Hematopoietic Stem Cell Transplant (HCT) Infusion Manual Change History through 3/31/15

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

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2.3	09/24/2014	Add	Questions 73-95 – added the following text: ***Note: Steps in Manipulation*** *If the manipulation consists of several steps, individual steps do not need to be reported as separate manipulations. For example, washing that is part of CD34+ expansion does not need to be reported as a separate manipulation. Similarly, T-cell depletion that is part of expansion does not need to be reported.* *In the cases above, if T-cell depletion and/or washing are done as stand-alone manipulations, they should be reported.* … ***Plasma reduced (removal):*** *Plasma reduction is performed to remove plasma via sedimentation or centrifugation.[1]* *Plasma reduction may be done in order to minimize the risks associated with ABO mismatched products or to prevent volume overload. Previous versions of the Form 2006 made a distinction between plasma removal and volume reduction; for the purpose of this form, both volume reduction and plasma removal should be reported here.* *Plasma reduction/removal that is part of the cryopreservation process should not be reported as manipulation.* ...
2.4	01/15/2015	Modify	Modified the explanatory text in question 66: *Report the time the thawed product was ready for infusion or expansion. This time is frequently when the product thaw is completed. Show the time using a 24-hour clock and indicate if daylight savings time or standard time was in effect. If the location of your institution or off-site laboratory does not observe daylight savings time, report the time as standard time. For more information about daylight savings time schedules, go to http://www.worldtimezone.org/.*

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2.4	01/15/2015	Add	Added additional explanatory text to question 158: *If the product arrives at your center (or is collected at your center), is tested, and the cryopreserved, report these values as "at arrival." If the product arrives, and is tested several times, and then cryopreserved, report the first testing results as "at arrival" and the last test results prior to cryopreservation as "pre-cryopreservation." If the product is thawed, but not retested prior to infusion, you can report the values prior to cryopreservation as "at infusion." If a viability assessment is completed, ensure that it is reported accurately for the at infusion time point.*
2.4	01/15/2015	Add	Added an informational box to the explanatory text following questions 161-176: ***NOTE:*** *Since total nucleated cells consist of both nucleated red and white blood cells, it is possible to calculate a missing value if the two other values are present on lab reports. Centers do not need to calculate and report these lab values if they don't appear on the laboratory paperwork.*
2.4	01/15/2015	Add	Added informational text to question 179-180: *If both methods of viability testing are performed, report 7-AAD results.*