

100-Day Post-HSCT Manual Change History through 3/31/15

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
1.2	02/07/2014	Modify	<p>Modified the explanatory text of questions 198-227 to read:</p> <p><i>Following an allogeneic HSCT, specific immunosuppressive therapy may be administered to prevent GVHD or to immunosuppress the host marrow, thereby promoting engraftment of the donor stem cells. Most transplant centers have specific GVHD prophylaxis protocols and graft rejection protocols. Any planned agent a recipient is scheduled to receives as a result of these protocols should be included in this section.</i></p>
1.2	02/07/2014	Add	<p>Added additional explanatory text to questions 72-76:</p> <p><i>If the results show the absolute lymphocyte count, but only percentages of lymphocyte subsets, it is necessary to calculate the absolute value of each lymphocyte subset for reporting purposes. This can be done by multiplying the percentage of each subset by the absolute lymphocyte count. See the example below: [See example in text]</i></p>
1.2	02/07/2014	Add	<p>Added additional explanatory note to questions 81-160:</p> <p><i>If the chimerism study is performed on peripheral blood, but no cell subtype is specified in the results, select "Other, specify" and report "Peripheral blood, NOS."</i></p> <p><i>Centers may test chimerisms frequently, and not every test needs to be reported. Chimerisms that should be reported, if assessed, are:</i></p> <ul style="list-style-type: none"> • Day 28 • Most recent prior to the 100 day, six month, and annual date of contact • Most recent prior to and after an intervention (such as a donor cellular infusion) • The first result to show 100% donor chimerism
1.3	06/01/2014	Add	Added "Revision 3" to the title of the manual.
1.3	06/01/2014	Modify	Modified question numbers to reflect updates to the form. Note that previous changes reflect the question numbers at the time of the change.

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1.3	06/01/2014	Remove	<p>Removed incorrect time points from explanatory note after question 81:</p> <p><i>Centers may test chimerisms frequently, and not every test needs to be reported. Chimerisms that should be reported, if assessed, are:</i></p> <ul style="list-style-type: none"> • Day 28 • Most recent prior to the 100 day, six month, and annual date of contact • Most recent prior to and after an intervention (such as a donor cellular infusion) • The first result to show 100% donor chimerism
1.3	06/01/2014	Modify	<p>Modified text box prior to questions 48-54:</p> <p>NOTE: Transfusions</p> <p><i>Currently there is an error on the Form 2100 (versions 1 and 2) regarding transfusion history. The form should read: "transfused RBC less than or equal to 30 days from date of most current testing" and "transfused platelets less than or equal to 7 days from date of most current testing."</i></p>
1.3	06/01/2014	Modify	<p>Modified text in chimerism tables for question 89, 90, 101, and 102. Example of explanatory text for question 90:</p> <p><i>If a non-quantitative method was used, in the box labeled "Non-Quant." enter a "1" to indicate the presence of host cells or a "-" to indicate the absence of host cells. Do not mark both quantitative and non-quantitative. If there are ≤5% host cells, report as "-." check the box if host/recipient cells were detected. check the box if host/recipient cells were detected.</i></p>
1.3	06/01/2014	Add	Added Table 3 illustrating chimerism cell types following questions 81-102.
1.3	06/01/2014	Modify	Replaced the word "liaison" with "CRC."
1.3	06/01/2014	Modify	Updated formatting to match CIBMTR brand standards.
1.3	06/01/2014	Modify	Updated Key Fields and Signature Line text to be consistent with other manuals.

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1.4	06/20/2014	Modify	<p>Modified explanatory text from question 1.</p> <p>Removed:</p> <p>Acceptable evaluations include those from the transplant center, referring physician, or other physician currently assuming responsibility for the recipient's care. If an evaluation was not performed on Day 100, choose the date of contact closest to the actual time point. Types of contact could include a documented phone call with the recipient, a laboratory evaluation, or any other recipient interaction on the date reported.</p> <p>If this form reports the recipient's death (on or before day 100), the date of contact must be the actual date the recipient died. This date must also be the same date reported on the Recipient Death Data Form (2900). If this form reports a subsequent stem cell infusion, report the date of contact as the day before the preparative regimen begins for the subsequent HSCT. If no preparative regimen is given, report the date of contact as the day before the subsequent HSCT.</p> <p>Added significant explanatory text to question:</p> <p><i>In general, the date of contact should be reported as close to the 100 day, six month, or annual anniversary to transplant as possible.</i></p> <p>...</p> <p>Example 6. <i>The recipient had a subsequent transplant without a preparative regimen.</i></p> <p>See text for full detail.</p>

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1.5	01/14/2015	Add	<p>Added information box in question 407:</p> <p>NOTE: Skin Cancers <i>For most malignancies, one does not report recurrence, progression or transformation of the recipient's primary disease (disease for which the transplant was performed) or relapse of a prior malignancy in the "New Malignancy" section.</i></p> <p><i>However, in the case of a basal cell or squamous cell skin cancer, one needs to report each discreet episode. For example, a recipient had a basal cell skin cancer diagnosed on the neck four months post-HCT and six months later had another basal cell located on the nose. The lesion on the nose is not considered a metastasis from the neck, but a new discreet lesion.</i></p> <p><i>These discreet episodes should be reported in the "Other skin malignancy" questions on the 100 Day forms (revision 3, questions 435-437).</i></p>