is inherited from parents, the likelihood of a complete match is greater between full biological siblings than two unrelated individuals. Each individual has two copies of chromosome six (one from each parent). This means that each parent will be a haploidentical (half) match. A full sibling will have a 25% chance of being an identical HLA match, a 25% chance of being completely non-identical, and a 50% chance of being a haploidentical match.

Figure 1. Example of Single HLA-A Locus Inheritance

HLA-A Heredity	***Biological Mother***	
Biological Father	*HLA-A*01*	*HLA-A*03*
*HLA-A*02*	01, 02	03, 02
*HLA-A*24*	01, 24	03, 24

The nomenclature (naming system) of HLA is an ever-evolving field, with an international committee dedicated to maintaining standards for identifying the genes and their allele sequences. Allele names consist of 3 to 5 parts, depending on what is known about that individual allele.

Figure 2. HLA Nomenclature[1]



[1] Anthony Nolan Research Institute. (2010). *HLA Nomenclature*. Web. 04 April 2013. http://hla.alleles.org/nomenclature/naming.html

The HLA prefix will precede the specific HLA locus (gene), which will be separated from allele-specific information by an asterisk. The first field will refer to a broad group of alleles (otherwise known as the "allele family"); this designation will be separated from the next field by a colon. The second field will refer to the specific allele, which yields a specific HLA protein. Third and fourth fields may be specified but are considered less important since they represent differences at a DNA level, rather than at a level of protein expression, due to a synonymous coding region (exon) or substitution in the non-coding region of the gene (intron). The name may be followed by a letter, which can alter the meaning of the preceding nomenclature. For example, the letter "N" signifies a null allele that does not test serologically.

DNA testing is done at low, intermediate, or high resolution.

Low-resolution testing is equivalent to serologic testing that identifies the allele group as represented by the first field of an HLA name (i.e., HLA-A*02).

Intermediate-resolution testing is molecular testing that may have remaining ambiguities. It reports allele groups that may contain 2 to 100 or more alleles. The nomenclature for these ambiguities is not internationally standardized; it is defined by the reporting lab or organization. NMDP reports frequently include letter sets that refer to possible genotypes within an allele group. Other laboratories may list all possible genotypes (i.e., DRB1*01:01 or 01:02, DRB1*01:01/01:02), where each specified allele is possible at a single locus.

High-resolution testing, or testing at the molecular level, provides further information about the gene itself, including what specific proteins will be expressed by the cells and

even differences in sequence that do not impact protein expression. For cellular transplant, matching at the high-resolution level is critically important.

Complete this form specifying the recipient or donor HLA *at the level it was typed*.

For a glossary of terms used in this section of the manual, see Appendix B: Glossary of Terms.

Links to Sections of Form:
Q1: Donor / Cord Blood Unit Identification
Q2 – 23: HLA Typing by DNA Technology
Q24 – 29: Antigens Defined by Serologic Typing
Q30 – 46: Optional Antigen Reporting

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.

To review the historical Manual Change History for this form, reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/Remove/Modify	Description
7/25/2025	2005: Confirmation of HLA Typing	Modify	Version 6 of the 2005: Confirmation of HLA Typing section of the Forms Instructions Manual released. Version 6 corresponds to revision 8 of the Form 2005.

Q1: Donor / Cord Blood Unit Identification

Question 1: Specify the person for whom this typing is being done

Indicate whether the reported HLA typing is the final **Recipient – final typing** or the final **Donor** typing for this transplant.

The CIBMTR no longer collects “optional typing” on relatives that were not the donor for this transplant.

Section Updates

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

Q2 – 23: HLA Typing by DNA Technology

Complete this section for all typing done by DNA based methods. Examples of HLA typing by DNA technology may include sequence-specific primer (SSP), sequence-specific oligonucleotide probe (SSOP), and sequence-based typing (SBT).

DNA technology can be used to type for a single allele, combinations of alleles (allele strings), or a “generic” allele designation similar to a serologic typing result. For this reason, the number of digits reported, as well as the number of alleles, will vary.

Laboratories may use a backslash (“ / ”) , a dash (“ – ”) or a combination of numbers and letters on the typing report as a shorthand notation for the results. The letters, called allele codes, will be one or more characters in length and represent a combination of possible alleles at a locus. The same allele combination may be reported by the lab several different ways (i.e., DRB1*01:01 or 01:02, DRB1*01:01/01:02, DRB1*01:01/02, or DRB1*01:AB). The Confirmation of HLA Typing (2005) Form has HLA typing validations and therefore, the use of a comma (“,”) will cause the typing to fail the validation. When the lab uses a comma in an allele string, report the comma as a backslash (“ / “). For example, 01:01,01:02 should be reported as 01:01/01:02.

There will be two alleles reported for each locus, unless the individual is presumed homozygous (i.e., carries two copies of the same allele) at a locus. Transcribe the first allele designation in the first box, and the second allele designation in the second box. If the person is homozygous, leave the second box blank.

Attaching HLA Report
CIBMTR strongly encourages centers to attach a copy of the HLA report in FormsNet3^{SM}.

Class I

Questions 2 – 3: Locus A

Indicate whether the allele designations at HLA-A are **Known** or **Unknown**. If **Known**, report the first A* allele and second A* allele designations; report a single allele, a string of alleles, or an allele code.
If **Unknown**, then the *A antigens defined by serologic typing* are required to be answered below.

Questions 4 – 5: Locus B

Indicate whether the allele designations at HLA-B are **Known** or **Unknown**. If **Known**, report the first B* allele and second B* allele designations; report a single allele, a string of alleles, or an allele code.

If **Unknown**, then the *B antigens defined by serologic typing* are required to be answered below.

Questions 6 – 7: Locus C

Indicate whether the allele designations at HLA-C are **Known** or **Unknown**. If **Known**, report the first C* allele and second C* allele designations; report a single allele, a string of alleles, or an allele code.

Class II

Questions 8 – 9: Locus DRB1

Indicate whether the allele designations at HLA-DRB1 are **Known** or **Unknown**.
If **Known**, report the first DRB1* allele and second DRB1* allele designations; report a single allele, a string of alleles, or an allele code.

Class II Optional Alleles
DRB3, DRB4, DQB1, DQ41, DPA1 are optional; however, if this information is available from the lab report, report the allele information.

Class II (Optional)

Questions 10 – 11: Class II Locus DRB3

Indicate whether the allele designations at HLA-DRB3
are **Known** or **Unknown.** If **Known**, report the first DRB3* allele and second DRB3* allele designations; report a single allele, a string of alleles, or an allele code.

Questions 12 – 13: Locus DRB4

Indicate whether the allele designations at HLA-DRB4 are **Known** or **Unknown**.
If **Known**, report the first DRB4* allele and second DRB4* allele designations; report a single allele, a string of alleles, or an allele code.

Questions 14 – 15: Locus DRB5

Indicate whether the allele designations at HLA-DRB5 are **Known** or **Unknown**.
If **Known**, report the first DRB5* allele and second DRB5* allele designations; report a single allele, a string of alleles, or an allele code.

Questions 16 – 17: Locus DQB1

Indicate whether the allele designations at HLA-DQB1
are **Known** or **Unknown.** If **Known**, report the first DQB1* allele and second DQB1* allele designations; report a single allele, a string of alleles, or an allele code.

Questions 18 – 19: Locus DPB1

Indicate whether the allele designations at HLA-DPB1 are **Known** or **Unknown**.
If **Known**, report the first DPB1* allele and second DPB1* allele designations; report a single allele, a string of alleles, or an allele code.

Questions 20 – 21: Locus DQA1

Indicate whether the allele designations at HLA-DQA1 are **Known** or **Unknown**.
If **Known**, report the first DQA1* allele and second DQA1* allele designations; report a single allele, a string of alleles, or an allele code.

Questions 22 – 23: Locus DPA1

Indicate whether the allele designations at HLA-DPA1 are **Known** or **Unknown**.
If **Known**, report the first DPA1* allele and second DPA1* allele designations; report a single allele, a string of alleles, or an allele code.

Section Updates

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

Q24 – 29: Antigens Defined by Serologic Typing

Complete this section for all serologic typing. If serologic typing was not performed, leave this section blank. Report broad antigens only when your laboratory was not able to confirm typing for a known split antigen.

Each HLA locus has a serologically defined "X" antigen specificity: AX, BX, CX, DRX, DPX, and DQX. At this time an "X" specificity is defined as "unknown but known to be different from the other antigen at that locus." This is different from a blank specificity, which is defined as "unknown but assumed to be the same as the other antigen at that locus." When comparisons between recipient and donor antigens involve an "X" or "blank" specificity, the "X" or "blank" is assumed to be homozygous for the antigen reported at the locus. In other words, the search algorithm treats typing containing "blank" or "X" antigens in the same manner as known homozygous typing.

Questions 24 – 26: Number of A antigens provided

Indicate if **One** or **Two** HLA-A antigens were identified.

If **One** antigen was identified, report the first antigen specificity in *Specificity – 1st antigen*.

If **Two** antigens were identified, report the first antigen specificity in *Specificity – 1st antigen* and the second antigen specificity in *Specificity – 2nd antigen*.

Questions 27 – 29: Number of B antigens provided

Indicate if **One** or **Two** HLA-B antigens were identified.

If **One** antigen was identified, report the first antigen specificity in *Specificity – 1st antigen*.

If **Two** antigens were identified, report the first antigen specificity in *Specificity – 1st antigen* and the second antigen specificity in *Specificity – 2nd antigen*.

Section Updates

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

Q30 – 46: Optional Antigen Reporting

Questions 30 – 32: Number of C antigens provided

Indicate if **One** or **Two** HLA-C antigens were identified.

If **One** antigen was identified, report the first antigen specificity in *Specificity – 1st antigen*.

If **Two** antigens were identified, report the first antigen specificity in *Specificity – 1st antigen* and the second antigen specificity in *Specificity – 2nd antigen*.

Question 33: Specificity Bw4 present?

Bw4 refers to an epitope expressed by HLA-B alleles; epitopes are presented on the surface of the antigen and are recognized by the immune system. Bw4 and Bw6 are mutually exclusive and may confer reactivity with lymphocytes. Select **Yes** if Bw4 specificity is present. Leave blank if specificity for Bw4 was not tested.

Question 34: Specificity Bw6 present?

Bw6 refers to an epitope expressed by HLA-B alleles; epitopes are presented on the surface of the antigen and are recognized by the immune system. Bw4 and Bw6 are mutually exclusive and may confer reactivity with lymphocytes. Select **Yes** if Bw6 specificity is present. Leave blank if specificity for Bw6 was not tested.

Questions 35 – 37: Number of DR antigens provided

Indicate if **One** or **Two** HLA-DR antigens were identified.

If **One** antigen was identified, report the first antigen specificity in *Specificity – 1st antigen*.

If **Two** antigens were identified, report the first antigen specificity in *Specificity – 1st antigen* and the second antigen specificity in *Specificity – 2nd antigen*.

Question 38: Specificity DR51 present?

HLA-DR51 is an HLA-DR variant that recognizes antigens from HLA-DRB5.
Select **Yes** if DR51 specificity is present. Leave blank if specificity for DR51 was not tested.

Question 39: Specificity DR52 present?

HLA-DR52 is an HLA-DR variant that recognizes antigens from HLA-DRB3.
Select **Yes** if DR52 specificity is present. Leave blank if specificity for DR52 was not tested.

Question 40: Specificity DR53 present?

HLA-DR53 is an HLA-DR variant that recognizes antigens from HLA-DRB4.
Select **Yes** if DR53 specificity is present. Leave blank if specificity for DR53 was not tested.

Questions 41 – 43: Number of DQ antigens provided

Indicate if **One** or **Two** HLA-DQ antigens were identified.

If **One** antigen was identified, report the first antigen specificity in *Specificity – 1st antigen*.

If **Two** antigens were identified, report the first antigen specificity in *Specificity – 1st antigen* and the second antigen specificity in *Specificity – 2nd antigen*.

Questions 44 – 46: Number of DP antigens provided

Indicate if **One** or **Two** HLA-DP antigens were identified.

If **One** antigen was identified, report the first antigen specificity in *Specificity – 1st antigen*.

If **Two** antigens were identified, report the first antigen specificity in *Specificity – 1st antigen* and the second antigen specificity in *Specificity – 2nd antigen*.

Section Updates

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

Instructions for Hematopoietic Cellular Transplant (HCT) Infusion (2006) Form

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

Hematopoietic Stell Cell Transplant (HCT) Infusion

Centers must complete the Hematopoietic Cellular Transplant (HCT) (2006) for each product when the recipient is assigned to the **Comprehensive Report Form track**. Centers must also complete the Hematopoietic Cellular Transplant (HCT) (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 Hematopoietic Cellular Transplant (HCT) (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 Hematopoietic Cellular Transplant (HCT) (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 Hematopoietic Cellular Transplant (HCT) (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: How to Distinguish Infusion Types and Appendix E: Definition of a Product.

Links to Sections of Form:
Q1 – 3: Pre-Collection Therapy
Q4 – 7: Product Collection
Q8 – 21: Product Transport and Receipt
Q22 – 41: Product Processing / Manipulation
Q42 – 83: Product Analysis at Infusion
Q84 – 133: Product Infusion
Q134 – 159: Donor / Infant Demographic Information

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.

To review the historical Manual Change History for this form, reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/Remove/Modify	Description
7/25/2025	Hematopoietic Stem Cell Transplant (HCT) Infusion: 2006	Add	Version 6 of the 2006: Hematopoietic Stem Cell Transplant (HCT) Infusion section of the Forms Instructions Manual released. Version 6 corresponds to revision 7 of the Form 2006.

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) (*check all that apply)*

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

Select all growth and mobilizing factors given.

- **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.

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.

Section Updates

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

Q4 – 7: Product Collection

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 Hematopoietic Cellular Transplant (HCT) (2006).

Question 4: Date of first collection for this mobilization

Report the first date the cell collection was performed. If a collection event occurs 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 as two separate products, and two Hematopoietic Cellular Transplant (HCT) (2006) forms 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**.

If anticoagulants were given directly to the donor before or during cell collection and not added to the stem cell product itself, 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)

Select all anticoagulants added to the reported product. Check all that apply.

- **Acid citrate dextrose** (ACD, ACD-A)
- **Citrate phosphate dextrose** (CPD, CPD-A)
- **Dimethylsulfoxide** (DMSO)
- **Ethylenediaminetetraacetic acid** (EDTA)
- **Heparin**
- **Plasmalyte**

If an anticoagulant added to the product is not listed on the form, check **Other agent**, and specify the anticoagulant's name.

Section Updates

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

Q8 – 21: Product Transport and Receipt

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

Indicate if the product was collected off-site and shipped to the transplant center.

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, report **No**.

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.

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

Indicate the shipping environment of the product(s).

- **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.) or Credo Cube ™ transporter.
- **Frozen (cryopreserved)**: Shipping environment where liquid components are maintained in a solid state. Examples include shipments utilizing dry ice 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 provided by the cord blood bank. 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. 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)

Q22 – 41: 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 received by the center 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) received by the center was thawed, select **Yes**.

If the entire product received by the center 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: Date thawing process initiated

Report the date when the thawing process began.

Question 25: Time at initiation of thaw (24-hour clock)

Report the time the product thaw began, using a 24-hour clock.

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 recipient's record or the stem cell laboratory processing record. If the start time is not documented, leave the data field blank and override the FormsNet3^{SM} error as 'not documented.'

Question 26: Time of thaw completion (24-hour clock)

Report the time the product thaw completed, using a 24-hour clock.

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 recipient's record or the stem cell laboratory processing record. If the stop time is not documented, leave the data field blank and override the FormsNet3^{SM} error as 'not documented.'

Question 27-28: 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 other method.

Question 29: 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 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 30: Was the product processed prior to infusion?

Product processing includes changes made to the original product that do 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 31: 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 32: 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 **Negative fraction** for the second product.

Questions 33 – 36: 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 CliniMACS®, Isolex, or Miltenyi devices.

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] If **Ex-vivo expansion** is selected, specify the type.
- **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. If **Genetic manipulation (gene transfer / transduction)** is selected, specify the type.
- **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.
- **Negative fraction:** Negative fraction refers to the portion of the collected blood or stem cell product that does not contain the desired cells and removed or discarded during processes like plasma reduction or cell separation.

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 37 – 38: 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 39-40: 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 41: 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)

Q42 – 83: Product Analysis at Infusion

This section is intended to capture the values for the actual product volume infused and should reflect the product infused regardless of when the analysis occurred.

For cord blood units, values reported 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. 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. 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.
    - 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.
- **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. 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; 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.

- **Processed product**: Report the last analysis performed prior to product infusion.
  - 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. In this scenario, the analysis for the TNC performed prior to RBC reduction will *not* be reported.

Question 43: Total volume of product received by the center plus additives

Enter the total volume of the product plus additives in the bag(s) infused. Report the volume in either milliliters (mL) or grams (g). The total volume reported should be the actual volume given to the recipient.

Questions 44 – 45: Report the total nucleated cells (TNC) (whole product)

Specify if the TNC count was quantified on the analysis date reported above. If **Done**, report the absolute number of the cells, not cells per kg.

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" 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 cell 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:

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

Example 4: 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): 8.96×10^8

Questions 46 – 47: Viability of total nucleated cells

Specify if the viability of the total nucleated cells was quantified. If **Done**, 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%.

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

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 of testing TNC viability*.

Questions 50 – 51: Report the nucleated white blood cells

Specify if the nucleated white blood cells (also known as leukocytes) were quantified on the analysis date reported above. Report the absolute number of cells, not cells per kg.

Questions 52 – 53: Report the mononuclear cells

The total mononuclear cell count includes lymphocytes and monocytes. Specify if the mononuclear cells were quantified on the analysis date reported above. Report the absolute number of cells, not cells per kg.

Questions 54 – 55: Report the nucleated red blood cells

Specify if the nucleated red blood cells (also known as normoblasts) were quantified on the analysis date reported above. Report the absolute number of cells, not cells per kg.

Questions 56 – 57: Report the CD34+ cells

Specify if the CD34+ cells were quantified on the analysis date reported above. Report the absolute number of cells, not cells per kg.

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

Questions 58 – 59: Viability of CD34+ cells

If the viability of the CD34+ cells was quantified, select **Done** and report the percentage of viable cells. 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%.

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

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 CD34+ cell viability was tested using a different method, select **Other method** and specify the method.

Questions 62 – 63: Report the CD3+ cells

Specify if the CD3+ cells were quantified on the analysis date reported above. Report the absolute number of cells, not cells per kg.

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%.

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

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 CD3+ cell viability was tested using a different method, select **Other method** and specify the method.

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

Specify if the CD3+CD4+ cells were quantified on the analysis date reported above. Report the absolute number of cells, not cells per kg.

Questions 70 - 71: Report the CD3+CD8+ cells

Specify if the CD3+CD8+ cells were quantified on the analysis date reported above. Report the absolute number of cells, not cells per kg.

Question 72: 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 73: Was there growth?

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

Questions 74 – 77: 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 78: Were any positive cultures (for bacterial or fungal infections) obtained from the product at the transplant center? (*complete for all cell products*)

Specify if any positive cultures were obtained from the product at the transplant center. If cultures were obtained and positive, select **Yes**.

If cultures were not obtained or obtained and negative, 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, culture assessments were not performed, or it is not known whether culture assessments were performed, select **Unknown**.

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 79 – 83: Specify organism code(s)

Specify the isolated organism(s) detected using the organism code(s) from the pull-down options.

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 purpose of reporting data to the CIBMTR.

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

Section Updates

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

Q84 – 133: Product Infusion

Question 84: 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 85: Was the entire volume of the product received by the center 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:

- Example 1: A PBSC product is collected and arrives at the transplant center in four bags. Two of the bags are infused fresh, and the remaining two bags are cryopreserved for future use. Since a portion of the product that was received was not infused, “no” should be reported for *Was the entire volume of the product received by the center infused?*
- Example 2: 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 product received by the center infused?*

Questions 86 – 87: Specify what happened to the reserved portion (check all that apply)

Report what happened to the reserved portion of the product. Select all that apply.

If **Other fate** is selected, report the outcome of this product.

Question88: Time product infusion initiated (24-hour clock)

Report the start time of the infusion, using a 24-hour clock. If multiple bags were infused, report the start time of the infusion of the first bag.

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

Question 89: 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 90: Time product infusion completed (24-hour clock)

If multiple bags of the same product were infused, report the completion time of the last bag, using a 24-hour clock.

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

Questions 91 – 92: 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.

Adverse Events
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. If this HCT used an autologous or NMDP products continue to the submit the form.

Question 93: 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 (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 recipient and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.* Review Adverse Event reporting in the Data Management Guide.

Questions 94 – 133: 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 clinician'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 clinician 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)

Q134 – 159: Donor / Infant Demographic Information

The Donor Demographic Information section 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, submit the form.

Question 134: Was the donor ever pregnant?

Report if the donor was ever pregnant. If there is no documentation regarding if the donor has ever been pregnant, select **Unknown**.

Questions 135 – 136: Number of pregnancies

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

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

Questions 137 – 138: Geographic ancestry (*select one or more options that closets identifies the donor's background.*)

Indicate the geographic ancestry of the donor, select all that apply. If the geographic ancestry or geographic ancestry detail is 'unknown' or 'other,' select **Not otherwise specified**.

For more information regarding race, see Appendix I: Ethnicity and Race.

Question 139: Was the donor a carrier for potentially transferable genetic diseases?

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

Questions 140 – 141: Specify potentially transferable genetic disease

Indicate the potentially transferable genetic disease for which the donor is a carrier. If the donor was a carrier for a potentially transferable 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 142: Was the donor / product tested for other transferable genetic or clonal abnormalities?

Specify if the donor / product was tested for other transferable genetic or clonal abnormalities.

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 submit the form.

It should be noted for cord blood unit transplants that almost all units are screened, or the infant is screened, for potentially transferable 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 143 – 146: Specify transferable genetic and / or clonal abnormalities tested

For each of the genetic or clonal abnormalities listed, indicate whether testing was done and specify the method of. 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.

Donor Informaiton
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, submit the form.

Question 148: 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 149: 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 150 – 151: 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 life-threatening complication(s).

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

Questions 152 – 154: 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 155 – 157: Did the donor receive blood transfusions as a result of the collection? (check all that apply)

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 158 – 159: 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 submit the form.

Section Updates

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