Pre-TED Data Manual Change History through 3/31/15

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
3.1	02/07/2014	Modify	Changed the explanatory text of question 93 to read: ***Recipients < 6 months:*** *If the recipient is less than 6 months old, report any positive CMV antibody results as "~~inconclusive~~ not done" due to the presence of maternal antibodies. However, in infants less than 6 months old, positive CMV PCR results indicate a CMV infection and the results may be reported as "reactive."*
3.1	02/07/2014	Modify	Question 578 – Modified Table 16. Disease Status of CLL/SLL, PLL under CR. Changed first bullet to read: *No ~~radiographic~~ evidence of lymphadenopathy** and added: **Absence of significant lymphadenopathy (e.g., lymph nodes > 1.5 cm in diameter) by physical examination. In clinical trials, a CT scan of the abdomen, pelvis, and thorax is desirable if previously abnormal. Lymph nodes should not be larger than 1.5 cm in diameter.* *Hallek, M., Cheson, B. D., Catovsky, D., Caligaris-Cappio, F., Dighiero, G., Döhner, H., ... & Kipps, T. J. (2008). Guidelines for the diagnosis and treatment of chronic lymphocytic leukemia: a report from the International Workshop on Chronic Lymphocytic Leukemia updating the National Cancer Institute–Working Group 1996 guidelines. Blood, 111(12), 5446-5456.*

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3.2	03/28/2014	Add	Added text to the Note preceding Question 31: *NOTE: Related CBU and Related Product From Same Donor* *If the recipient receives a cord blood unit and another product from the same related donor, complete two instances of the Donor Information section (questions 31-62) on the Pre-TED Form 2400.* *For example, if a related donor gave a cord blood unit and bone marrow, you would report the cord blood unit information in one instance with the donor type listed as 'Related cord blood unit'. Create another instance with the donor type reported as 'Related donor' to report the bone marrow information. This allows CIBMTR to capture all the necessary donor information needed.* *For these cases, complete a Form 2004 for each product. When the donor type is an HLA matched or mismatched relative, only one Form 2005 is required.*
3.2	03/28/2014	Add	Added text to Question 155: *Even if the recipient does not receive a preparative regimen, the height is still required.*
3.2	03/28/2014	Modify	Question 156 – modified text to read: *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~~ . report the actual weight at the time the preparative regimen starts (which may be different than the weight used to determine preparative regimen doses). This weight is usually documented on the transplant orders (for 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 adjusted body weight, lean body weight, or ideal body weight.* and added: *Even if the recipient does not receive a preparative regimen, the weight is still required.*
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		/ Remove / Modify)	
3.2	03/28/2014	Modify	Question 158 – modified text to read: *Based on the CIBMTR operatoinal guidelines below, report if the regimen was myeloablative, reduced intensity, or non-myeloablative. The determination of whether the intent of the regimen was ~~myeloablative, NST, or RIC~~ reduced intensity or non-myeloablative should be based either on the protocol at your center or the opinion of the physician overseeing the care of the recipient at your center.* And added *Table 1. Example of Myeloablative, Reduced Intensity and Non-Myeloablative Regimens*
3.2	03/28/2014	Add	Added text to Question 356: *If the recipient was diagnosed prenatally (in utero), report the date of birth as the date of diagnosis.*
3.2	03/28/2014	Add	Added Note to Questions 594-596: *NOTE:* *Currently there is an issue on Form 2400 regarding the ISS Staging. Stage I requires albumin greater or equal to 3.5 g/dL* And added *Table 24. I.S.S. Staging System for Multiple Myeloma*
3.2	03/28/14	Add	Added Note to Question 619: *NOTE:* *Currently there is an issue on Form 2400 regarding the number of plasma cells required for CR. CR requires less than (but not equal to) 5 % plasma cells in the bone marrow.*
3.3	06/01/2014	Modify	Updated formatting to match CIBMTR brand standards

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3.3	06/01/2014	Add / Modify	Added explanatory Note and modified text for questions 489 and 532: *NOTE:* *Currently there is an issue on the 2400 form regarding RBC transfusion dates. The question should read: "Were RBCs transfused ≤ 30 days before the date of test?"* *Transfusions temporarily increase the red blood cell count. It is important to distinguish between a recipient whose body is creating these cells and a recipient who requires transfusions to support the counts.* *Indicate if red blood cells were transfused less than or equal to 30 days prior to the testing reported in question X.*
3.3	06/01/2014	Add / Modify	Added explanatory Note and modified text for questions 492 and 535: *Note: Currently there is an issue on the 2400 form regarding platelet transfusion dates. The question should read: "Were platelets transfused ≤ 7 days before the date of test?"* *Transfusions temporarily increase the platelet count. It is important to distinguish between a recipient whose body is creating the platelets and a recipient who requires transfusions to support the counts.* *Indicate if platelets were transfused less than or equal to 7 days prior to the testing reported in question X.*

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3.3	06/01/2014	Add / Modify	The note regarding drugs on the preparative regimen was moved under questions 168-315 and the explanatory text was changed to reflect operational reporting standards when drugs are given both pre- and post-transplant: ***NOTE: Preparative Regimen - Drugs*** *The following questions report the* ***prescribed*** *drug therapy that was part of the preparative regimen. Do not report the dose that was actually given. If the recipient has comprehensive report forms due, the actual dose given will be reported on the Recipient Baseline Form (Form 2000).* ***Do not include drugs that are intended to offset the side effects of the chemotherapy*** *(e.g., corticosteroids for nausea, MESNA for hemorrhagic cystitis, etc.).* *Occasionally, protocols list drugs that may be given before and after day 0. If the drugs are planned to be given before and after day 0, only the doses given before day 0 should be quantified in the preparative regimen section. The doses given after day 0 should be reported in the* ***Post-HCT Disease Therapy Planned as of Day 0*** *or* ***GVHD Prophylaxis*** *section. For example, if bortezomib or rituximab are planned to be given on Days -2, +1, +4, and +7, report the Day -2 dose in the preparative regimen section, and the post-transplant doses as planned post-HCT therapy.* *ATG or alemtuzumab (Campath) given for GVHD prophylaxis planned prior to Day 0 should be reported in the preparative regimen section of the Pre-TED. If ATG, alemtuzumab, or cyclophosphamide is planned after Day 0, it should be reported in the GVHD prophylaxis section (questions 316-341).* *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 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.*

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3.3	06/01/2014	Modify	The explanatory text before the GVHD prophylaxis questions (316-341) was updated to include cyclophosphadmide: ***NOTE: Questions 316-341*** *The following GVHD prophylaxis questions are to be completed for allogeneic HCTs only. Autologous and syngeneic HCTs continue with question 342.* *If it was planned that ATG or campath, were to be given for GVHD prophylaxis prior to Day 0, this should be reported in the preparative regimen section of the Pre-TED (questions 168-315). If it was planned that ATG, Campath, or cyclophosphamide were to be given after Day 0, this should be reported in the GVHD prophylaxis section (questions 316-341).*
3.4	06/23/2014	Add	Added explanatory text to the text box following questions 168-315: ***NOTE: Preparative Regimen - Drugs*** *The following questions report the* ***prescribed*** *drug therapy that was part of the preparative regimen. Do not report the dose that was actually given. If the recipient has comprehensive report forms due, the actual dose given will be reported on the Recipient Baseline Form (Form 2000).* ***Do not include drugs that are intended to offset the side effects of the chemotherapy*** *(e.g., corticosteroids for nausea, MESNA for hemorrhagic cystitis, etc.).* *…* *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.*

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3.5	07/11/2014	Add	Added text to Multiple Myeloma Disease Reponse Criteria for VGPR: ***One or more*** *of the following must be present:* • *Serum and urine M-protein detectable by immunofixation but not on electrophoresis* • *≥ 90% reduction in serum M-protein and urine M-protein level < 100 mg/24 hours.* *If the serum and urine M-protein are not measurable (i.e., do not meet the following criteria at time of diagnosis):* • *Serum M-protein ≥ 1 g/dL* • *Urine M-protein ≥ 200 mg/24 hours;* *then a ≥ 90% decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria.* *VGPR requires two consecutive assessments (by the same method) made at any time before the institution of any new therapy. If radiographic studies were performed, there must be no known evidence of new or progressive bone lesions. Radiographic studies are not required to satisfy VGPR requirements.*
3.6	08/22/2014	Modify	In Question 592-592, the calcium criteria for Durie-Salmon was changed from ≤12 to <10.5 mg/dL to match the case report form. • *Serum calcium normal (< 10.5 mg/dL)*
3.7	09/24/2014	Add	Question 71 – added the following text: *If any part of the product was manipulated in any way prior to infusion at the transplant center, select "yes."* ***Do not report cryopreservation (including plasma removal as part of cryopreservation) as a method of manipulation; cryopreservation of the product(s) is reported on the 2006 form, if applicable.*** *If the product was shipped to your facility, do not report manipulation of the product performed at the collection center.*

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3.7	09/24/2014	Add	Questions 73-89 – added the following text: ***Note: Steps in Manipulation*** *If the manipulation consists of several steps, individual steps do not need to be reported as separate manipulations. For example, washing that is part of CD34+ expansion does not need to be reported as a separate manipulation. Similarly, T-cell depletion that is part of expansion does not need to be reported.* *In the cases above, if T-cell depletion and/or washing are done as stand-alone manipulations, they should be reported.* … ***Plasma reduced (removal):*** *Plasma reduction is performed to remove plasma via sedimentation or centrifugation.*[1] *Plasma reduction may be done in order to minimize the risks associated with ABO mismatched products or to prevent volume overload. Previous versions of the Form 2006 made a distinction between plasma removal and volume reduction; for the purpose of this form, both volume reduction and plasma removal should be reported here.* *Plasma reduction/removal that is part of the cryopreservation process should not be reported as manipulation.* ...
3.7	09/24/2014	Modify	Modified explanatory text for question 525: … *MDS/MPN subtypes may also transform/progress from one into another.* ~~*For example RAEB-1 may transform into RAEB-2.*~~ *A progression from one subtype of MDS to another indicates that the number of cytopenias, number of blasts, and/or morphology of marrow sufficiently qualified them for a higher grade (i.e., more severe) MDS. For example, an MDS classified as RCUD at diagnosis whose blast count rises to 8% as documented on bone marrow aspirate would have progressed to RAEB-1.*

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3.7	09/24/2014	Modify	***(cont. from above)*** *Conversely, do not report a progression/transformation if the recipient's assessments after diagnosis show that they qualify for a lower grade (i.e., less severe MDS). For example, a recipient who is diagnosed with RAEB-2, but whose assessments show that they meet the criteria for RAEB-1 as a response to treatment, would* ***not*** *qualify as a progression or transformation. In this example, the disease is lower grade (i.e., less severe), rather than a higher grade (i.e., more severe) so it should not be reported as a progression/transformation. See the table below for guidance in determining the severity of MDS/MPN progressions and transformations.* *[See table in text]*
3.7	09/24/2014	Add	Added row for HL <u>to</u> NHL transformation in Table 3, with additional explanatory text. *[See table 3]* ** Ensure that the disease process is a transformation from Hodgkin lymphoma <u>to</u> Non-Hodgkin lymphoma (typically diffuse large B-cell lymphoma), rather than the distinct entity "B-cell lymphoma, unclassifiable, with features indeterminate between DLBCL and classical Hodgkin Lymphoma."*

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3.8	01/15/2015	Add	Added text under Question 63: ***When to use the "Not Approached" option for the Research Database Consent*** *CIBMTR expects all transplant centers to approach all patients for the Research Database consent. The "not approached" option should only be used in the rare event when the physician feels it would be in the best interest of the patient not to be consented.* ***Recipients who transfer to another facility for a subsequent HCT*** *Any time a recipient transfers to another transplant center, an IRB approved research database consent would need to be obtained at the new center before data could be reported to the CIBMTR.* *See the table below for additional information regarding how to report consent status for those with planned tandem or previous transplants.* *[see table in text]*
3.8	01/15/2015	Add	Added text under Question 67: *Blood samples are not submitted for subsequent transplants, however, this question is asked for subsequent transplants. If the recipient previously consented to submit research blood samples to NMDP/CIBMTR, select "yes (patient consented)."*
3.8	01/15/2015	Add	Added text under question 358: *Report the most specific entity that applies to the recipient. For example, if the recipient was classified using both cytogenetic data and the M5 FAB classification, the more specific cytogenetic data should be reported for classification purposes.*

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3.9	01/26/2015	Add	Added text box to question 96: ***NOTE: Hepatic and Renal Comorbidities*** *In addition to the guidelines listed on the Pre-TED form, include the following time-specific guidelines when reporting hepatic and renal comorbidities.* ***Hepatic Comorbidity:*** *The assessment of liver function tests (ALT, AST and/or Total Bilirubin) has to include at least 2 values per test on two different days within a period extending between days -24 & -10 (or between days -40 & -10 if only a single value was reported between days -24 & day -10) before HCT.* ***Renal (Moderate/Severe) Comorbidity:*** *Serum creatinine > 2 mg/dL or > 177 µmol/L, as detected in at least two lab values on two different days within a period extending between days -24 & -10 before HCT. The evaluation period may be extended to span between days -40 & -10 if the serum creatinine was only evaluated once between days -24 & -10; or on dialysis within a period of 4 weeks prior to transplant, or prior renal transplantation.* *Sorror, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. Blood, 121(15), 2854-2863.*
3.9	01/26/2015	Modify	Added the following caveat to the consent section: *To be compliant with Federal Regulations for human research subject protection, centers must obtain IRB-approved informed consent from recipients and donors (if applicable, for the related donor sample repository) to allow data submitted to the CIBMTR to be used for observational research.*