



Instructions for Baseline Form (Form 2000)

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

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

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Baseline Data

A transplant center designated as a *Comprehensive Report Form* center will submit data on the Pre-TED Form, followed by either the Post-TED Form or the Comprehensive Report Forms. The type of follow-up forms used for a specific recipient is determined by the CIBMTR’s form selection algorithm (see General Instructions, [Center Type and Data Collection Forms](#)).

The Baseline Form is one of the Comprehensive Report Forms. This form captures pre-HSCT data such as: recipient demographics, clinical status of the recipient, preparative regimen, and socioeconomic information. The Baseline Form is due within 60 days after HSCT.

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For recipients receiving a subsequent HSCT the recipient will remain on the original follow-up form track (TED or Comprehensive Report Forms) assigned by the form selection algorithm. For recipients assigned to Comprehensive Report Forms by the form selection algorithm, centers will not submit another Pre-TED, but will instead submit a Baseline Form (Form 2000) for the subsequent HSCT.

Key Fields

Accuracy of the Key Fields is essential for ensuring that:

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

For instructions regarding the completion of the Key Fields, see [appendix K](#). Key fields include all fields listed in the box found in the upper right-hand corner of the first page of the paper form, or on the “key page” in the FormsNet™2 application.

Recipient Demographics

Question 1: State of residence of recipient (for residents of USA):

Enter the recipient’s state of permanent residence at the time of transplant. If the recipient is a non-US resident, continue with question 3.

Question 2: Zip or postal code for place of recipient’s residence (USA recipients only):

Enter the zip code in which the recipient resides.

Questions 3-4: Country of primary residence (check only one):

Select the recipient’s resident country. If “other” is chosen, continue with question 4 and specify the country.

Question 5: Gender:

Indicate the biological gender (sex) as *male* or *female*.

Question 6: Ethnicity:

Indicate the recipient’s ethnicity.

For more information regarding ethnicity, see [Appendix I](#).

Question 7: Race: (Mark the group(s) in which the recipient is a member. Check all that apply.)

Indicate the race of the recipient, check all that apply. The race groups provided are specific to the United States. For non-US centers, consult with the recipient to select the race group they most closely identify with. If the recipient declines to provide this information, select “decline.”

For more information regarding race, see [Appendix I](#).

Question 8: Date of birth:

Enter the recipient’s date of birth (MM/DD/YYYY).

Primary Disease for HSCT

NOTE: Primary Disease

The Baseline Form uses the World Health Organization (**WHO**) disease classifications. Each disease classification contains the Primary (or Broad) Disease category and the disease subtypes (detailed disease options). The “Other, Specify” category should **only** be used if the recipient’s Primary Disease is not one of the listed options. For more information regarding disease classification, consult a transplant physician, contact your center’s CIBMTR liaison, or visit the WHO website at: <http://www.who.int/classifications/icd/en/>.

Questions 9-19: What was the primary disease for which the HSCT was performed?

Select the primary disease (or broad disease grouping) and the disease subtype for which the recipient is receiving the transplant. Answer any additional disease specific question(s), and complete the Disease Specific Form(s) specified in the box.

If the indication for HSCT is due to a combination of diseases or a transformation of one disease to another, multiple Baseline Disease Specific Forms **may be** required. Table 1 lists common examples of disease combinations and transformations, and the Disease Specific Form(s) required pre-HSCT.

Table 1. Common Disease Combinations and Transformations

Initial Diagnosis (disease code*)	Pre-HSCT Diagnosis (disease code*)	Required Disease Specific Form(s) Pre-HSCT
MDS (50's)	AML (10's)	MDS <u>and</u> AML
SAA (300)	MDS (50's) or AML (10's)	APL <u>and</u> MDS or AML
Fanconi anemia (311)	AML (10's), ALL (20's), or MDS (50's)	FAN <u>and</u> ALL, AML, or MDS
Myeloma (170's) with Amyloidosis (174)	Myeloma (170's) with Amyloidosis (174)	MYE <u>and</u> AMY
CLL (34, 71)	Richter transformation (107)	CLL <u>and</u> LYM

*The CIBMTR database disease codes are represented in parentheses after the disease subtype. These same disease codes are located on the Pre-TED Form, ensuring consistency in disease subtype reporting between the Pre-TED and the Baseline (ex. Myeloid Sarcoma (280)).

Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)

Question 20: *For allogeneic HSCT only:* What is the recipient's blood type and Rh factor?

Indicate the recipient's blood type and Rh factor.

Question 21: What was the functional status of the recipient prior to the preparative regimen?

The CIBMTR uses the Karnofsky/Lansky scale to determine the functional status of the recipient immediately prior to the start of the preparative regimen. For the purposes of this manual, the term "immediately prior" represents the **pre-HSCT work-up phase**, or **approximately one month** prior to the start of the preparative regimen.

The Karnofsky Scale is designed for recipients aged 16 years and older, and is not appropriate for children under the age of 16. The Lansky Scale is designed for recipients less than 16 years old.

Recipient performance status is a critical data field that has been determined to be essential for all outcome-based studies. Determination of performance status is ideally performed by a healthcare provider. Centers are encouraged to put tools in place to facilitate this collection. If a Karnofsky/Lansky score is not documented in the source documentation (e.g., inpatient progress note, physician's clinic note), data professionals are encouraged to discuss a determination with the healthcare provider rather than make an assignment themselves, based on inadequate information.

The CIBMTR recognizes that some transplant centers prefer to assign and use the ECOG performance score as opposed to the Karnofsky/Lansky score. Although the ECOG and Karnofsky/Lansky performance score systems are based on similar principles, the scales are not the same. For example, the Karnofsky/Lansky scale is described in 10 categories, whereas the ECOG performance status is reported in six categories. Due to the overlap between the two systems, an ECOG score of “one” can represent either “80” or “90” on the Karnofsky/Lansky scale; whereas, a Karnofsky/Lansky score of “80” or “90” is converted directly to an ECOG score of “one.” Therefore, the Karnofsky/Lansky scale can be more accurately converted into ECOG.

However, for centers that collect only an ECOG performance score, CIBMTR will make the following accommodations when auditing the source data:

- Centers assigning ECOG scores should do so using standard practices to ensure accuracy.
- For the purposes of CIBMTR reporting, conversion of ECOG to Karnofsky/Lansky should follow a standard and consistent practice to account for the lack of direct mapping. This practice should be clear and reproducible.

Select the appropriate performance scale, Karnofsky or Lansky, based on the recipient’s age. Using this scale, select the score (10-100) that best represents the recipient’s activity status immediately prior to the start of the preparative regimen. The only valid scores are 10-100, zero is not a valid response for this scale, nor are values not ending in zero, such as “85.” The Karnofsky/Lansky scale can be found in [appendix L](#).

Question 22: Was there a history of malignancy other than the primary disease for which this HSCT is being performed?

The intent of this question is to identify other malignancies which may have an affect on the outcome of the HSCT. A history of any benign tumor(s) should **not** be reported in this section.

If the recipient is transplanted for a disease that has transformed from one disease to another, the original malignancy should **not** be reported in this section. Report the original malignancy as part of the appropriate disease subtype description in questions 9-19, and/or on the appropriate Disease Specific Form. For more information regarding disease combinations and transformations, refer to [Table 1](#).

Indicate if there was a history of malignancy other than the disease for which this HSCT is being performed.

Questions 23-60: Specify which malignancy(ies) occurred:

For each listed prior malignancy, check “yes” or “no.” If “yes,” enter the year of diagnosis of the corresponding malignancy.

The “other prior malignancy, specify” category should be used to report any prior malignancies that are not listed on the form.

NOTE: Coexisting Diseases and Organ Impairment

This question also appears on the Pre-TED. The options listed on the Baseline Form may be found under different categories than on the Pre-TED. Read the options carefully before completing.

Question 61: Were there *clinically significant* coexisting diseases or organ impairment at any time prior to the preparative regimen?

The intent of this question is to identify *serious* pre-existing conditions that may have an affect on the outcome of the HSCT. For the purposes of this manual, the term “clinically significant” refers to conditions that are being treated at the time of pre-HSCT evaluation, or have affected the recipient’s medical history and may cause complications post-HSCT. Conditions listed in the recipient’s medical history that have been resolved, and/or that would not pose a concern during or after the HSCT should not be reported (e.g., seasonal allergies, appendicitis).

If the recipient has a documented history of clinically significant co-existing disease(s) or organ impairment(s), check “yes” and continue with question 62.

If the recipient does not have a documented history of clinically significant disease(s) or organ impairment(s), check “no” and continue with question 136.

Questions 62-135: Specify the diagnoses:

For each listed coexisting disease or organ impairment, check “yes” or “no.” If “yes,” specify the diagnosis from the options listed.

The “other significant coexisting disease, specify” category should be used to report coexisting conditions that are of similar clinical concern as the other listed options. Chromosomal abnormalities, impairments and/or disorders associated with the primary disease should not be reported in this section, (e.g., Ph+ for CML/ALL recipients). Also, do not report surgical procedures or infections in this section. Report any infections in the infection section starting at question 163. For assistance with reporting coexisting conditions, consult with a transplant physician.

For each listed coexisting disease or organ impairment, check “yes” or “no.” If “yes,” specify the diagnosis.

Question 136: Does the recipient have a history of smoking cigarettes?

The intent of this question is to determine the recipient's history of smoking cigarettes only. Do not report the use of cigars, pipe tobacco, chewing tobacco, or other drugs. The recipient's smoking history is usually documented on the transplant admission summary.

Indicate whether the recipient has a history of smoking cigarettes. If "yes," continue with question 137. If "no," continue with question 141.

Question 137: Has the recipient smoked cigarettes within the past year?

Indicate if the recipient has a history of smoking cigarettes within the year prior to HSCT.

Question 138: Has the recipient smoked cigarettes prior to but not during the past year?

Indicate if the recipient smoked cigarettes previous to but not during the year prior to HSCT.

Question 139: Number of years:

Report the number of years the recipient smoked cigarettes. If the information is not documented, select "duration unknown."

Question 140: Average number of packs per day:

Report the average number of packs per day the recipient smoked/smokes. See the conversion chart below to calculate the number of packs per day from a reported cigarette(s) per day history. See the example below to calculate packs per day from a reported pack year history. If this information is not documented, select "amount unknown."

NOTE: Conversion of cigarettes per day into packs per day

Cigarettes/Day = Packs/Day

1-2	0.1
3-4	0.2
5-6	0.3
7-8	0.4
9-10	0.5
11-12	0.6
13-14	0.7
15-16	0.8
17-19	0.9

Example:

Progress Note: The recipient has smoked for 20 years- and has a 40 pack year history.

Packs per day: 40 pack year history / 20 years = 2 packs per day

Report “average number of packs per day” as: 2

Organ Function Prior to the Preparative Regimen (Conditioning)

Questions 141-152: Provide last laboratory values recorded for recipient’s organ function (testing done within 30 days of start of the preparative regimen):

These questions are intended to determine the clinical status of the recipient prior to the preparative regimen for stem cell transplantation. Testing may be performed multiple times within the 30 days prior to the preparative regimen; report the most recent laboratory value obtained for each specific test.

Laboratory values obtained on the first day of the preparative regimen may be reported as long as the blood was drawn before any radiation or systemic therapy was administered.

- **AST (SGOT):** Aspartate aminotransferase, or serum glutamic oxalic transaminase, is an enzyme measured in serum or plasma that reflects liver function and liver cell integrity. Elevated levels of AST may indicate liver damage.
- **Total serum bilirubin:** Bilirubin is a pigment that is formed from the breakdown of hemoglobin in red blood cells. Serum bilirubin is a test of liver function as it reflects the ability of the liver to take up, process, and secrete bilirubin. Total bilirubin includes the direct (conjugated) and indirect (unconjugated) bilirubin count. If your laboratory reports direct and indirect separately, add the two together to report the total serum bilirubin.
- **LDH:** Lactate dehydrogenase is an enzyme found in the cytoplasm of almost all tissues that converts L-lactate into pyruvate, or pyruvate into L-lactate depending on the oxygen level. For some diseases, high levels indicate active disease (e.g., Lymphoma and Multiple Myeloma).
- **Serum creatinine:** Creatinine is a normal metabolic waste excreted in the urine, primarily by filtration. Since it is generally produced at a constant rate, the clearance rate and the serum level are widely used as an index of kidney function.

Report the laboratory value, unit, and date tested for each listed organ function. If an organ function was not tested, select “not tested” and continue with the next laboratory value.

For each laboratory value reported in this section, report your institution's upper limit of normal.

For information regarding converting laboratory units, refer to:

http://www.gfmer.ch/Clinical_tools/Tools.php

Hematologic Findings Prior to the Preparative Regimen (Conditioning)

Questions 153-162: Provide last laboratory values recorded just prior to preparative regimen:

These questions are intended to determine the hematological status of the recipient prior to the preparative regimen. Testing may be performed multiple times within the 30 days prior to the preparative regimen, report the most recent laboratory value. Laboratory values obtained on the first day of the preparative regimen may be reported as long as the blood was drawn before any radiation or systemic therapy was administered.

Report the laboratory value and unit (if applicable) for each listed hematologic finding. If a value was not tested, select "not tested" and continue with the next laboratory value.

For hemoglobin and hematocrit, also indicate if red blood cells were transfused less than or equal to 30 days prior to the testing.

For platelets, also indicate if platelets were transfused less than or equal to seven days prior to the testing.

Transfusions temporarily increase the blood cell counts. In analysis it is important to distinguish between a recipient whose own body was creating the cells and a recipient who required transfusions to support the counts.

Infection

Question 163: Did the recipient have a history of *clinically significant* fungal infection (documented or suspected) at any time prior to the preparative regimen?

Fungal infections play a major role in the clinical outcome of a transplant recipient. The intent of this question is to identify serious fungal infection(s) that may have an affect on the outcome of the HSCT. For the purposes of this manual, the term "clinically significant" refers to conditions that are treated at the time of pre-HSCT evaluation, or have affected the recipient's medical history and may cause complications post-HSCT.

Examples of fungal infections include, but are not limited to the following: invasive aspergillosis (infection codes 210-213, 219), zygomycosis (infection code 240) and other molds (infection codes 230, 240, 242, 261), invasive candidiasis (infection codes 200-209), cryptococcosis (infection code 220), endemic mycosis (infection code 241), other yeasts (infection code 250), and pneumocystis pneumonia (PCP) (infection code 260). Include any fungal abscesses of the lungs, sinuses, liver or spleen.

Non-invasive fungal infections such as thrush and nail fungus should not be reported.

If the recipient has a history of clinically significant fungal infection at **any time** prior to this HSCT event, check “yes” and continue with question 164. For a subsequent HSCT, report any documented significant fungal infections in the recipient’s medical history, starting with the preparative regimen of the previous HSCT to the time prior to the preparative regimen for the current HSCT.

If the recipient does not have a history of clinically significant fungal infection at any time prior to this HSCT event, check “no” and continue with question 172.

For assistance with reporting fungal infections, consult with a transplant physician.

Question 164: Did the recipient have more than one fungal infection (documented or suspected) at any time prior to the preparative regimen?

Indicate if the recipient had more than one fungal infection at any time prior to the preparative regimen.

If the infection is due to yeast, and recurs in less than or equal to 14 days, it is considered a single incident and should **not** be reported multiple times.

If the infection is due to mold, and recurs in less than or equal to 90 days, it is considered a single incident and should **not** be reported multiple times.

If “yes,” complete questions 165-171 for each infection in the FormsNet™2 application. For paper form submission, make a copy of the fungal infection section to report multiple fungal infections.

Question 165: Date of onset:

Enter the date of onset of the fungal infection. For suspected fungal infections, enter the date of a radiology test or date treatment was started as the date of onset.

Question 166-167: Select organism from list below:

From the table “Codes for Commonly Reported Fungal Organisms,” select the code corresponding to the identified or suspected fungus. Report the code in the boxes provided. If the specific organism is not listed, use the “other, specify” code 209- candida, 219- apsergillus, or 259- fungus and report the name of the organism in the space provided for question 167.

For organisms marked with a section symbol (§), also complete a Fungal Infection Form (2046). If code 503, suspected fungal infection, is selected, complete a Fungal Infection Form (2046) by answering “no” to the listed organisms, and completing the Antifungal Therapy section.

Questions 168-170: Select site(s) from list below:

From the table “Codes for Common Sites of Infection,” select the code corresponding to the site of the infection. If more than one site was involved, report the codes for up to three affected sites.

If three or more sites are infected with the same fungal organism, enter code 2 (Disseminated- generalized, isolated at 3 or more distinct sites).

NOTE: Disseminated Infections

The CIBMTR acknowledges that a discrepancy exists between the CIBMTR definition (3 or more sites) and the BMT CTN definition (2 or more sites) for disseminated infections. The CIBMTR will be reviewing this and will make a decision in the near future.

Question 171: Was this fungal infection active within 2 weeks prior to the preparative regimen?

Indicate if the fungal infection was active within the two weeks prior to the start of the preparative regimen.

For suspected fungal infections, answer this question, “yes” if the recipient is receiving fungal treatment (not prophylaxis) and/or had a finding on an x-ray or CT scan consistent with a suspected fungal infection within 2 weeks prior to the preparative regimen.

Testing for serological evidence of prior viral exposure/infection

NOTE: Serological Testing

Serological testing should be completed during the **pre-HSCT work-up phase**, or **approximately one month** prior to the start of the preparative regimen.

Exception: a recipient with a documented history of a “reactive” CMV test result. In this case, the CMV test might not be repeated during the pre-HSCT work-up phase. Therefore the timeframe of greater than one month prior to the start of the preparative regimen is acceptable for CMV.

For hepatitis types marked with a dagger (†) that have a positive result, also complete the HEP Form (2047).

For HIV tests marked with a double dagger (‡) that have a positive result, also complete the HIV Form (2048)

Question 172: HTLV1 antibody

The Human T-Lymphotropic virus I/II (HTLV I/II) is a retrovirus in the same class as HIV. HTLV I/II is associated with certain leukemias and lymphomas, as well as demyelinating diseases such as multiple sclerosis.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

Question 173: Cytomegalovirus antibody

CMV is a common virus that infects 50-80% of adults worldwide, and is transmitted from person to person through bodily fluids. The virus that causes CMV is part of the herpes virus family and, like other herpes viruses, CMV may be dormant for a period of time before the virus is activated in the host. CMV infections are usually harmless in a healthy immune system and typically cause only mild symptoms, if any. However, if a person's immune system is seriously weakened (as in an immunosuppressed stem cell recipient) the virus can have serious consequences such as pneumonia, liver failure, and even death.

Most laboratory reports indicate a positive result as *reactive*, and a negative result as *non-reactive*. Occasionally, laboratory reports show a specific antibody titer. In this case, the laboratory result must be compared to the reported standards to determine the reactive or non-reactive result.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

If the laboratory reports a CMV IgM antibody only, not total IgG/IgM or CMV IgG antibody; report the result as “not tested.”

If the laboratory reports CMV testing by PCR (DNA detection), report the result as “not tested.” CMV testing by PCR is used to detect the presence of the CMV virus and does not test for prior exposure.

Question 174: Epstein-Barr antibody

The Epstein-Barr Virus (EBV) is a common virus of the herpes family which can cause infectious mononucleosis, but in most cases is asymptomatic. EBV establishes a lifelong dormant infection in some cells of the body’s immune system. Serious post-transplant complications related to EBV include EBV viremia (reactivation) and post-transplant lymphoproliferative disease (PTLD).

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

Question 175: Hepatitis B surface antibody

Hepatitis B is caused by the hepatitis B virus (HBV). Infection with this virus can cause scarring of the liver, liver failure, liver cancer, and even death. Hepatitis B is spread through infected blood and other body fluids. Acute hepatitis B infection does not usually require treatment because most adults clear the infection spontaneously. Treatment of chronic infection may be necessary to reduce the risk of cirrhosis and liver cancer.

The hepatitis B surface antibody test reveals the presence of hepatitis B antibodies, indicating previous exposure to HBV (or successful vaccination), but the virus is no longer present and the person cannot pass on the virus. Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

A Hepatitis insert (Form 2047) is **not** required for a positive result.

Question 176: Hepatitis B core antibody

The enzyme-linked immunosorbent assay (ELISA) technique tests for the antibody directed against the hepatitis B virus core proteins. The hepatitis B core antibody test can indicate previous HBV infection. Currently there is no licensed confirmatory test for Anti-HBc. If the screening test is reactive, a second Anti-HBc test is performed using a different manufacturer’s test kit.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

If the result is “positive,” a Hepatitis insert (Form 2047) is also required.

Question 177: Hepatitis B surface antigen

The ELISA or enzyme immunoassay (EIA) techniques test for the presence of proteins produced by the hepatitis B virus. Confirmatory testing is done using a neutralization test. The first marker appears approximately three weeks following infection, and disappears approximately six months later.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

If the result is “positive,” a Hepatitis insert (Form 2047) is also required.

Question 178: Hepatitis B—DNA

The HBV DNA test is more sensitive than regular serological tests, and is often used in conjunction with those tests to monitor patients with chronic HBV infections.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

If the result is “positive,” a Hepatitis insert (Form 2047) is also required.

Question 179: Hepatitis C antibody

Hepatitis C is a serious infection caused by the hepatitis C virus (HCV) which attacks the liver and may cause life-long infection. HCV is considered the most serious hepatitis infection because of its significant long-term health consequences. The infection is often asymptomatic, but once established, chronic infection can cause inflammation of the liver. This condition can progress to fibrosis and cirrhosis. In some cases, those with cirrhosis will go on to develop liver failure or liver cancer. Presence of the antibody in the blood represents exposure to hepatitis C virus, which is most often spread by blood-to-blood contact. No vaccine against hepatitis C is available.

The ELISA technique tests for antibodies to the hepatitis C virus. Confirmatory testing is done using the recombinant immunoblot assay (RIBA) test. These tests can determine past exposure to the hepatitis C virus, but not current viral load.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

If the result is “positive,” a Hepatitis insert (Form 2047) is also required.

Question 180: Hepatitis C—NAT

Nucleic acid testing (NAT) is a combination PCR test which detects the presence of viral genes (both HIV-1 and HCV RNA) rather than antigens or antibodies. This test allows earlier detection and provides more sensitivity than previously used tests.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

If the result is “positive,” a Hepatitis insert (Form 2047) is also required.

Question 181: Hepatitis A antibody

Hepatitis A is an acute infectious disease of the liver caused by the hepatitis A virus (HAV). HAV is often transmitted via contaminated food and drinking water, and is prevalent in developing countries and areas with poor hygiene standards. Hepatitis A may cause influenza-like symptoms, but is often asymptomatic. There is a highly effective HAV vaccine available which can provide protection for up to 20 years.

A total antibody test (which detects both IgM and IgG antibodies) detects both current and previous infection with HAV and also will be positive after receiving the hepatitis A vaccine.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

If the laboratory reports a HAV IgM antibody only, not total IgG/IgM or HAV IgG antibody; report the result as “not tested.”

A Hepatitis insert (Form 2047) is **not** required for a positive result.

Question 182: HIV antibody

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 lymphocytes which 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. Infection with HIV occurs by the transfer of bodily fluids and is present as both free virus particles and virus within infected immune cells.

HIV antibody testing is done using combination ELISA which detects antibodies to the HIV-1 and HIV-2 viruses. HIV-1 is confirmed by Western Blot, which detects specific proteins using gel electrophoresis. There is currently no licensed confirmatory test for HIV-2. If the screening test is reactive, HIV-2 is confirmed by specific ELISA.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

If the result is “positive,” an HIV insert (Form 2048) is also required.

Question 183: HIV—NAT

Nucleic acid testing (NAT) is a combination PCR test which detects the presence of viral genes (both HIV-1 and HCV RNA) rather than antigens or antibodies. This test allows earlier detection and provides more sensitivity than previously used tests.

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not tested.”

If the result is “positive,” an HIV insert (Form 2048) is also required.

Pre-HSCT Preparative Regimen (Conditioning)

Question 184: Height at initiation of pre-HSCT preparative regimen:

Report the recipient’s height just prior to the start of the preparative regimen. The intent of this question is to determine the height used when calculating preparative regimen drug doses. This height is usually documented on the transplant (radiation and/or systemic therapy) or admitting orders. Report height to the nearest whole centimeter or inch (round up if 0.5 or greater).

Question 185: Actual weight at initiation of pre-HSCT preparative regimen:

Report the recipient’s actual body weight just prior to the start of the preparative regimen. The intent of this question is to determine the weight used when calculating preparative regimen drug doses. This weight is usually documented on the transplant (radiation and/or systemic therapy) or admitting orders. Report weight to the nearest whole kilogram or pound (round up if 0.5 or greater). Do not report lean body weight or ideal body weight.

Question 186: Dosing body weight used for pre-HSCT preparative regimen (adjusted body weight):

Report the recipient’s dosing (adjusted) body weight calculated by the pharmacy/physician to determine the total dose of the drugs given as part of the preparative regimen. The dosing body weight is usually documented on the transplant (radiation and/or systemic therapy) or admitting orders.

If a dosing body weight is not calculated and/or documented, report the actual weight of the recipient.

Question 187: Was a pre-HSCT preparative regimen given?

Recipients are generally transplanted under a specific protocol that defines the radiation and/or systemic therapy the recipient is intended to receive as a preparative regimen. This protocol, which may be either a research protocol or standard of care protocol, should be referred to when completing this section.

However, there are instances when a preparative regimen may not be given. Examples may include, but are not limited to:

- Primary diagnosis of an immune deficiency. See [disorders of the immune system](#)
- Subsequent allogeneic HSCT due to loss of, or poor, neutrophil engraftment.

If a preparative regimen is prescribed per protocol, check “yes” and continue with question 188. If a preparative regimen is not prescribed, check “no” and continue with question 372.

For more information regarding the recipient’s preparative regimen, consult with a transplant physician, or contact your center’s CIBMTR liaison.

Question 188: Specify protocol requirement (*check only one*):

Indicate whether “all agents given as outpatient,” “some, but not all, agents given as inpatient,” or “all agents given as inpatient.” Agents are defined as systemic therapy drugs or radiation therapy.

Question 189: Classify the recipient’s preparative regimen:

The purpose of a myeloablative HSCT is to destroy cells using high-dose radiation and/or systemic therapy. A myeloablative regimen may also be used for recipients with a non-malignant disease requiring a stem cell transplant for marrow reconstitution (i.e., immunodeficiencies), or to produce a complete donor chimerism.

In contrast, non-myeloablative (**NST**) and reduced-intensity (**RIC**) preparative regimens generally use lower doses of radiation and/or systemic therapy to prevent graft rejection and suppress the recipient’s hematopoietic immune system, but not eliminate it completely. A NST relies on the immune cells of the donor to destroy the disease (called graft versus tumor, or GVT), and typically produces a mixed chimerism. NST is a common treatment option for older recipients, and recipients with other health problems, as the lower radiation and/or systemic therapy doses are easier for the recipient to tolerate.

Currently, there are no published definitions of the difference between NST and RIC preparative regimens. However, in general, a RIC includes any regimen not meeting the criteria for either myeloablative or NST regimens. Centers must attribute the intent of the regimen based on the standards at their center. Generally speaking, the attribution should be based on protocol, or the opinion of the physician overseeing the care of the recipient at your center.

Indicate whether the intent of the preparative regimen is myeloablative (produce marrow ablation or pancytopenia), non-myeloablative, or reduced intensity.

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NOTE: Date Pre-HSCT Preparative Regimen Began

Additional radiation and/or intrathecal chemotherapy start dates may be **prior** to the date the preparative regimen begins. Report additional radiation in questions 211-277 and intrathecal chemotherapy in questions 301-314.

Example:

Radiation Order: TBI, 200 cGy/day April 15-17, 2009
CNS Radiation, 200 cGy/day April 1-3, 2009
Report "Additional Radiation start date": April 1, 2009
Report "Date preparative regimen began" as: April 15, 2009

Question 190: Date pre-HSCT preparative regimen (irradiation or drugs) began:

Enter the date the preparative regimen began. Use the earliest date from questions 194, 200, 206 (radiation), or 232-300, 325-365 (systemic therapy). All dates reported in the preparative regimen section must be equal to or after the date reported for this question.

Question 191: Was irradiation performed as part of the pre-HSCT preparative regimen?

If irradiation is performed as part of the preparative regimen, check "yes" and continue with question 192. If irradiation is not performed, check "no" and continue with question 211. Irradiation performed as previous treatment should not be reported in this section. Report irradiation performed as previous treatment on the appropriate Disease Specific Form or in question 211 if applicable (radiation given within 14 days of the pre-HSCT preparative regimen).

Question 192: What was the radiation field?

Indicate if the recipient received irradiation to "total body," "total body by tomotherapy," "total lymphoid or nodal regions," or "thoraco-abdominal region." Complete all of the questions within the section for the specified field.

Question 193, 199, 205: Total dose

Enter the total dose of radiation given. If radiation is given as a single dose, the amount of radiation delivered in the single dose constitutes the total dose. If the radiation is given in fractionated doses, multiply the total number of fractions by the dose per fraction to determine the total dose. Enter the total dose of radiation in either grays (Gy) or centigrays (cGy).

Example:

Radiation Order: TBI, 200 cGy/day for three days (3 doses)
Total dose: 200 cGy x 3 doses = 600 cGy
Report "Total Dose" as: 600 cGy

Question 194, 200, 206: Date started:

Enter the date the single dose or first fraction of radiation was administered.

Question 195, 201, 207: Was the radiation fractionated?

Radiation is either delivered as a single dose or in several treatments (fractions). Radiation is fractionated to increase the loss of diseased cells as they do not recover as quickly as disease-free cells.

If the radiation was fractionated, check “yes” and continue with question 196/202/208. If the radiation was not fractionated, check “no” and continue with question 211.

Question 196, 202, 208: Dose per fraction:

Enter the dose per fraction in either grays (Gy) or centigrays (cGy).

The dose per fraction multiplied by the total number of fractions (question 198/202/208) must be equal to the total dose reported in question 193/199/205.

Question 197, 203, 209: Number of days:

Enter the total number of days radiation therapy was delivered including any days of rest between days when therapy was administered. The number of days radiation was administered can be greater than the number of fractions.

Example:

Radiation Order: TBI, 200 cGy/day every other day (Mon-Wed-Fri) x 3 doses

Total dose: 200 cGy x 3 doses = 600 cGy

Report “Number of days” as: 5

Question 198, 204, 210: Total number of fractions:

Enter the total number of fractions (treatments) of radiation that were administered. The recipient may receive more than one fraction per day (hyperfractionation).

The total number of fractions multiplied by the dose per fraction (question 196/202/208) must be equal to the total dose reported in question 193/199/205.

NOTE: Additional Radiation

Additional radiation start dates may be **prior** to the date the preparative regimen began.

If additional radiation began **more than** 14 days prior to the start of preparative regimen, but at least one dose was **received within** 14 days prior to the preparative regimen, report the actual start date of the additional radiation in this section.

Radiation treatments **completed** more than 14 days prior to the start of the preparative regimen should be reported on the appropriate Disease Specific Form in the treatment section.

Question 211: Was additional radiation given to other sites within 14 days prior to the start of the pre-HSCT preparative regimen?

Report in this section any sites that received a “radiation boost.” Boosts are often given to smaller sites that may have residual malignant cells or to areas that were shielded (ex. chest wall or lung). Include any radiation boosts that were administered **within 14 days prior** to the preparative regimen start date.

Questions 212-227: Specify radiation field, total dose, and date started:

For each site listed, indicate if the recipient received radiation to that site. For each site that received additional radiation, indicate the dose, units, and start date.

NOTE: Preparative Regimen: Drugs

The following questions refer to the drug therapy that was **actually given** as part of the preparative regimen versus the *prescribed* drug therapy which was reported on the Pre-TED. In this section, include any intrathecal drugs the recipient received for prophylaxis or treatment of CNS disease **within 14 days prior** to the start date of the preparative regimen.

Do not include drugs that are intended to offset the side effects of the systemic therapy (e.g., corticosteroids for nausea, MESNA for hemorrhagic cystitis, etc.).

The form lists each drug by the generic name. The form also lists some drugs by broad categories, with specific drugs listed individually. For example, *Anthracycline* is listed as the broad drug category, followed by the specific drugs of *daunorubicin*, *doxorubicin*, and *idarubicin*. The following website provides the trade names under which generic drugs are manufactured:

<http://www.rxlist.com/script/main/hp.asp>.

Question 229: Were drugs given for pre-HSCT preparative regimen?

If the recipient received drugs as part of the preparative regimen, check “yes” and continue with question 230. If the recipient did not receive drugs as part of the preparative regimen protocol, check “no” and continue with question 372.

Question 230-366: Drugs:

For each drug listed, indicate whether or not it was given as part of the preparative regimen. Report the total dose of each drug that was actually given. **Do not report the prescribed dose or the daily dose.** The pharmacy record or Medication Administration Record (MAR) should be used for determining the exact total doses given.

Some drugs used as part of the preparative regimen are administered with guidance of serum pharmacokinetic testing to determine the recipient’s metabolism of the drug. This allows for “customization” of the drug dosing to the individual to optimize the desired effect and minimize the toxicity. Depending upon how the dose of the drug used to monitor drug levels is given; it can be reported in one of two different ways on the CIBMTR Pre-TED (2400) and Baseline (2000) forms.

Busulfan represents a common example of this situation. In some cases, the first dose of the drug is given in the usual fashion as part of the preparative regimen, serum drug levels are drawn after this first dose and sent to a reference lab, and the drug is continued at the starting dose with adjustment of later doses once the lab results are reported. In other situations, a “test dose” of the drug is given before the actual preparative regimen is started, and this dose is used for acquiring drug levels that are used to adjust the dose that will be used in the preparative regimen.

When a drug is used for the preparative regimen where pharmacokinetics will be tested, it is important to distinguish whether the testing will be done using the first dose of the preparative regimen or if the drug will be given with a “test dose” distinct from the beginning of the preparative regimen. The reporting of the dosing for the CIBMTR forms depends upon this distinction. This helps distinguish whether the dose is part of the therapeutic regimen, or not.

1. The first dose of therapeutic dosing is used for monitoring.
 - **Example:** Patient with MDS receives allogeneic HSCT from an unrelated donor using Busulfan and Fludarabine preparative regimen. He is admitted to the hospital 7 days before his HSCT, and receives a dose of Busulfan at 0.8 mg/kg IV at 6 AM. Serum samples are drawn every 30 minutes until the next dose of Busulfan at 0.8 mg/kg IV is given at 12 noon. His blood is sent to a reference lab, and he continues to receive Busulfan every 6 hours. On day -6, the lab calls with his drug levels, and it is determined that the current dose is correct. No adjustment is made, and he

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completes all 16 doses of Busulfan. Since the dose of Busulfan (0.8 mg/kg) that was used for drug testing was ALSO his first dose of the preparative regimen, it should be included in the amount of drug that was given for preparative regimen.

- If the first dose of the preparative regimen will be used to determine pharmacokinetics, the following should be reported:
 - a. On the Pre-TED (2400) form, the total prescribed dose per protocol would include the dose used for monitoring.
 - b. On the Baseline (2000) form, the start date of the chemotherapy agent should be reported as the date the first dose was administered. The actual dose received would include the dose used for monitoring.
2. The test dose is given \geq **24 hours** prior to the intended therapeutic dosing.
- **Example:** Patient with AML undergoes allogeneic HSCT from sibling using Busulfan and Cyclophosphamide preparative regimen. The patient presents to clinic 9 days before the HSCT, where a dose of Busulfan at 0.5 mg/kg is given intravenously. Blood samples are drawn for the next 6 hours, after which the patient leaves the clinic. His samples are sent to a lab, results are returned the next day and an adjusted dose of Busulfan is calculated. He returns to the hospital 6 days before HSCT, and begins to receive Busulfan at the adjusted dose intravenously for 4 days, followed by Cyclophosphamide and proceeds to receive his cells. Since he received 0.5 mg/kg as a “test dose”, this would not be reported in his total preparative regimen dose.
 - If a test dose is given, where the dose is distinct from the therapeutic dosing preparative regimen (often 1-2 or more days prior to the initiation of regular dosing), the following should be reported.
 - a. On the Pre-TED (2400) form, the total prescribed dose per protocol would NOT include the test dose.
 - b. On the Baseline (2000) form, the start date of the chemotherapy agent should be reported as the date the first therapeutic dose was administered. The actual dose received would NOT include the test dose.

Test doses must be reported consistently at your center. Since most centers follow a consistent approach to pharmacokinetic testing, it should be straightforward for the center to adopt a consistent approach to the reporting of “test doses.”

Drug doses must be reported in whole numbers. If the total dose includes a decimal, round to the nearest whole number (round up if 0.5 or greater). For paper submission, do not modify the number of boxes or include decimal values.

NOTE: Calculating Drug Doses

Drug doses are calculated either by recipient weight or recipient body surface area (BSA) in m². The HSCT protocol will specify “x mg/m²” or “x mg/kg” and the total number of doses to be administered. Convert the drug dose to mg by multiplying mg/m² by the recipient’s BSA, or mg/kg by the recipient’s weight in kg. The recipient’s BSA and weight in kg are usually documented on the transplant (radiation and/or systemic therapy) or admitting orders.

To calculate the total dose administered: multiply “mg of drug per dose” x “total number of doses.” If the dose was prescribed in grams (gm) rather than milligrams (mg), multiply the total dose in gm by 1,000 to convert to mg.

The pharmacy record or Medication Administration Record (MAR) should be used for determining the exact total dose given.

Example 1:

Drug Order: Fludarabine, 53 mg once daily for five days (5 doses)

Total dose: 53 mg x 5 doses = 265 mg

Report “Total Dose” as: 265 mg

Example 2:

Drug Order: Busulfan, 54.4 mg every 6 hours for four days (16 doses)

Dose Change: After 2 doses, Busulfan changed to 48.6 mg (14 doses)

Given: 54.4 mg x 2 doses = 108.8 mg

48.6 mg x 14 doses = 680.4 mg

Total Dose: 108.8 mg + 680.4 mg = 789.2 mg

Report “Total Dose” as: 789 mg

The “other, specify” category should only be used if the drug is not one of the listed options. If more than one “other” drug is prescribed, list the generic name of the drugs in the space provided and attach a copy of the source document using the Log of Appended Documents (Form 2800). Drugs given for prophylaxis for infection, GVHD, or organ toxicity should not be reported in this section. Report these drugs on the 100 Day Follow-up Form (2100).

NOTE: ATG given as GVHD prophylaxis

Report ATG given **before** Day 0 in the preparative regimen section (questions 230-366).

Report ATG given **after** Day 0 in the GVHD prophylaxis section on the 100 Day Follow-up Form (2100).

If the Baseline is completed for a subsequent HSCT, do not report therapy that was given to treat the recipient's disease (between the previous and current planned HSCTs) in the preparative regimen section. Report this therapy on the appropriate Disease Specific Form.

Question 367: Were pharmacokinetics performed to determine preparative regimen drug dosing?

Pharmacokinetic testing can be used to determine whether the drug concentration in the bloodstream is appropriate to the dose given. This reflects the speed of absorption and elimination of the drug. These tests are usually performed using the first dose of systemic therapy, or a test dose, where multiple serologic samples are drawn at specific time points following the first dose. The tests are sent to a laboratory that performs the testing to determine the drug concentration. If it is not known whether or not this testing was performed, consult with a transplant physician.

Indicate whether or the not pharmacokinetics were performed to determine preparative regimen drug dosing. If "yes," continue with question 368. If "no," continue with question 372.

Questions 368-371: Specify Drugs

Indicate which drug(s) were pharmacokinetically tested. If "other" is chosen, specify the drug.

HSCT History

Question 372: Was this the first HSCT for this recipient?

Indicate if this is the recipient's first transplant. First transplant is defined as the first transplant the recipient ever receives, not the first transplant the recipient receives at your facility.

If "yes," and this is an autologous transplant, continue with question 373.

If "yes," and this is an allogeneic transplant, continue with question 373 and select "not applicable; allogeneic HSCT", continue with question 390.

If "no," continue with question 375.

Question 373: For autologous HSCTs only: Is a subsequent HSCT planned as part of the overall treatment protocol (not as a reaction to post-HSCT disease assessment)?

If, at the time of the current HSCT, a second (tandem transplant) or subsequent HSCT is planned according to the protocol, check "yes" even if the recipient does not receive the planned second HSCT. The word "planned" **should not** be

interpreted as: *if the recipient relapses, then the “plan” is to perform a subsequent HSCT.*

Question 374: Specify subsequent HSCT planned:

Indicate whether the planned subsequent HSCT is autologous or allogeneic and continue with question 390.

Question 375: Specify the number of prior HSCTs:

An HSCT event is defined as an infusion of mobilized peripheral blood stem cells (PBSC), bone marrow, or cord blood. For more information on how to distinguish infusion types (example: HSCT versus DCI), see [Appendix O](#).

For recipients who have received a previous HSCT (prior to the HSCT for which this form is being completed), the following are examples of how to calculate the chronological number of this HSCT.

Example 1:

A recipient was previously transplanted under a protocol that included an infusion of cells over multiple days: day 0, day +1 and day +2. This series of infusions is considered one HSCT event, as opposed to three HSCT events and should be counted as *HSCT Event #1*.

After receiving the infusion, the recipient had relapse of disease. The recipient is scheduled to receive a subsequent HSCT including a preparative regimen. This HSCT should be reported as *HSCT Event #2*.

Example 2:

A recipient previously received an **allogeneic** HSCT (*HSCT Event #1*). Then, due to delayed neutrophil recovery, the recipient received additional cryopreserved **allogeneic** mobilized PBSC from the original donor, without a preparative regimen (i.e., “boost” – *HSCT Event #2*).

After receiving the boost, the recipient had relapse of disease. The recipient is scheduled to receive a subsequent allogeneic HSCT with preparative regimen (*HSCT Event #3*).

Example 3:

A recipient previously received an **autologous** HSCT (*HSCT Event #1*). Then due to delayed neutrophil recovery, the recipient received additional cryopreserved **autologous** cells without a preparative regimen (i.e., “boost” which is not counted as an HSCT event because the intent of the infusion is to treat the graft failure.).

The boost is successful, but a few years later the recipient develops a new malignancy. The recipient is scheduled to receive a subsequent autologous HSCT with preparative regimen (*HSCT Event #2*).

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If the recipient receives an infusion due to poor graft response, count the infusion as a *subsequent HSCT*. The exception to this is “autologous rescue.” Autologous rescue is generally used to treat the recipient’s poor graft response, rather than their disease. Autologous rescue **should not** be counted as a separate HSCT, and the data collection forms **will not** start over (i.e., the forms will continue from the previous HSCT).

Questions 376-380: What was (were) the prior HSC source(s)?

Report the stem cell source for each of the recipient’s previous HSCTs as either autologous, allogeneic unrelated, allogeneic related, or syngeneic (identical twin).

Question 381: Date of the last HSCT (just before current HSCT):

Report the date of the recipient’s **last** autologous or allogeneic (related or unrelated) HSCT. Although the CIBMTR requests either a Pre-TED and/or Recipient Baseline Data (Form 2000) for each HSCT, there may be circumstances where a prior HSCT was not reported (e.g., prior autologous HSCT or HSCT performed at another center). Reporting the recipient’s last HSCT enables the CIBMTR to appropriately account for recipient survival status in the database.

Question 382: Was the last HSCT performed at a different institution?

Indicate if the last HSCT was performed at another institution. If “yes” continue with question 383. If “no” continue with question 384.

Question 383: Specify the institution that performed the last HSCT:

Report the name, city, state and country of the institution where the recipient’s last HSCT was performed. These data are used to identify and link the recipient’s existence in the database and, if necessary, obtain data from the previous transplant center.

Question 384: What was the HSC source for the last HSCT?

Report the stem cell source of the recipient’s last HSCT as either autologous, allogeneic unrelated or syngeneic / allogeneic related.

Question 385-389: Reason for current HSCT:

Indicate the reason for the current HSCT (check only one). If this was a subsequent transplant, verify that this answer is consistent with the reason for the subsequent transplant reported on the previous series of report forms.

- **No hematopoietic recovery:**
Additional stem cells are required because the recipient did not recover their granulocytes following previous high-dose therapy and HSCT.

- **Partial hematopoietic recovery:**
Additional stem cells are required because the recipient's hematopoietic recovery was deemed insufficient or too slow for the recipient to survive following previous high-dose therapy and HSCT (ANC was never greater than or equal to $0.5 \times 10^9/L$ for three consecutive days).
- **Graft failure/rejection after achieving initial hematopoietic recovery:**
Additional stem cells are required because the recipient's hematopoietic recovery indefinitely declined after the initial hematopoietic recovery (ANC was greater than or equal to $0.5 \times 10^9/L$ for three consecutive days, and then declined to below $0.5 \times 10^9/L$ for three consecutive days). If the reason is graft failure or rejection after initial recovery, also complete question 386.
- **Persistent primary disease:**
Additional stem cells are required because the recipient was transplanted with disease present, and never entered a remission following the previous transplant.
- **Recurrent primary disease:**
Additional stem cells are required because the disease for which the recipient was transplanted relapsed following the previous transplant. If the reason is recurrent primary disease, also complete question 387.
- **Planned second HSCT, per protocol:**
Additional stem cells are given because the protocol planned for a subsequent transplant/infusion. This transplant is not based upon recovery, disease status, or any other assessment.
- **New malignancy (including PTLD and EBV lymphoma):**
Additional stem cells are required because the recipient has developed a new malignancy. This does not include a transformation or progression of the original malignancy for which the recipient was transplanted. If the reason is a new malignancy, also complete question 388, and attach a copy of the pathology report using the Log of Appended Documents (Form 2800).
- **Stable, mixed chimerism:**
In the case of a stable, mixed chimerism, the infusion of additional stem cells is typically classified as a DCI. Verify with the transplant physician that the cells given should be reported as a subsequent transplant and that stable, mixed chimerism is the reason for the transplant.

- **Declining chimerism:**
Additional stem cells are required because the percentage of donor cells present versus recipient cells present are decreasing. This is usually due to an underlying cause such as graft failure, graft rejection, or recurrent disease.
- **Other:**
Additional stem cells are required and/or given for a reason other than the options listed. If the HSCT is for another reason, select “other” and complete question 389.

Socioeconomic Information

Question 390: Is the recipient an adult (18 years of age or older) or emancipated minor?

Indicate if the recipient is 18 years of age or older, or if under 18, has been declared by law, an emancipated minor. An emancipated minor is a child who has been granted the status of adulthood by a court order or other formal arrangement.

If “yes,” continue with question 391. If “no,” continue with question 392.

Question 391: Specify the recipient’s marital status:

Report the recipient’s marital status as of the date of HSCT.

Questions 392-393: Specify the category which best describes the recipient’s occupation:

Report the recipient’s occupation category prior to illness.

If the recipient is unemployed, check the box that best describes his/her most recent job.

If the recipient is “under school age,” select this option, and continue with question 398.

The “other, specify” category should only be used if the recipients occupation does not fit into one of the broad occupation categories listed.

Questions 394-395: What was the recipient's current or most recent work status prior to illness?

Report the recipient's most recent work status as of the date of HSCT.

If the recipient's occupation was reported as "student" in question 392, specify "full time," "part time," or "unknown" in question 394.

If "retired" is selected, continue with question 395.

Question 396: What is the highest educational grade the recipient completed?

Report the recipient's highest completed educational level as of the date of HSCT.

Question 397: Is the recipient currently in school, or was enrolled prior to illness?

Indicate if the recipient is a current student, or was a student prior to illness.

Question 398: Is the recipient covered by health insurance?

Indicate if the recipient has health insurance.

If "yes," continue with question 399. If "no," continue with question 407.

Questions 399-406: Specify type of health insurance:

Report the recipient's source of health insurance as of the date of HSCT. If the recipient carries more than one source, check all that apply.

Question 407: For U.S. residents only: Specify the recipient's combined household gross annual income. *Include earnings by all family members living in the household, before taxes.*

Indicate the sum total of the annual incomes for all family members living in the recipient's household, before taxes.

Consent Status

To be compliant with Federal Regulations for human research subject protection, centers must obtain IRB-approved informed consent from recipients and donors to allow data submitted to the Stem Cell Therapeutics Outcomes Database (SCTOD) to be used for research. Informed consent must also be obtained from recipients and donors prior to submitting blood samples to the Research Sample Repository. The NMDP/CIBMTR has written protocols and informed consent documents for the [Observational Database](#) and [Research Sample Repository](#). All centers must have local IRB approval for the Observational Database protocol. All centers that are NMDP member centers must also have local IRB approval for the Research Sample Repository protocol. Allogeneic related recipients and

donors will participate at select sites. All other centers performing only related donor transplants and/or autologous transplants will not be submitting research samples and do not need to obtain local IRB approval for the repository protocol. The NMDP and Medical College of Wisconsin (MCW) IRBs have approved these protocols and consent forms and the documents are provided to participating sites to include with their local IRB submissions.

International Centers must obtain consent of each patient participating in the Observational Database in a manner consistent with the laws and regulations in effect in that country.

Under new federal legislation, U.S. centers are required to submit outcomes data on all allogeneic transplants, related and unrelated. Data submitted without informed consent from the recipient should be reported on the TED Forms and will only be used for federally required research such as the center-specific outcomes analysis.

Question 408: Has the recipient signed an IRB-approved consent form to donate research blood samples to the CIBMTR?

The Research Sample Repository contains blood samples from unrelated recipients and/or their adult volunteer donor, or cord blood unit. Related allogeneic recipients and/or donors will participate at selected transplant centers. The primary objective of the Research Repository is to make blood samples available for research studies related to histocompatibility and hematopoietic stem cell transplantation.

Studies in which these data may be used include:

- Improve the understanding of tissue matching for hematopoietic stem cell donors and recipients
- Determine and evaluate the factors that affect transplant outcome
- Study the distribution of HLA tissue types in different populations (e.g., study tissue typing differences between different racial and ethnic populations to help develop methods to improve tissue matching between donors and recipients, including testing of rare HLA types)

Indicate if the recipient has signed an IRB-approved consent form to donate research blood samples to the CIBMTR. If “yes,” continue with question 409. If “no,” continue with question 410.

Question 409: Date form was signed:

Report the date the research sample consent form was signed by the recipient. Do not report the date that the witness or health care professional signed the consent form.

Question 410: Has the recipient signed an IRB-approved consent form for submitting research data to the CIBMTR?

When a recipient consents to participate in the Observational Database, their data are contained in the CIBMTR's Observational Database and used for research. The database includes recipient baseline and outcome data for related and unrelated allogeneic transplants from any cell source, and for autologous transplants. Data are also collected on unrelated donors and their donation experiences. The data contained in the database are observational data. The primary purpose of the Observational Database is to have a comprehensive source of data that can be used to study hematopoietic stem cell transplantation. Studies in which these data may be used include:

- How well recipients recover from their transplants
- How recovery after transplantation can be improved
- Long-term outcomes after transplantation
- How access to transplantation for different groups of recipients can be improved
- How well donors recover from collection procedures
- The application and success of transplantation in the management of marrow-toxic injuries

Indicate if the recipient has signed an IRB-approved consent form to participate in the Observational Database. If "yes," continue with question 411. If "no," continue with question 412.

Question 411: Date form was signed:

Report the date the research database consent form was signed by the recipient. Do not report the date that the witness or health care professional signed the consent form.