General Instructions for Recipient Baseline and Follow-up Data Collection Forms

NATIONAL MARROW DONOR PROGRAM®
General Instructions

Transplant Centers are responsible for submitting recipient baseline and follow-up forms on each recipient who receives an unrelated donor stem cell transplant facilitated by the National Marrow Donor Program® (NMDP). The same set of forms are completed regardless if the stem cell product is marrow, peripheral blood stem cells (PBSC) or cord blood. The NMDP STAR™ database will assign a 100 series number for forms completed for marrow, 500 series number for forms completed for PBSC, and 600 series number for forms completed for cord blood. Following is a complete list of the recipient baseline and follow-up forms and the time points at which each form becomes due and past due.

<table>
<thead>
<tr>
<th>Form ID and Description</th>
<th>Date Form Becomes Due/Past Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form 120, 520, 620 v8 – Recipient Baseline and Transplant Data</td>
<td>Date of transplant&lt;br&gt;Past due 60 days after the transplant date</td>
</tr>
<tr>
<td>Form 120, 520, 620 – Disease-specific Inserts&lt;br&gt;Insert I v2 – Acute Myelogenous Leukemia&lt;br&gt;Insert II v2 – Acute Lymphoblastic Leukemia&lt;br&gt;Insert III v2 – Chronic Myelogenous Leukemia (CML)&lt;br&gt;Insert IV v2 – Other Leukemias&lt;br&gt;Insert V v2 – Myelodysplasia/Myeloproliferative Disorders&lt;br&gt;Insert VI v2 – Multiple Myeloma&lt;br&gt;Insert VII v2 – Other Malignancy&lt;br&gt;Insert VIII v2 – Aplastic Anemia&lt;br&gt;Insert IX v2 – Hodgkin and Non–Hodgkin Lymphoma&lt;br&gt;Insert X v1 – Severe Combined Immunodeficiency (SCID)&lt;br&gt;Insert XI v1 – Wiskott Aldrich Syndrome (WAS)&lt;br&gt;Insert XIII v1 – Leukodystrophies&lt;br&gt;Insert XIV v1 – mucopolysaccharidoses and Other Storage Diseases&lt;br&gt;Insert XV v1 – Chediak-Higashi Syndrome&lt;br&gt;Insert XVI v1 – Hemophagocytic Lymphohistiocytosis&lt;br&gt;Insert XVII v1 – X-Linked Lymphoproliferative Disease&lt;br&gt;Form 580 v2 – Transplant Center PBSC Product Analysis&lt;br&gt;Form 680 v1 – Cord Blood Unit Supplement</td>
<td>Date of transplant&lt;br&gt;Past due 60 days after the transplant date</td>
</tr>
<tr>
<td>Form ID and Description</td>
<td>Date Form Becomes Due/Past Due</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Form 130, 530, 630 v9 – 100-Day Follow-Up Visit of Recipient</td>
<td>100 day anniversary of transplant Past due 120 days after the 100 day anniversary</td>
</tr>
<tr>
<td>Form 130, 530, 630 / 140, 540, 640 Disease-specific Inserts I and II</td>
<td>• 100 day anniversary of transplant</td>
</tr>
<tr>
<td>Insert I v1 – Severe Combined Immunodeficiency (SCIDS)</td>
<td>• Six month anniversary of transplant</td>
</tr>
<tr>
<td>Insert II v1 – Wiscott Aldrich Syndrome (WAS)</td>
<td>• One year anniversary of transplant</td>
</tr>
<tr>
<td>Form 130, 530, 630 / 140, 540, 640 / 150, 550, 650 Disease Specific Insert III</td>
<td>• Two year anniversary of transplant</td>
</tr>
<tr>
<td>Insert III v1 – Post-Transplant Information for Hodgkin and Non-Hodgkin Lymphoma</td>
<td>Past due 120 days (100 day report) or 90 days after the transplant anniversary date</td>
</tr>
<tr>
<td>Form 130, 530, 630 Disease Specific Inserts V and VI</td>
<td></td>
</tr>
<tr>
<td>Insert V v1 – Leukodystrophies 100-Day Follow-Up Visit of Recipient</td>
<td></td>
</tr>
<tr>
<td>Insert VI v1 – Mucopolysaccharidoses and Other Storage Diseases 100-Day Follow-Up Visit of Recipient</td>
<td></td>
</tr>
<tr>
<td>Form 130, 530, 630 / 140, 540, 640 Disease Specific Inserts VIII, IX and X</td>
<td></td>
</tr>
<tr>
<td>Insert VIII v1 – Chediak-Higashi Syndrome Post-Transplant Follow-Up Form</td>
<td></td>
</tr>
<tr>
<td>Insert IX v1 – Hemophagocytic Lymphohistiocytosis Post-Transplant Follow-Up Form</td>
<td></td>
</tr>
<tr>
<td>Insert X v1 – X-Linked Lymphoproliferative Disease Post-Transplant Follow-Up Form</td>
<td></td>
</tr>
<tr>
<td>Form ID and Description</td>
<td>Date Form Becomes Due/Past Due</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------------</td>
</tr>
</tbody>
</table>
| Form 140, 540, 640 v6 – Six Month to Two Year Follow-Up Visit of Recipient | • Six month anniversary of transplant  
• One year anniversary of transplant  
• Two year anniversary of transplant  
*Past due 90 days after the transplant anniversary date* |
| Form 130, 530, 630 / 140, 540, 640 Disease-specific Inserts I and II  
  Insert I v1 – Severe Combined Immunodeficiency (SCIDS)  
  Insert II v1 – Wiscott Aldrich Syndrome (WAS)  
Form 130, 530, 630 / 140, 540, 640 / 150, 550, 650 Disease-specific Insert III  
  Insert III v1 – Post-Transplant Information for Hodgkin and Non-Hodgkin Lymphoma  
Form 140, 540, 640 / 150, 550, 650 Disease-specific Inserts V and VI  
  Insert V v1 – Leukodystrophies Annual Follow-Up Visit of Recipient  
  Insert VI v1 – Mucopolysaccharidoses and Other Storage Diseases Annual Follow-Up Visit of Recipient  
Form 130, 530, 630 / 140, 540, 640 Disease-specific Inserts VIII, IX and X  
  Insert VIII v1 – Chediak-Higashi Syndrome Post-Transplant Follow-Up Form  
  Insert IX v1 – Hemophagocytic Lymphohistiocytosis Post-Transplant Follow-Up Form  
  Insert X v1 – X-Linked Lymphoproliferative Disease Post-Transplant Follow-Up Form | Yearly anniversary of transplant  
*Past due 90 days after the transplant anniversary date* |
<table>
<thead>
<tr>
<th>Form ID and Description</th>
<th>Date Form Becomes Due/Past Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form 150, 550, 650 v3 – Yearly Follow-Up for Greater Than Two Years Post-Transplant</td>
<td>Starting year three, every transplant anniversary date &lt;br&gt; <em>Past due 45 days after the transplant anniversary date</em></td>
</tr>
<tr>
<td>Form 130, 530, 630 / 140, 540, 640 / 150, 550, 650 Disease-specific Insert III  &lt;br&gt; Insert III v1 – Post-Transplant Information for Hodgkin and Non-Hodgkin Lymphoma  &lt;br&gt; Form 140, 540, 640 / 150, 550, 650 Disease Specific Inserts V and VI  &lt;br&gt; Insert V v1 – Leukodystrophies Annual Follow-Up Visit of Recipient  &lt;br&gt; Insert VI v1 – Mucopolysaccharidoses and Other Storage Diseases Annual Follow-Up Visit of Recipient</td>
<td>Yearly anniversary of transplant &lt;br&gt; <em>Past due 45 days after the transplant anniversary date</em></td>
</tr>
<tr>
<td>Form 190, 590, 690 v5 – Recipient Death Information</td>
<td>At time of recipient’s death</td>
</tr>
</tbody>
</table>

**Forms Due Report**

Recipient baseline and follow-up forms are listed on the Transplant Center’s Forms Due Report. This report allows Transplant Centers to track which forms are currently due, or past due, for each recipient. The Forms Due Report is generated once a month on the first Saturday of the month. Transplant Centers will receive the Forms Due Report the following week in the weekly mailing from the NMDP. See Appendix A for a sample Forms Due Report, and a detailed explanation of how to read the report. The Forms Due Report can also be accessed via TransLink™. See Appendix B.

**Submitting Forms to the NMDP Registry**

A copy of all recipient baseline and follow-up forms must be mailed to the NMDP Registry at 3001 Broadway Street NE, Suite 500, Minneapolis, MN 55413. Retain the original form at the Transplant Center.
Error Correction Reports and Submitting Error Corrections to the NMDP Registry

Errors on the follow-up forms will appear on the Daily Error Report received via MCI mail. Any errors not resolved by month end will also appear on the Monthly Error Report. See Appendix C for a sample Daily Error Report and Monthly Error Report. Errors must be corrected by completing the Error Correction form corresponding to the page of the form containing the error. Also use the Error Correction form to correct data that did not generate an error report from the NMDP. Write “Transplant Center Initiated” across the top of the error correction page. See Appendix D for a sample error correction page and instructions on how to complete it. The Registry cannot accept error corrections or data updates made using any other method. Fax error corrections to the Registry at 612/627-5895.

How to Order Forms, Error Correction Pages and Registry Mailing Labels

Recipient baseline and follow-up forms and master copies of the error correction pages can be printed off of the NMDP Network website. Recipient baseline and follow-up forms, master copies of the error correction pages, and Registry mailing labels can also be ordered through the NMDP Materials Catalog. To obtain a copy of the NMDP Materials Catalog, call the NMDP Communications and Education Administrative Assistant at 612/627-5800.
General Guidelines for Completing Forms

1. Forms should be completed in only blue or black ink. Do not use a pencil to complete the forms.

2. Complete the “key fields” (recipient ID, today’s date, Transplant Center code, transplant date, product type, and, on the Form 140, 540, 640 and Form 150, 550, 650, the follow-up visit for which form is being completed) found in the upper right hand corner of the first page of every form. The form cannot be entered into the database until all the “key fields” are complete and correct.

3. Write the recipient identification number in the field labeled “NMDP Recipient ID” located at the top of each page of the form.

4. If an exact date is not known, but the month and year are known, report the day of the month as 15.

5. If a mistake is made when completing the forms, do not erase the error or use white-out. Instead, draw a line through the error, write in the correct answer, circle it and initial the correction.

6. Answer all primary questions that lead into a box.

7. Carefully follow all the arrows on the form and the “continue with” instructions.

8. If a question lists a series of responses with a “yes” or “no” check box for each response, check either “yes” or “no” for each response. Do not leave any responses blank.
How to Avoid Errors

When a form is entered into the NMDP database, the form goes through a series of validation checks to make sure the data entered are correct. If any data does not pass one of the validation checks, an error report will be generated. Transplant Centers can avoid generating most errors by reviewing a completed form for potential errors prior to submitting it to the NMDP. When reviewing the form, it is helpful to keep in mind the types of validation the form will go through when it is entered. Following are the types of validation:

1. **Mandatory field validation:** Certain fields on the forms must be completed for all patients (e.g., primary questions that lead into a box). Other fields must be completed depending on how a primary question is answered (e.g., “yes” to “developed acute GVHD” will make mandatory all acute GVHD questions). The computer will check to make sure all the mandatory fields are completed.

2. **Range validation:** The computer checks all lab values, drug doses, heights and weights against established upper and lower limits. See Appendix E for validation ranges listed by form and question number. To avoid generating range errors, follow the following procedure:
   a) After completing a form, check the responses against the established validation range.
   b) If the value falls outside the validation range, verify that the reported value is correct.
   c) If the value is correct, write in the margin of the form that the value has been verified. An error will not be generated.

3. **Consistency between forms:** The computer checks for consistency between data reported on the current form and related data reported on a previous form. For example, on the Forms 130, 530, 630 and 140, 540, 640, the disease for which the post-transplant disease status is reported is validated against the disease reported on the Form 120, 520, 620.

4. **Consistency within a form:** The computer also checks for consistency between related data reported on the same form. For example, all dates are validated against the “date of contact.”
Declaring Recipients Lost to Follow-Up

Since the NMDP cannot accurately assess outcome of unrelated stem cell donor transplants without survival status of recipients, lost to follow-up declaration will only be allowed on a visit-by-visit basis with the hope that the recipient will eventually be located. A recipient may be declared as lost to follow-up if the Transplant Center cannot obtain follow-up data from a local physician and if the Transplant Center does not have a current address or phone number for the recipient.

Use the following procedure to declare a recipient as lost to follow-up:

1. Request that the NMDP perform a search through Search America for a current address or phone number for the recipient. To request a search, fill out a Search America Search Request Form and fax it to the Research Department. An example of this form is in Appendix F. Copies of this form can be ordered through the NMDP Materials Catalog, item number 4192. If the search is successful, you will be provided with the current address and, in some cases, the phone number for the recipient. You can then pursue follow-up with the recipient.

2. If the Search America search does not provide any leads for reaching the recipient, you may declare a recipient lost to follow-up for a specific visit by filing a “Lost to Follow-Up Declaration” form. An example of this form is in Appendix G. Copies of this form can be ordered through the NMDP Materials Catalog, item 4191. This form verifies that the phone numbers and address on file at your Transplant Center are not current and that a search through Search America did not yield a current address or phone number for the recipient. In some instances, Search America may provide a phone number or address for the recipient that is different from the one on file at your Transplant Center but is still not current. Filing this form will result in removing the current follow-up form that is due for the recipient from the Forms Due Report. If you are still not able to locate the recipient at the time the next follow-up form comes due, you will be asked to follow this process again.
Reimbursement for Forms Completion

The NMDP reimburses Transplant Centers for all completed recipient baseline and follow-up forms. A form is not considered complete until it is error-free. Forms are reimbursed at the following rate:

<table>
<thead>
<tr>
<th>Form</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form 120, 520, 620 and inserts</td>
<td>$135</td>
</tr>
<tr>
<td>Form 130, 530, 630 and inserts</td>
<td>$110</td>
</tr>
<tr>
<td>Form 140, 540, 640 and inserts</td>
<td>$  85</td>
</tr>
<tr>
<td>Form 150, 550, 650 and inserts</td>
<td>$  27.50</td>
</tr>
<tr>
<td>Form 190, 590, 690</td>
<td>$  27.50</td>
</tr>
</tbody>
</table>

Continuous Process Improvement (CPI) Phase II

The NMDP has established criteria for submitting the recipient baseline and follow-up forms. To be compliant with CPI Phase II, Transplant Centers must submit at least 90% of the forms due within the following time periods:

<table>
<thead>
<tr>
<th>Form</th>
<th>Due Date</th>
<th>90% Submitted Within</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form 120, 520, 620 and disease-specific inserts, and product analysis forms</td>
<td>Transplant date</td>
<td>60 days</td>
</tr>
<tr>
<td>Form 130, 530, 630 and inserts</td>
<td>Day 100 post-transplant</td>
<td>120 days</td>
</tr>
<tr>
<td>Form 140, 540, 640 and inserts</td>
<td>6 month, 1 year, 2 year transplant anniversary</td>
<td>90 days</td>
</tr>
<tr>
<td>Form 150, 550, 650 and inserts</td>
<td>Starting year 3, annually on transplant anniversary</td>
<td>45 days</td>
</tr>
</tbody>
</table>

Transplant Centers receive CPI Phase II reports three times a year (January, May, September) listing the number of follow-up forms that were due in a given trimester, and the number and percentage of each that were submitted within the trimester. A form is not counted as submitted until all errors have been resolved. Transplant Centers not compliant with CPI Phase II standards will enter a due process procedure that could eventually lead to a Transplant Center being suspended from initiating new patient searches until the due forms are submitted. See Appendix H for the complete CPI Phase II document.
On-Site Data Audits of Recipient Baseline and Follow-Up Forms

As part of the NMDP’s data quality assurance programs, the NMDP conducts on-site data audits of the recipient baseline and follow-up data. All U.S. Transplant Centers that have performed at least ten transplants will be eligible for an on-site audit. Transplant Centers will be audited once every four years. A comprehensive summary of the on-site data audit plan is in Appendix I.

Helpful Phone and Fax Numbers/E-mail Addresses

See Appendix J for a list of NMDP staff who can answer questions regarding forms completion, error corrections, and CPI Phase II.
Instructions for Form 120, 520, 620 Recipient Baseline and Transplant Data Collection Forms

NATIONAL MARROW DONOR PROGRAM®
FORM 120, 520, 620
Recipient Baseline and Transplant Data

Form 120, 520, 620 is designed to obtain data on the recipient’s clinical condition just prior to conditioning for transplant, the anti-tumor and/or immunosuppressive conditioning regimen, the stem cell shipping conditions, stem cell manipulation method, and recipient reaction (if any) associated with the infusion of the stem cell product.

This form becomes due on the transplant date and is past due if not received within 60 days of the date of transplant. Depending on the primary disease for which the recipient is being transplanted, a disease-specific insert may also be due. Form 120, 520, 620 is not considered complete until any required inserts or product analysis forms have been completed. A Form 120, 520, 620 (with appropriate inserts or product analysis forms) is expected on every recipient transplanted with an NMDP donor.

Form Key Fields:

A. Unrelated Recipient NMDP ID:
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:
   Print the recipient’s last name using capital letters.

C. Recipient Local ID (optional):
   Enter your Transplant Center’s local ID for the recipient.

D. Donor NMDP ID:
   Enter the nine-digit NMDP Unrelated Donor ID.

E. Today’s Date:
   Enter the date on which you are completing this form.

F. TC Code:
   Enter your Transplant Center’s three-digit code.

G. Date of Transplant for which this form is being completed:
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

H. Product Type:
   □ Marrow  (Form 120)
   □ PBSC  (Form 520)
   □ Cord blood  (Form 620)
   Check the box that corresponds to the transplant product type.
Demographic Data

Question 1  Recipient name:
Enter the recipient’s full name, last name followed by first name.

Question 2a  State of residence of recipient:
Enter the state (U.S. recipients only) in which the recipient resides. If the recipient is a non-resident of the U.S. continue with question 2c.

Question 2b  Zip or postal code for place of recipient’s residence:
Enter the zip or postal code (U.S. recipients only).

Question 2c  Country if non-resident of USA:
Enter the recipient’s resident country.

Question 3  Does the recipient have a U.S. Social Security Number (or Canadian Social Insurance Number)?
If the recipient has a Social Security or Canadian Social Insurance Number, check “yes” and continue with question 4.
If the recipient does not have a Social Security Number, check “no” and continue with question 5.
If your center is not allowed to provide this number, check “Transplant Center is not allowed to report this information.”

Question 4  Social Security Number/Social Insurance Number:
Enter the recipient’s Social Security Number or, if Canadian, the recipient’s Social Insurance Number.

Question 5  Sex:
Indicate if the recipient is “male” or “female.”
Question 6  Race:

It is important to obtain detailed race information. If the information is not available in the chart, contact the attending physician to determine the race of the recipient. If the recipient’s parents are from two separate racial/ethnic groups, check both groups.

The racial/ethnic groups are categorized into six primary groups: “Caucasian/White,” “Black,” “Asian/Pacific Islander,” “Hispanic,” “Native American,” or “Other.” Under the recipient’s primary group or groups, indicate the recipient’s detailed race description. If the recipient is “Native American - Alaskan Native or Aleut,” or “Native American - American Indian,” indicate which tribal nation the recipient belongs to.

If the recipient does not fall into any of the specified categories, check “Other” and specify the race.

Question 7  Date of birth:

Enter the recipient’s date of birth.

Primary Disease

Question 8  What was the primary disease for which the transplant was performed?

Step One: Select the primary disease (or the broad disease grouping the primary disease is included in) for which the recipient is receiving the transplant, e.g., “AML” or “Inherited disorders of metabolism.”

Step Two: Follow the arrow into the box next to the primary disease or broad disease grouping, and check the detailed disease description, e.g., “M1, myeloblastic” or “Hurler syndrome (IH).”

Step Three: Complete the Form 120, 520, 620 disease-specific insert specified in the box.
Example:

Step One: Primary disease is AML.

Step Two: Disease classification is M2, myelocytic.

Step Three: Complete Form 120, 520, 620 - Insert I. Please refer to the disease-specific instructions to complete the inserts.

NOTE:

If a recipient with Fanconi Anemia has transformed to a leukemic or myelodysplastic phase, indicate that the recipient’s primary disease is Fanconi Anemia by checking Box 11 (Inherited abnormalities of erythrocyte differentiation or function) and Fanconi Anemia (Box 10.1). Thereafter, complete the insert appropriate for the recipient’s current clinical disorder: acute myelogenous leukemia (Insert I instead of Insert VIII), acute lymphoblastic leukemia (Insert II instead of Insert VIII), or myelodysplastic syndrome (Insert V instead of Insert VIII). If the recipient has not transformed to a leukemic or myelodysplastic phase, complete Insert VIII.

For recipients with MDS, report the most advanced stage the disease ever evolved to as the primary disease for which the transplant was performed. For example, if the recipient was diagnosed with refractory anemia with excess blasts, then progressed to AML, and after treatment was classified as refractory anemia, report AML as the primary disease.

For recipients with AML that transformed to AML from MDS or pre-leukemia, two inserts are required: Insert I for AML (disease for which recipient received the transplant) and Insert V for MDS (the antecedent hematologic disorder).
### Potential Source Documents to Verify Recipient Disease

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>AML</td>
<td>Bone Marrow Pathology Report, Flow Cytometry Report, Cell Marker Report, Chromosome Report, PCR Study for BCR-ABL</td>
</tr>
<tr>
<td>CML</td>
<td>Chromosome Report</td>
</tr>
<tr>
<td>MDS</td>
<td>Pathology Report</td>
</tr>
<tr>
<td>Other Leukemias</td>
<td>Pathology Report</td>
</tr>
<tr>
<td>Lymphomas</td>
<td>Pathology Report</td>
</tr>
<tr>
<td>Multiple Myeloma</td>
<td>Pathology Report</td>
</tr>
<tr>
<td>Other Malignancies</td>
<td>Pathology Report</td>
</tr>
<tr>
<td>Severe Aplastic Anemia</td>
<td>Pathology Report;</td>
</tr>
<tr>
<td>Immune Deficiency Disorders</td>
<td>Immune Studies</td>
</tr>
<tr>
<td>Platelet Disorders</td>
<td>Pathology Report</td>
</tr>
</tbody>
</table>

### Clinical Status of Recipient Prior to Conditioning

#### Question 9
What is the recipient’s blood type?

Indicate the recipient’s blood type.

#### Karnofsky & Lansky Scales

Two scales are used to report the functional status of the recipient prior to conditioning. The Karnofsky Scale is designed for recipients aged 16 years and older, and is not appropriate for children under the age of 16 years. The Lansky scale is designed for recipients less than 16 years old.

#### Question 10
What was the functional status of the recipient prior to conditioning?

Based on the age of the recipient, complete either the Karnofsky or Lansky Scale. Check the phrase that best indicates the recipient’s activity status.
Coexisting Disease

**Question 11** Were there clinically significant coexisting diseases at any time prior to conditioning?

Report any coexisting disease or organ impairment at any time prior to conditioning.

If “yes,” continue with question 12.

If “no,” continue with question 13.

**Question 12** Indicate the diagnoses:

For each diagnosis listed, check “yes” or “no.” Chromosomal abnormalities, impairments and/or disorders associated with the primary disease should not be reported in this section, e.g., Ph+ for CML/AML/MDS recipients. Also, do not report infections or chemical liver disease in this section.

**Question 13** Does the recipient have a history of smoking cigarettes?

If “yes,” continue with question 14.

If “no” or “unknown,” continue with question 16.

**Question 14** Has the recipient smoked cigarettes within the past year?

Indicate “yes,” “no,” or “unknown.”

**Question 15** Has the recipient smoked cigarettes prior to but not during the past year?

Indicate “yes,” “no,” or “unknown.”

Organ Function Prior to Conditioning

These questions are intended to determine the clinical status of the recipient prior to conditioning for stem cell transplantation. Report the most recent lab values obtained prior to the onset of conditioning for the transplant. Lab values obtained on the first day of conditioning may be reported as long as the blood was drawn before any radiation or chemotherapy was administered. For each lab value reported in this section, also report your institution’s upper limit of normal. The institution’s value for upper limit of normal can usually be found on the lab report next to the test result in the column titled “normal range” or “reference range.”
Question 16  AST (SGOT):
Enter the AST level in units per liter (U/L).

Question 17  Date tested:
Enter the date the AST test was performed.

Question 18  What is the upper limit of normal for your institution?
Enter your institution’s upper limit of normal for AST in units per liter (U/L).

Question 19  Serum creatinine:
Enter the total serum creatinine. Indicate if the total serum creatinine was measured in milligrams per deciliter (mg/dL) or micromoles per liter (µmol/L).

Question 20  Date tested:
Enter the date the serum creatinine test was performed.

Question 21  What is the upper limit of normal for your institution?
Enter your institution’s upper limit of normal for serum creatinine in milligrams per deciliter (mg/dL) or micromoles per liter (µmol/L).

Question 22  Total serum bilirubin:
Enter the total serum bilirubin. Indicate if the total serum bilirubin was measured in milligrams per deciliter (mg/dL) or micromoles per liter (µmol/L).

Question 23  Date tested:
Enter the date the total serum bilirubin test was performed.

Question 24  What is the upper limit of normal for your institution?
Enter your institution’s upper limit of normal for total serum bilirubin. Indicate if the total serum bilirubin was measured in milligrams per deciliter (mg/dL) or micromoles per liter (µmol/L).

Question 25  LDH:
Enter the LDH level in units per liter (U/L).
**Question 26**  
Date tested:  
Enter the date the LDH test was performed.

**Question 27**  
What is the upper limit of normal for your institution?  
Enter your institution’s upper limit of normal for LDH in units per liter (U/L).

**Question 28**  
Did the recipient have a history of clinically significant fungal infection (documented or suspected) at any time prior to conditioning for transplant?  
Fungal infections play a major role in the clinical outcome of recipients of unrelated donor stem cell transplants. Indicate if the recipient had a significant documented or suspected fungal infection at any time prior to conditioning for transplant. Include any fungal abscesses of the lungs, sinuses, liver or spleen. Do not include any superficial fungal infections of the oropharynx, e.g., thrush, oral candidiasis.  
If “yes,” continue with question 29.  
If “no,” continue with question 33.

**Question 29**  
Did the recipient have an active fungal infection within 2 weeks prior to conditioning?  
Indicate “yes” or “no.”

**Question 30**  
Select organism from list below. If more than one organism is documented or suspected, copy this page and complete a separate form for each organism.  
From the “Commonly Reported Fungal Organisms” chart on page 8 of the Form 120, 520, 620, select the code corresponding to the identified fungus. Enter the code in the boxes provided. If the specific organism is not listed on the chart, use code F15 “other fungus, specify above” and write the name of the organism in the space provided.

**Question 31**  
Date of onset:  
Enter the date of onset of the most significant fungal infection.
Question 32  Select site(s) from list. If more than one site was involved, list one site of infection in the first set of boxes, second site in the second set.

From the “Common Sites of Infection” chart on page 8 of the Form 120, 520, 620, select the code corresponding to the site of the infection. If more than one site was involved, enter the codes for both sites.

Testing for Serological Evidence of Prior Viral Exposure/Infection

Question 33 to Question 40  For each of the listed tests for viral exposure or infection, indicate if the test results were “positive,” “negative,” “inconclusive” or “not tested.” If state law prohibits you from reporting HIV test results, check “confidential.”

Pre-Transplant Conditioning

All recipients are transplanted under a specific protocol that defines the radiation and chemotherapy the recipient will receive for conditioning for the transplant. This protocol should be referred to when completing this section.

Question 41  Date pre-transplant conditioning began:

Enter the date the pre-transplant conditioning began. With the exception of “intrathecal drugs” and “additional radiation” start dates, all dates reported in the conditioning section must be equal to or after the date reported in question 41.

Question 42  Height at initiation of pre-transplant conditioning (nearest centimeter without shoes):

Enter the recipient’s height, rounded to the nearest centimeter (without shoes). Refer to Appendix K for a chart converting inches to centimeters.

Question 43  Weight at initiation of pre-transplant conditioning (nearest kilogram):

Enter the recipient’s weight, rounded to the nearest kilogram (without shoes). Refer to Appendix L for a chart converting pounds to kilograms.

Question 44  Was high-dose therapy (conditioning) given?

If “yes,” continue with question 45.

If “no,” continue with question 46.
**Question 45**  Indicate the protocol requirements for conditioning agents to be given to the recipient:

Indicate whether the protocol requires the conditioning agents to be given to the recipient are to be given as “all conditioning agents given as outpatient,” “some, but not all, conditioning agents given as inpatient,” or “all agents given as inpatient.”

**Radiation**

**Question 46**  Was irradiation performed as part of the pre-transplant preparative regimen, or given within 14 days of preparative regimen?

If “yes,” continue with question 47.

If “no,” continue with question 66.

**Question 47**  What was the radiation field?

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

**Total Dose**

**Questions 48**  Total dose:

| 54 | If the radiation was delivered in a single dose, the amount of radiation delivered in the single dose constitutes the total dose. If the radiation was fractionated (several treatments), then the total dose is the sum of all the doses given per fraction. |
| 60 | Enter the total dose of radiation in centigrays (cGy). |

**Starting Date**

**Questions 49**  Starting date:

| 55 | Enter the date the single dose or first fraction of radiation was administered. |
| 61 |
Radiation Fractionated

Questions 50, 56, 62

Was radiation fractionated?

Radiation is either delivered as a single dose or in several treatments (fractions). If the radiation was fractionated, check “yes.” If the radiation was given as a single dose, check “no” and continue with question 66.

Dose Per Fraction

Questions 51, 57, 63

Dose per fraction:

Enter the dose per fraction in centigrays (cGy).

Number of Days

Questions 52, 58, 64

Number of days:

Enter the total number of days it took to complete the radiation therapy including the rest days between days when therapy was administered. The number of days radiation was administered can be greater than the number of fractions.

NOTE:
Example for Counting Radiation Days:
Recipient receives radiation on Day -7 and Day -5. Three is the number of inclusive days radiation is given.

<table>
<thead>
<tr>
<th></th>
<th>Day -7</th>
<th>Day -6</th>
<th>Day -5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 fractions</td>
<td>None</td>
<td>3 fractions</td>
</tr>
<tr>
<td></td>
<td>200 cGy</td>
<td>None</td>
<td>200 cGy</td>
</tr>
</tbody>
</table>
## Radiation Fractionated

<table>
<thead>
<tr>
<th>Questions 53</th>
<th>Total number of fractions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>59</td>
<td>Enter the total number of fractions (treatments) of radiation that were administered. The recipient may receive more than one fraction per day (hyperfractionation).</td>
</tr>
<tr>
<td>65</td>
<td>NOTE: Number of fractions x dose per fraction = total dose</td>
</tr>
<tr>
<td></td>
<td>The number of fractions multiplied by the dose per fraction will equal the total dose reported in questions 48, 54, or 60.</td>
</tr>
</tbody>
</table>

## Additional Radiation

Report in this section any sites that received a “radiation boost.” Boosts are often given to smaller sites that may have residual malignant cells. Include any radiation boosts that were administered within 14 days prior to the conditioning start date.

**Question 66**  
Was additional radiation given to other sites within 14 days prior to start of pretransplant conditioning?

If “yes,” continue with question 67.  
If “no,” continue with question 79.

**Question 67**  
For each site listed, check “yes” or “no” to indicate if the recipient received radiation to that site. Do not leave any responses blank. For each site that received additional radiation, enter the total dose in centigrays (cGy).

**Question 78**  
Date radiation started:  
Enter the date the first dose of radiation was administered.

**Question 79**  
Was the recipient transplanted on a protocol with a conditioning regimen intended to be non-myeloablative?  
Answer “yes” or “no” and continue with question 80.
Pretransplant Conditioning Drugs

In this section report only drugs that are listed as part of the conditioning protocol. Do not include drugs that were administered to offset the side effects of the chemotherapy, e.g., corticosteroids for nausea, MESNA for hemorrhagic cystitis. Also in this section report any intrathecal drugs the recipient received for prophylaxis or treatment of CNS disease within 14 days prior to the start date of conditioning. Drugs listed in this section are generic drug names. See Appendix M for a list of trade names under which generic drugs are manufactured.

**Question 80** Were drugs given for pretransplant conditioning?

If the recipient did not receive drugs as part of the conditioning protocol, check “no” and continue with question 83.

If the recipient received immunosuppressive drugs or anti-neoplastic drugs as part of the conditioning protocol, check “yes” and continue with the list of drugs. Indicate which drugs the recipient received as part of the conditioning regimen. Check “yes” or “no” for each drug listed. Do not leave any responses blank.

**NOTE:**

Drug doses are calculated either by recipient weight or recipient body surface area (BSA) in m² (see Appendix Q). The conditioning protocol will specify “x mg/kg” or “x mg/m²” and the total number of doses to be administered.

Check the physician orders in the medical record chart to determine the drug dose and total number of doses that were ordered. Then verify that the drug was administered in the medication administration record.

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.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Daily Dose</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARA-C</td>
<td>5.2 gm</td>
<td>twice daily x 6 days (12 doses total)</td>
</tr>
<tr>
<td>Total dose: 5.2 gm x 12 doses = 62.4 gm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>62.4 gm x 1000 = 62,400 mg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Enter the date the first dose of the drug was administered.

**NOTE:**
This date must be on or after the date entered in question 41, “Date pre-transplant conditioning began.” The only exceptions are the start dates entered for intrathecal drugs (responses m or n). Start dates for intrathecal drugs may be within 14 days prior to the conditioning start date.

**Question 81** Radionuclide-tagged monoclonal antibody, specify:

Indicate “yes” or “no.” If “yes,” specify the antibody given.

**Question 82** Other monoclonal antibody, specify:

Indicate “yes” or “no.” If “yes,” specify the antibody given.

**Transplant Maneuver**

**NOTE:**
Questions 83 through 97 are for marrow only. For peripheral blood stem cells, continue with question 98 and, in addition, complete Form 580 – Filgrastim Mobilized PBSC Protocol – Transplant Center PBSC Product Analysis. For cord blood, continue with question 98 and, in addition, complete Form 680 – Cord Blood Unit Supplement.

**Question 83** Date of receipt of marrow at your facility:

Enter the date the marrow was received at your facility.

**Question 84** Time (24-hour clock) at receipt of marrow:

Using the 24 hour clock, enter the time the marrow was received at your facility. Indicate if the recorded time was “standard” or “daylight savings” time. See Appendix N for a table converting 12-hour clock times to 24-hour clock times.
Question 85  Storage temperature during transport:

Indicate if the marrow was “Refrigerated: 1º-8º C” or at “Room temperature” during transport. If the marrow was transported on wet ice or ice packs, check “Refrigerated at 1–8º C.”

Question 86  Nucleated cell count of the marrow before processing (uncorrected cell count):

Enter the uncorrected nucleated cell count of the marrow prior to processing, or prior to infusion if no processing was performed. An uncorrected cell count does not have the peripheral blood white cell count subtracted from it.

**NOTE:**

The cell count derived at the Collection Center should not be entered for this question. Repeat the cell count immediately after receipt of the marrow at your facility.

**NOTE:**

**Tips for Reporting Nucleated Cell Counts**

Report as a cell concentration (cells/volume). Example: 35 x 10⁶ cells/mL

Do not report as a cell dose (cells/recipient weight). Example: 2.5 x 10⁸ cells/kg

Do not report as a total dose (cells). Example: 17.5 x 10⁹ cells

**Equivalent units for Nucleated Cell Concentrations:**

\[ n \times 10^9/L = n \times 10^6/mL = \frac{n \text{ cells}}{\text{mm}^3} = n \text{ cells} \times 10^3/\text{mm}^3 \]

**Example:**

Nucleated cells = \(4.6 \times 10^9/L = 4.6 \times 10^6/mL = \frac{4600 \text{ cells}}{\text{mm}^3} = 4.6 \times 10^3/\text{mm}^3\)

Question 87  Total volume of marrow before processing:

Enter the total volume of marrow in milliliters. If the volume was not measured at your Transplant Center, this value can be derived from the Collection Center information provided on Form 60. The total volume of marrow indicated should reflect the full volume received by your Transplant Center before manipulation, cryopreservation or withdrawal of marrow for research purposes. The total volume will include any media added to the marrow at the collection site.
The total volume of marrow can also be calculated from the weight of the marrow by using the following calculation:

<table>
<thead>
<tr>
<th>NOTE: Calculating Total Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight of marrow in grams*</td>
</tr>
<tr>
<td>1.06 (Density)</td>
</tr>
</tbody>
</table>

**Example:**

Weight of marrow: \(\frac{1050 \text{ grams}}{1.06}\) = 951 mL

*Weight of marrow in bag minus weight of empty bag.

### Marrow Manipulation

**Question 88**  
Was the marrow manipulated at your facility prior to transplant?

If “yes,” continue with question 89.

If “no,” continue with question 92.

**Question 89**  
Specify the reason the marrow was manipulated:

Check “volume reduction only” if the only reason the marrow was manipulated was to reduce the volume of the marrow. Volume reduction is typically performed for small pediatric recipients. Do not check “volume reduction only” if the marrow was manipulated for a minor (plasma depleted) or major ABO incompatibility, or if it was T-cell depleted.

Check “plasma depleted only” if the marrow was plasma depleted because of a minor ABO incompatibility between the donor and recipient. Do not check “plasma depleted only” if the marrow was plasma depleted during the removal of red cells for a major ABO incompatibility or T-cell depletion.

Check “ABO incompatibility only” if red cells were depleted from the marrow because of a major ABO incompatibility between the donor and recipient. Do not check “ABO incompatibility only” if a major ABO incompatibility existed between the donor and recipient, but the marrow was also T-cell depleted.

Check “GVHD prophylaxis” if the marrow was T-cell depleted, and continue with question 90.
Question 90 Specify method used:
Indicate the method used to deplete the T-cells from the marrow. If “antibody + complement,” “antibody + toxin,” “antibody affinity column,” or “antibody coated plates,” continue with question 91.

Question 91 Specify antibody:
Check “yes” or “no” for each antibody listed. If antibodies were not used, check “no” for each antibody listed, and also check “no antibodies used.”

Question 92 Time (24-hour clock) at start of infusion:
Using the 24-hour clock, enter the time the infusion was started. Indicate if the recorded time was “standard” or “daylight savings time.” See Appendix N for a table converting 12-hour clock times to 24-hour clock times.

Question 93 Total volume of marrow infused on the day of transplant:
Enter the total volume of marrow in milliliters (mL).

Question 94 Cell count of infused marrow (uncorrected cell count):
Enter the uncorrected cell count (concentration) of the infused marrow. See Note: “Tips for Reporting Nucleated Cell Counts” associated with the instructions for question 86 in this manual. An uncorrected cell count does not have the peripheral blood white cell count subtracted out. This count will be different from the cell count entered in question 86 if the marrow was manipulated prior to infusion.

Question 95 Was a fraction of the collected marrow cryopreserved for back-up infusion?
If only a small amount (< 5 mL) of marrow was cryopreserved for research purposes or quality control studies, answer “no.”
If “yes,” continue with question 96.
If “no,” continue with question 98.

Question 96 Total volume of cryopreserved marrow:
Enter the total volume of cryopreserved marrow in milliliters (mL).
Question 97  Nucleated cell count of cryopreserved marrow:

Enter the total nucleated cell count (concentration).

See Note: “Tips for Reporting Nucleated Cell Counts” associated with the instructions for question 86 in this manual.

NOTE:
If marrow or any donor blood samples are being used for research purposes, the protocol must first be reviewed and approved by the NMDP Institutional Review Board.

Questions 98–103 must be completed for all product types: marrow, peripheral blood stem cells, and cord blood.

Question 98  Was this the first transplant for this recipient?

If “yes,” continue with question 104.

If “no,” continue with question 99.

Question 99  Specify the number of prior transplants:

Record the total number of previous transplants. Include transplants from all stem cell sources.

Question 100  What was (were) the prior stem cell source(s):

Indicate the source of stem cells for all previous transplants. Xenogeneic refers to stem cells that are obtained from a species different from that of the recipient. Syngeneic refers to stem cells that are obtained from an identical twin sibling.

Question 101  Date of the last transplant (transplant just before current transplant):

Enter the date of the transplant that was just prior to the current transplant.

Question 102  Reason for current transplant:

Indicate the reason for the current transplant. If the current transplant was performed due to a recurrent malignancy, continue with question 103.
**Question 103**  Date of relapse:

Enter the date of relapse for the recurrent malignancy.

### Socioeconomic Information

**Question 104**  Is the recipient an adult (18 years of age or older) or emancipated minor?

If “yes,” continue with question 105.

If “no,” continue with question 108.

**Question 105**  Specify recipient’s marital status:

Check the recipient’s marital status as of the date of contact.

**Question 106**  Specify recipient’s highest completed educational level:

Check the recipient’s highest completed educational level as of the date of contact.

**Question 107**  Specify the category which best describes the recipient’s occupation:

Check the recipient’s occupation category as of the date of contact. If the recipient is not currently employed, check the box that best describes his/her last job.

**Question 108**  Specify recipient’s type of health insurance (check all that apply):

Check the recipient’s source of health insurance as of the date of contact. If the recipient carries more than one source, check all that apply.

### Confidential Socioeconomic Information

Questions 109 and 110 must be completed for recipients who are legal residents of the United States. If the recipient is not a legal resident of the U.S., skip questions 109 and 110 and continue with the signature lines at question 111.
**Question 109** Specify type of fee reimbursement:

Check the type of fee reimbursement granted by the recipient’s health insurance.

**Question 110** Specify recipient’s combined household gross annual income:

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

**Signature** The person completing the form must sign the form, print his/her name, and provide a phone number, fax number, and e-mail address where he/she can be reached.
Instructions for Form 120, 520, 620 – Insert I
Acute Myelogenous Leukemia

NATIONAL MARROW DONOR PROGRAM®

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Form 120, 520, 620 – Insert I
Acute Myelogenous Leukemia (AML)

This form is designed to obtain data on the recipient’s hematologic findings and cytogenetic findings at the time of diagnosis, on the course of the disease prior to transplant, and on the status of the disease just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520, 620 question 8 is AML. Both Insert I and Insert V – Myelodysplasia/Myeloproliferative Disorders must be completed if the recipient had a Myelodysplastic/Myeloproliferative Syndrome that transformed to AML prior to transplant. Form 120, 520, 620 is not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

Form Key Fields:

All data reported in the key field section must be identical to the data reported in the key field section for the corresponding Form 120, 520, 620.

A. Unrelated Recipient ID:  
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:  
   Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional)  
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:  
   Enter the date on which you are completing this form.

E. TC Code:  
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:  
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type:  
   Check the box that corresponds to the transplant product type.
   - Marrow (Form 120)
   - PBSC (Form 520)
   - Cord blood (Form 620)
Question 1  What was the date of diagnosis of Acute Myelogenous Leukemia?

Enter the date the recipient was diagnosed with AML. The date of diagnosis will usually be the date the stem cells were obtained for examination. Do not enter the date symptoms first appeared.

Question 2  Was this a secondary (therapy-linked) leukemia?

Indicate if the AML is related to therapy the recipient received for a prior disease. This will usually be radiation or chemotherapy. Do not answer this question “yes” if the recipient developed AML after an environmental exposure, e.g., exposure to benzene.

If “yes,” continue with question 3.

If “no,” continue with question 6.

Question 3  Cite prior disease (malignant or nonmalignant):

Indicate if the prior disease was “Hodgkin lymphoma,” “Non-Hodgkin lymphoma” or “Other.” If “Other,” specify the disease.

Question 4  What was the date of diagnosis of prior disease?

Enter the date the prior disease was diagnosed. This date must be prior to the AML diagnosis date entered in question 1.

Question 5  Treatment for prior disease included:

Check “yes” or “no” for each treatment listed. If treatment was “Other,” specify the type of treatment given. Do not leave any responses blank.

NOTE:

Include all drugs administered in the chemotherapy section. Do not specify individual drugs in question 5.
Question 6  Did the recipient have a documented antecedent hematologic disorder (preleukemia or myelodysplastic syndrome)?

NOTE:
If the response to question 6 is “yes,” complete Insert V – Myelodysplasia/Myeloproliferative Disorders in addition to Insert I. Insert V provides more detailed information on the preleukemic or myelodysplastic syndrome prior to the recipient’s developing AML.

If “yes,” continue with question 7.
If “no,” continue with question 11.

Question 7  What was the date of diagnosis of antecedent hematologic disorder?
Enter the date the antecedent hematologic disorder was diagnosed. This date must be prior to the AML diagnosis date entered in question 1.

Question 8  What was the classification of hematologic disorder at diagnosis?
Indicate the classification of the hematologic disorder at diagnosis. If the disorder was “Other myelodysplasia or myeloproliferative disorder,” specify the condition in the space provided.

Question 9  Did recipient have a cytogenetic abnormality at any time during the course of the disease?
If “yes,” continue with question 10.
If “no” or “unknown” continue with question 11.

Question 10  What was (were) the cytogenetic abnormality(ies)?
See Appendix O for a list of cytogenetic abbreviations/terms and their definitions, and an explanation of how to interpret a cytogenetic report.
Check “yes” or “no” for each cytogenetic abnormality listed. If the abnormality was “Other,” specify the cytogenetic abnormality. Do not leave any responses blank.

Question 11  Did recipient have a predisposing condition prior to diagnosis of leukemia?
If “yes,” continue with question 12.
If “no,” continue with question 13.
Question 12  Please specify:

Indicate the condition the recipient had prior to diagnosis of leukemia. If the condition was “Other,” specify the condition.

**NOTE:**
If the response to question 12 is Fanconi Anemia, then Fanconi Anemia must be the primary disease listed on the Form 120, 520, 620 question 8.

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**Hematologic Findings at Diagnosis of Acute Myelogenous Leukemia**

**Question 13**  WBC:

Indicate if the white blood cell (WBC) count at the time the AML was diagnosed is known.

If “known,” enter the WBC in 10^9/L.

**Question 14**  Blasts in blood:

Indicate if the percent of peripheral blood blasts at the time the AML was diagnosed is known.

If “known,” enter the percent of blasts found in the peripheral blood.

**Question 15**  Blasts in bone marrow:

Indicate if the percent of bone marrow blasts at the time the AML was diagnosed is known.

If “known,” enter the percent of blasts found in the bone marrow.

**NOTE:**
If the bone marrow pathology report states a range for blasts, enter the average of the range rounded to the nearest whole number; e.g., if 0% - 5%, enter 3%. If the report states > 90% blasts, packed marrow, or sheets of blasts, enter 91% on the form. If the report states < 5% blasts, enter 4% on the form.
Question 16  Was extramedullary disease present at diagnosis?

NOTE:
Extramedullary refers to disease found in organs or tissue outside the bone marrow or blood stream (e.g., central nervous system, testis, skin, soft tissue, etc.)

If “yes,” continue with question 17.
If “no,” continue with question 18.

Question 17  Please specify sites:
Indicate “yes” or “no” for both sites listed. If site is “Other,” specify the site. Do not leave any responses blank.

Question 18  Were cytogenetics tested at diagnosis, prior to start of treatment?

See Appendix O for a list of cytogenetic abbreviations/terms and their definitions, and an explanation of how to interpret a cytogenetic report.

Indicate if chromosome studies (cytogenetics) were obtained at the time the recipient was diagnosed with AML, but prior to the start of any treatment for the disease. If cytogenetic studies were obtained but there were not adequate cells (metaphases) to determine the results, check “yes, but no evaluable metaphases.”

If “yes,” continue with question 19.
If “yes, but no evaluable metaphases,” “no” or “unknown,” continue with question 22.

Question 19  Number of metaphases examined:

NOTE:
Metaphase refers to the cell stage at which chromosomes are examined. The number of cells examined is equivalent to the number of metaphases examined.

Enter the number of metaphases.
Question 20  Was karyotype normal?

NOTE:
Karyotype refers to the designation of the results of the chromosome analysis. The karyotype may be defined at a cell level, a cell line or clone level, or at the level of the entire individual.

If “yes,” continue with question 22.
If “no,” continue with question 21.

Question 21  Specify the abnormality(ies):
Check “yes” or “no” for each abnormality listed. If karyotype abnormality was “Other,” specify the abnormality. Do not leave any responses blank.

Question 22  Was a first complete remission achieved?

NOTE:
Remission is defined as a marrow with normal cellularity, and less than or equal to 5% blasts. Recipients with persistent cytogenetic abnormality or extramedullary disease should be considered to have persistent disease or to be in relapse.

If “yes,” continue with question 23.
If “no,” continue with question 29.

Question 23  Date:
Enter the date the first remission was achieved. This date must be later than the date of AML diagnosis in question 1.

Question 24  Did relapse occur pretransplant?
If “yes,” continue with question 25.
If “no,” continue with question 29.

Question 25  Date of first relapse:
Enter the date of the first relapse. This date must be later than the date of first complete remission in question 23.
Question 26  Did the first relapse occur on chemotherapy?
Indicate if the recipient relapsed while receiving chemotherapy.

Question 27  Was additional therapy given after the first relapse?
If “yes,” continue with question 28.
If “no,” continue with question 29.

Question 28  Indicate what therapy was given:
Check “yes” or “no” for each listed therapy. If therapy was “Other,” specify the type of therapy given. Do not leave any responses blank.

Question 29  What was the status of primary disease immediately prior to conditioning of recipient for transplant?

NOTE:
Report the status of the AML, do not report the status of the underlying condition (e.g., Fanconi Anemia).

Indicate the status of the primary disease.
If the recipient failed to achieve a first complete remission, check “Primary Induction Failure” and continue with question 31.
If “1st relapse” or “≥ 2nd relapse,” indicate if the relapse was “medullary” (in the bone marrow), “extramedullary” (in organs or tissue outside the bone marrow) or “both.”

Question 30  What was the initial date this disease status was achieved?
Enter the date the disease status was achieved.

NOTE:
If the recipient is in first complete remission at the time of transplant, then the date entered in question 30 must be the same date entered in question 23, “Date of first complete remission.”
If the recipient is in first relapse at the time of transplant, then the date entered in question 30 must be the same date entered in question 25, “Date of first relapse.”
Hematologic Findings Just Prior to Conditioning

NOTE:
For questions 31 – 34 report the most recent lab values obtained prior to the onset of conditioning for the transplant. Lab values obtained on the first day of conditioning may be reported as long as the sample was drawn before any radiation or chemotherapy was given.

Question 31  WBC:
Enter the white blood cell (WBC) count in $10^9/L$.

Question 32  Blasts in blood:

NOTE:
If a differential was performed and there were no blasts present in the peripheral blood, the lab report may not display a column for blasts. In this case, it can be assumed that no blasts were present and “0” can be entered on the form.

Enter the percent of blasts in the blood.

Question 33  Blasts in bone marrow:
Enter the percent of blasts in bone marrow.

NOTE:
If the bone marrow pathology report states a range for blasts, enter the average of the range rounded to the nearest whole number; e.g., 0%–5%, enter 3%. If the report states > 90% blasts, packed marrow, or sheets of blasts, enter 91% on the form. If the report states < 5% blasts, enter 4% on the form.

Question 34  Date of bone marrow examination:
Enter the date the bone marrow was examined.
Instructions
for
Form 120, 520, 620 – Insert II
Acute Lymphoblastic Leukemia

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert II
Acute Lymphoblastic Leukemia (ALL)

This form is designed to obtain data on the recipient’s hematologic and cytogenetic findings at the time of diagnosis, on the course of the disease prior to transplant, and on the status of the disease just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease reported on the Form 120, 520, 620 question 8 is ALL. Insert II must also be completed for recipients with inherited abnormalities of erythrocyte differentiation, e.g., Fanconi Anemia, who have developed ALL. Form 120, 520, 620 is not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

Form Key Fields:
All data reported in the key field section must be identical to the data reported in the key field section for the corresponding Form 120, 520, 620.

A. Unrelated Recipient ID: __________ - __________ - ______
Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: ________________________________
Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional) ____________
Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: ______ ______ ______
Month Day Year
Enter the date on which you are completing this form.

E. TC Code: __________
Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: ______ ______ ______
Month Day Year
Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type: □ Marrow (Form 120) □ PBSC (Form 520) □ Cord blood (Form 620)
Check the box that corresponds to the transplant product type.
Question 1  What was the date of diagnosis of Acute Lymphoblastic Leukemia?
Enter the date the recipient was diagnosed with ALL. The date of diagnosis will usually be the date the bone marrow was obtained for examination. Do not enter the date symptoms first appeared.

Question 2  Did recipient have predisposing condition prior to diagnosis of leukemia?
Indicate if there was an underlying condition that predisposed the recipient to ALL.
If “yes,” continue with question 3.
If “no,” continue with question 4.

Question 3  Please specify:
Indicate the predisposing condition prior to diagnosis of leukemia. If condition was “Other,” specify the condition.

NOTE:
If the response to question 3 is Fanconi’s Anemia, then Fanconi’s Anemia must be the primary disease indicated on the Form 120, 520, 620 question 8.

Hematologic Findings at Diagnosis of Acute Lymphoblastic Leukemia

Question 4  WBC:
Indicate if the white blood cell (WBC) count at the time the ALL was diagnosed is known.
If “known,” enter the WBC in $10^9$/L.

Question 5  Blasts in blood:
Indicate if the percent of peripheral blood blasts at the time the ALL was diagnosed is known.
If “known,” enter the percent of blasts found in the peripheral blood.
Question 6  Blasts in bone marrow:

NOTE:
If the bone marrow pathology report states a range for blasts, enter the average of the range rounded to the nearest whole number (e.g., if 0%–5%, enter 3%). If the report states > 90% blasts, packed marrow, or sheets of blasts, enter 91% on the form. If the report states < 5% blasts, enter 4%.

Indicate if the percent of bone marrow blasts at the time the ALL was diagnosed is known.

If “known,” enter the percent blasts found in the bone marrow.

Question 7  Was extramedullary disease present at diagnosis?

NOTE:
Extramedullary refers to disease found in organs or tissue outside the bone marrow or blood stream, e.g., central nervous system, testis, skin, soft tissues, etc.

If “yes,” continue with question 8.

If “no,” continue with question 9.

Question 8  Please specify:

Indicate “yes” or “no” for each site listed. If site is “Other,” specify the site. Do not leave any responses blank.

Question 9  Were cytogenetics tested at diagnosis, prior to start of treatment?

Indicate if chromosome studies (cytogenetics) were obtained at the time the recipient was diagnosed with ALL, but prior to the start of any treatment for the disease. If cytogenetic studies were obtained but there were not adequate cells (metaphases) to determine the results, check “yes, but no evaluable metaphases.”

If “yes,” continue with question 10.

If “yes, but no evaluable metaphases,” “no,” or “unknown,” continue with question 13.
Question 10  Number of metaphases examined:

NOTE:

Metaphase refers to the cell stage at which chromosomes are examined. The number of cells examined is equivalent to the number of metaphases examined.

Enter the number of metaphases.

Question 11  Was karyotype normal?

NOTE:

Karyotype refers to the designation of the results of the chromosome analysis. The karyotype may be defined at a cell level, a cell line or clone level, or at the level of the entire individual.

If “yes,” continue with question 13.
If “no,” continue with question 12.

Question 12  Specify the abnormality(ies):

See Appendix O for a list of cytogenetic abbreviations/terms and their definitions, and an explanation of how to interpret a cytogenetic report.

Check “yes” or “no” for each abnormality listed. If karyotype abnormality was “Other,” specify the abnormality. Do not leave any responses blank.

Question 13  Was a first complete remission achieved?

NOTE:

Remission is defined as a marrow with normal cellularity, and less than or equal to 5% blasts. Recipients with persistent cytogenetic abnormality or extramedullary disease should be considered to have persistent disease or to be in relapse.

If “yes,” continue with question 14.
If “no,” continue with question 20.

Question 14  Date:

Enter the date the first remission was achieved. This date must be later than the date of ALL diagnosis in question 1.
Question 15  Did relapse (marrow or extramedullary) occur pretransplant?
If “yes,” continue with question 16.
If “no,” continue with question 20.

Question 16  Date of first relapse:
Enter the date of the first relapse. This date must be later than the date of first complete remission in question 14.

Question 17  Did the first relapse occur on chemotherapy?
Indicate if the recipient relapsed while receiving chemotherapy.

Question 18  Was additional therapy given after the first relapse?
If “yes,” continue with question 19.
If “no,” continue with question 20.

Question 19  Indicate what therapy was given:
Check “yes” or “no” for each listed therapy. If therapy was “Other,” specify the type of therapy given. Do not leave any responses blank.

Question 20  What was the status of primary disease immediately prior to conditioning of recipient for transplant?

**NOTE:**

Report the status of the ALL; do not report the status of the underlying condition, e.g., Fanconi Anemia.

Indicate the status of the primary disease.

If the recipient failed to achieve a first complete remission, check “Primary Induction Failure” and continue with question 22.

If “1st relapse” or “≥ 2nd relapse,” indicate if the relapse was “medullary” (in the bone marrow), “extramedullary” (in organs or tissue outside the bone marrow) or “both.”
Question 21  What was the initial date of this disease status?
Enter the date the disease status was achieved.

NOTE:
If the recipient is in first complete remission at the time of transplant, then the date entered in question 21 must be the same date entered in question 14, “Date of first complete remission.”

If the recipient is in first relapse at the time of transplant, then the date entered in question 21 must be the same date entered in question 16, “Date of first relapse.”

Hematologic Findings Just Prior to Conditioning

NOTE:
For questions 22–25 report the most recent lab values obtained prior to the onset of conditioning for the transplant. Lab values obtained on the first day of conditioning may be reported as long as the sample was drawn before any radiation or chemotherapy was given.

Question 22  WBC:
Enter the white blood cell (WBC) count in $10^9/L$.

Question 23  Blasts in blood:

NOTE:
If a differential was performed and there were no blasts present in the peripheral blood, the lab report may not display a column for blasts. In this case, it can be assumed that no blasts were present and “0” can be entered on the form.

Enter the percent of blasts in the blood.
Question 24  Blasts in bone marrow:

**NOTE:**

If the bone marrow pathology report states a range for blasts, enter the average of the range rounded to the nearest whole number (e.g. if 0%–5%, enter 3%). If the report states > 90% blasts, packed marrow, or sheets of blasts, enter 91% on the form. If the report states < 5% blasts, enter 4%.

Enter the percent of blasts in bone marrow.

Question 25  Date of bone marrow examination:

Enter the date the bone marrow was examined.
Instructions
for
Form 120, 520, 620 – Insert III
Chronic Myelogenous Leukemia

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert III
Chronic Myelogenous Leukemia (CML)

This form is designed to obtain data on the recipient’s hematologic and cytogenetic findings at the time of diagnosis, on the course of disease prior to transplant, and the status of the disease just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520, 620 question 8 is CML. Form 120, 520, 620 is not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

Form Key Fields:

A. Unrelated Recipient ID: [ blank ] - [ blank ] - [ blank ]
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: [ blank ]
   Print the recipient's last name in all capital letters.

C. Unrelated Recipient Local ID: (optional) [ blank ]
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: [ blank ] [ blank ] [ blank ]
   Enter the date on which you are completing this form.

E. TC Code: [ blank ]
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: [ blank ] [ blank ] [ blank ]
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type: ☐ Marrow (Form 120) ☐ PBSC (Form 520) ☐ Cord blood (Form 620)
   Check the box that corresponds to the transplant product type.
Question 1  What was the date of diagnosis of Chronic Myelogenous Leukemia?

Enter the date the recipient was diagnosed with CML. The date of diagnosis will usually be the date the bone marrow was obtained for examination. Do not enter the date symptoms first appeared.

Hematologic Findings at Diagnosis of Chronic Myelogenous Leukemia

Question 2  Hemoglobin (only recipients untransfused within four weeks):

Leave this question blank if the recipient received either packed red blood cells or whole blood within four weeks prior to being diagnosed.

Enter the hemoglobin in grams per deciliter (g/dL). If the hemoglobin at diagnosis is not known, check “unknown.”

Question 3  Hematocrit (only recipients untransfused within four weeks):

Leave this question blank if the recipient received either packed red blood cells or whole blood within four weeks prior to being diagnosed.

Enter the percent of hematocrit. If the hematocrit at diagnosis is not known, check “unknown.”

Question 4  Platelets (only recipients untransfused within four weeks):

Leave this question blank if the recipient received single donor platelets or pooled platelet concentrates within four weeks prior to being diagnosed.

Enter the platelets in 10^9/L. If the platelet count at diagnosis is not known, check “unknown.”

Question 5  WBC:

Enter the white blood cell count (WBC) in 10^9/L. If the WBC at diagnosis is not known, check “unknown.”

Question 6  Eosinophils:

Enter the percent of eosinophils. If the percent of eosinophils at diagnosis is not known, check “unknown.”
Question 7  Basophils:

Enter the percent of basophils. If the percent of basophils at diagnosis is not known, check “unknown.”

Question 8  Blasts:

Enter the percent of blasts in the peripheral blood. If the percent of blasts at diagnosis is not known, check “unknown.”

---

**NOTE:**

If a differential was performed and there were no blasts present in the peripheral blood, the lab report may not display a column for blasts. In this case, it can be assumed that no blasts were present and “0” can be entered on the form.

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Question 9  Did the recipient receive a splenectomy?

If “yes,” continue with question 10.

If “no,” continue with question 11.

Question 10  Date:

Enter the date the splenectomy was performed.

Question 11  Did the recipient receive chemo- or immunotherapy at any time prior to pretransplant conditioning?

If “yes,” continue with question 12.

If “no,” continue with question 13.

Question 12  Please specify drugs used:

Check “yes” or “no” for each drug. If “Other,” specify the drug. Do not leave any responses blank.
**Question 13** What was the status of the primary disease just prior to conditioning of recipient for transplant?

If “First chronic phase,” continue with question 20.

If “Accelerated phase,” continue with question 14.

If “Blastic Phase,” continue with question 16.

If “Second or greater chronic phase (for those recipients who have not had a previous BMT),” continue with question 18.

**NOTE:**
This option should be checked if the recipient is in second or greater chronic phase at the time of transplant and has not had a previous stem cell transplant.

If “Chronic phase following previous BMT,” continue with question 19.

**NOTE:**
This option should be checked if the recipient had a previous stem cell transplant (including autologous transplant) and, at the time of the transplant for which this form is being completed, is in a chronic phase.

If this option is checked, then the answer to Form 120, 520, 620 question 98, “Was this the first transplant for this recipient?” must be “no,” and questions 99–103 on the Form 120, 520, 620 must be completed.

**Question 14** Was this the first accelerated phase?

Indicate if this is the first time the recipient was in accelerated phase.

**Question 15** Indicate which of the following were present:

If accelerated phase is indicated, at least one condition in question 15 must be checked.
Check “yes” or “no” for each condition. If condition was “Other,” specify the condition. Do not leave any responses blank. Continue with question 20.

**NOTE:**
If any of the following peripheral blood or marrow findings are reported as indications for accelerated phase, then the corresponding values must be reported on page 3 of this the Form 120, 520, 620 in either the “Peripheral Blood Findings Immediately Prior to Conditioning” section or the “Most Recent Bone Marrow Findings” section.

<table>
<thead>
<tr>
<th>Blood/Marrow Finding</th>
<th>Corresponding Blood/Marrow Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukocytosis</td>
<td>WBC &gt; 100 x 10⁹/L (question 25)</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>Platelets &lt; 100 x 10⁹/L (question 24)</td>
</tr>
<tr>
<td>Thrombocytosis</td>
<td>Platelets &gt; 1000 x 10⁹/L (question 24)</td>
</tr>
<tr>
<td>≥ 10% blasts in blood or marrow</td>
<td>Peripheral blood blasts (question 28) or bone marrow blasts (question 30, part 1) must be ≥ 10%</td>
</tr>
<tr>
<td>≥ 20% basophils plus eosinophils</td>
<td>Percent eosinophils (question 26) plus percent basophils (question 27) must be ≥ 20%</td>
</tr>
</tbody>
</table>

**Question 16**  How many blast crises has the recipient ever experienced?

If blastic phase is indicated, question 28 (peripheral blood blasts) or question 30, part 1 or part 2 (bone marrow blasts plus promyelocytes) must be ≥ 30%.

Indicate the number of blast crises.

**Question 17**  Indicate type of blast cells:

Indicate the type of blast cells. Continue with question 20.

**Question 18**  How many chronic phases has the recipient experienced?

Indicate the number of chronic phases the recipient has had. Continue with question 20.

**Question 19**  Please specify:

Indicate if this was the first chronic phase, or greater than or equal to second chronic phase post-transplant. Continue with question 20.
Within Four Weeks Prior to Conditioning

Question 20  Did recipient receive red blood cell transfusions within four weeks prior to conditioning?

Indicate if the recipient received red blood cell transfusions (packed red blood cells or whole blood) within four weeks prior to conditioning. If the answer to question 20 is “yes,” proceed to question 24 and do not complete questions 22 and 23.

NOTE:
If the answer to question 13 is “First chronic phase,” then question 20 is expected to be answered “no.”

Question 21  Did recipient receive platelet transfusions within four weeks prior to conditioning?

Indicate if the recipient received platelet transfusions (pooled platelet concentrate or single donor concentrate) within four weeks prior to conditioning. If the answer to question 21 is “yes,” do not complete question 24.

NOTE:
If the answer to question 13 is “First chronic phase,” then question 21 is expected to be answered “no.”

Peripheral Blood Findings Immediately Prior to Conditioning

NOTE:
For questions 22–28, report the most recent lab values obtained prior to onset of conditioning for transplant. Lab values obtained on the first day of conditioning may be reported as long as the sample was drawn before any radiation or chemotherapy was given.
Question 22  Hemoglobin (only recipients untransfused within four weeks):

Leave this question blank if the recipient received either packed red blood cells or whole blood within four weeks prior to transplant.

Enter the hemoglobin in grams per deciliter (g/dL). If the hemoglobin prior to conditioning is not known, check “unknown.”

NOTE:

If the answer to question 15 is “anemia,” then the hemoglobin count must be less than 8 g/dL.

Question 23  Hematocrit (only recipients untransfused within four weeks):

Leave this question blank if the recipient received either packed red blood cells or whole blood within four weeks prior to transplant.

Enter the percent of hematocrit. If the hematocrit prior to conditioning is not known, check “unknown.”

Question 24  Platelets (only recipients untransfused within four weeks):

Leave this question blank if the recipient received single donor platelets or pooled platelet concentrates within four weeks prior to transplant.

Enter the platelet count in $10^9/L$. If the platelet count prior to conditioning is not known, check “unknown.”

NOTE:

If the answer to question 15 is “thrombocytopenia,” then the platelet count must be less than $100 \times 10^9/L$. If the answer to question 15 is “thrombocytosis,” then the platelet count must be greater than $1000 \times 10^9/L$.

Question 25  WBC:

Enter the WBC in $10^9/L$.

NOTE:

If the answer to question 15 is “leukocytosis,” then the WBC count must be greater than $100 \times 10^9/L$. 
Question 26  Eosinophils:

Enter the percent of eosinophils.

NOTE:
If the answer to question 15 is “≥ 20% basophils plus eosinophils,” then the sum of eosinophils (question 26) and basophils (question 27) must be ≥ 20%.

Question 27  Basophils:

Enter the percent of basophils.

NOTE:
If the answer to question 15 is “≥ 20% basophils plus eosinophils,” then the sum of eosinophils (question 26) and basophils (question 27) must be ≥ 20%.

Question 28  Blasts:

Enter the percent of blasts.

NOTE:
If the answer to question 15 is “≥ 10% blasts in blood or marrow,” then either question 28 or question 30 must be ≥ 10%. If the answer to question 15 is “≥ 20% blasts plus promyelocytes in blood or marrow,” then the sum of percent blasts (question 28) added to the sum of percent blasts plus promyelocytes (question 30) must be ≥ 20%.

Most Recent Bone Marrow Findings

Indicate the bone marrow findings just prior to conditioning.

Question 29  Date of the most recent bone marrow examination prior to conditioning (should be within 30 days of conditioning but not more than six months prior to conditioning):

Enter the date of the most recent bone marrow examination.
Question 30  Indicate the percent of blasts and promyelocytes present according to the laboratory’s reporting method:

If your Transplant Center’s laboratory report provides separate percentages for blasts and promyelocytes, enter the percent of blasts and the percent of promyelocytes in option “1.”

If your Transplant Center’s laboratory reported a combined percent of blasts plus promyelocytes, enter the percent blasts plus promyelocytes in option “2.”

If your Transplant Center’s laboratory provided a narrative report that stated less than 5% blasts plus promyelocytes, check option “3.”

Question 31  Myelofibrosis:

Indicate if myelofibrosis was “absent,” “mild,” “moderate,” “severe” or “unknown.”

Question 32  Was Philadelphia chromosome (9;22 translocation or variant) present?

Indicate “yes,” “no,” or “not tested.” The response to this question must correspond with the answer to Form 120, 520, 620 question 8, “Primary disease.”

Question 33  Was other cytogenetic abnormality present?

See Appendix O for a list of cytogenetic abbreviations/terms and their definitions, and an explanation of how to read a report.

If “yes,” continue with question 34.

If “no,” or “not tested,” continue with question 35.

Question 34  Please specify:

Specify the other cytogenetic abnormality(ies).

Question 35  Was BCR-ABL rearranged?

Indicate “yes,” “no,” or “unknown.” The response to this question must correspond with the answer to Form 120, 520, 620 question 8, “Primary disease.”
Instructions
for
Form 120, 520, 620 – Insert IV
Other Leukemias

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert IV  
Other Leukemias

This form is designed to obtain data on the hematologic findings, cytogenetic abnormalities, and stage of disease just prior to conditioning.

This form must be completed for all recipients whose primary disease on Form 120, 520, 620 question 8 is Other Leukemia. Form 120, 520, 620 is not considered complete until the appropriate disease-specific insert is submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient ID:  
Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:  
Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional)  
Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:  
Enter the date on which you are completing this form.

E. TC Code:  
Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:  
Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type:  
- Marrow  
  (Form 120)  
- PBSC  
  (Form 520)  
- Cord blood  
  (Form 620)  
Check the box that corresponds to the transplant product type.
Question 1  What was the date of diagnosis of the leukemia?

Enter the date the recipient was diagnosed with leukemia. The date of diagnosis will usually be the date the bone marrow was obtained for examination. Do not enter the date symptoms first appeared.

### Hematologic Findings Immediately Prior to Conditioning

<table>
<thead>
<tr>
<th>Question</th>
<th>Parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Hemoglobin:</td>
</tr>
<tr>
<td></td>
<td>Enter the hemoglobin in grams per deciliter (g/dL).</td>
</tr>
<tr>
<td>3</td>
<td>WBC:</td>
</tr>
<tr>
<td></td>
<td>Enter the white blood cell count (WBC) in $10^9$/L.</td>
</tr>
<tr>
<td>4</td>
<td>Lymphocytes:</td>
</tr>
<tr>
<td></td>
<td>Enter the percent of lymphocytes.</td>
</tr>
<tr>
<td>5</td>
<td>Platelets:</td>
</tr>
<tr>
<td></td>
<td>Enter the platelet count in $10^9$/L.</td>
</tr>
<tr>
<td>6</td>
<td>Blasts in blood:</td>
</tr>
<tr>
<td></td>
<td>Enter the percent of blasts in blood.</td>
</tr>
</tbody>
</table>

**NOTE:**

If a differential was performed and there were no blasts present in the peripheral blood, the lab report may not display a column for blasts. In this case, it can be assumed that no blasts were present and “0” can be entered on the form.
Question 7  Blasts in bone marrow:

Enter the percent of blasts in bone marrow.

NOTE:

If the bone marrow pathology report states a range for blasts, enter the average of the range rounded to the nearest whole number (e.g., if 0%–5%, enter 3%). If the report states > 90% blasts, packed marrow, or sheets of blasts, enter 91% on the form. If the report states < 5% blasts, enter 4%.

Question 8  Date of bone marrow examination:

Enter the date bone marrow examination was performed.

Question 9  Did the recipient receive a splenectomy?

Indicate “yes” or “no.”

Question 10  Was (were) cytogenetic abnormality(ies) present prior to conditioning?

If “yes,” continue with question 11.
If “no” or “unknown,” continue with question 12.

Question 11  Please specify:

See Appendix O for a list of cytogenetic abbreviations/terms and their definitions, and an explanation of how to interpret a cytogenetic report.
List the specific cytogenetic abnormality(ies) that was (were) present prior to conditioning.

Question 12  What was the status of the primary disease immediately prior to conditioning of recipient for transplant?

Indicate the status of the primary disease immediately prior to conditioning.
If the recipient’s disease is JCML, and the recipient received treatment prior to transplant, write “N/A” in the margin.
Question 13  What was the initial date this disease status was achieved?

Enter the date this disease status was achieved.

NOTE:
This date must be equal to or later than the diagnosis date in question 1.
Instructions for
Form 120, 520, 620 – Insert V
Myelodysplasia/Myeloproliferative Disorders

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert V
Myelodysplasia/Myeloproliferative Disorders (MDS/MPD)

This form is designed to obtain data on the FAB classification at diagnosis and just prior to conditioning for transplant; prior disease history and treatment; and hematologic, bone marrow, and cytogenetic findings at diagnosis and just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease on Form 120, 520, 620 question 8 is either MDS/MPD or AML that evolved from a Myelodysplastic Syndrome. It is also required for recipients with inherited abnormalities of erythrocyte differentiation (e.g., Fanconi Anemia) that evolved into a myelodysplastic syndrome prior to transplant. Form 120, 520, 620 is not considered complete until the appropriate disease-specific insert has been submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient ID:  

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient’s Last Name:  

Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional)  

Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:  

Enter the date on which you are completing this form.

E. TC Code:  

Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:  

Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type:  

Check the box that corresponds to the transplant product type.

□ Marrow (Form 120)  
□ PBSC (Form 520)  
□ Cord blood (Form 620)
Question 1  What was the date of diagnosis of myelodysplastic/myeloproliferative disorder?

NOTE:
The diagnosis of MDS is made by examining the bone marrow of patients who have a cytopenia or pancytopenia. The date the bone marrow is obtained is usually an adequate date of diagnosis. An exception to this rule is a patient with aplastic anemia who, many years after the diagnosis of aplastic anemia, has a FISH study performed on blood cells and a chromosomal abnormality is demonstrated. The date of this blood study is the date of diagnosis of MDS.

Enter the date the recipient was diagnosed with an MDS/MPD disorder. Do not enter the date symptoms first appeared.

Question 2  FAB type at diagnosis (this may differ from FAB type immediately prior to conditioning):

NOTE:
The reported FAB classification for myelodysplastic syndromes should be based on the following standard FAB classification criteria: Refractory Anemia (RA), Refractory Anemia with Excess Blasts (RAEB), Refractory Anemia with Excess Blasts in transformation (RAEB-t), Chronic Myelomonocytic Leukemia (CMML) and Acquired Idiopathic Sideroblastic Anemia (RARS) are all classified as Myelodysplastic Syndromes. The other diagnoses listed in question 2 are Myeloproliferative Disorders and are not addressed in the following table.

<table>
<thead>
<tr>
<th>FAB CLASSIFICATION OF MDS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RA</strong></td>
</tr>
<tr>
<td>BLOOD</td>
</tr>
<tr>
<td>Cytopenia (s)</td>
</tr>
<tr>
<td>Monocytes</td>
</tr>
<tr>
<td>Blasts (%)</td>
</tr>
<tr>
<td>BONE MARROW</td>
</tr>
<tr>
<td>Blasts (%)</td>
</tr>
<tr>
<td>Auer rods</td>
</tr>
<tr>
<td>Dysplasia</td>
</tr>
<tr>
<td>Ringed sideroblasts (%)</td>
</tr>
</tbody>
</table>

* Required for diagnosis (see atypical cases below.)
** One of these features must be present for diagnosis.

Patients with > 30% blasts in the bone marrow are classified as AML.
NOTE:

Atypical Cases

- Patients with either neutropenia and/or thrombocytopenia, but without anemia, should be classified as RA (it should be refractory cytopenia).
- Patients with blood blast count between 1%–4% and a marrow blast count < 5% should be classified as RAEB.
- Patients with > 15% ringed sideroblasts and ≥ 5% blasts in the bone marrow should be classified as RAEB or RAEB-t, and not as RARS.
- Patients with a blood blast count between 5%–30% and a marrow blast count between 5%–20% should be classified as RAEB-t.
- Patients with blasts with Auer rods and a marrow blast count between 1%–20% should be classified as RAEB-t.
- Patients with a blood blast count > 5%, monocytosis, and a marrow blast count ≤ 20% should be classified as RAEB-t.
- Patients with a blood blast count > 30%, but a marrow blast count ≤ 30%, should be classified as AML.

Indicate the FAB type that was present at diagnosis.

If the FAB type was “Other myelofibrosis or myelosclerosis,” specify the condition and continue with question 3.

Question 3  Classification of other myelofibrosis:

Refer to the appendix on page 7 of the form to determine the classification. If classification is “Other,” specify the condition.

Question 4  Was this a secondary (therapy-linked) disorder?

Indicate if the MDS/MPD disorder resulted from treatment the recipient received for a prior disease. This treatment is usually radiation or chemotherapy.

If “yes,” continue with question 5.

If “no,” or “unknown,” continue with question 11.

Question 5  Cite prior disease (malignant or nonmalignant):

Indicate the prior disease. If “Other,” specify the prior disease.
Question 6  What was the date of diagnosis of prior disease?
Enter the date the prior disease was diagnosed. This date must be prior to the date of diagnosis of the MDS/MPD diagnosis.

Question 7  Treatment for prior disease included:

Question 8  Indicate all treatments the recipient received for the prior disease. If the recipient received a treatment not listed, but which is thought to have contributed to development of MDS/MPD, check “yes” for other and specify the treatment.

Question 9  Did recipient have other predisposing conditions prior to diagnosis of hematologic disorder?
If “yes,” continue with question 12.
If “no” continue with question 13.

NOTE: If the response to question 12 is Fanconi Anemia, it must be the primary disease reported on Form 120, 520, 620 question 8.

Question 10  Please specify:
Indicate the predisposing condition. If the condition is “Other,” specify the condition. This could include environmental exposures, e.g., exposure to benzene.

Clinical Features at Diagnosis

Question 11  Did recipient have systemic symptoms (fever, sweats, weight loss > 10%) at diagnosis?
Check “yes,” “no,” or “unknown.”

Question 12  Did recipient have splenomegaly at diagnosis?
Indicate if the spleen was enlarged at diagnosis.
Check “yes,” “no,” or “unknown.”

Question 13  Did recipient have hepatomegaly at diagnosis?
Indicate if the liver was enlarged at diagnosis.
Check “yes,” “no,” or “unknown.”
Hematologic Findings at Diagnosis

The responses to questions 16–21 must be obtained from a complete blood count (CBC) and white cell differential (the percentage of different types of white blood cells) that was performed at diagnosis of MDS/MPD and before any treatment was administered for MDS/MPD.

**Question 16**  Hemoglobin (untransfused):

Leave this question blank if the recipient received packed red blood cells or whole blood within one week prior to diagnosis.

Enter the hemoglobin at diagnosis in (grams per deciliter) g/dL. If the hemoglobin is not known, check “unknown.”

**Question 17**  Platelets (untransfused):

Leave this question blank if the recipient received single donor platelets or pooled platelet concentrates within one week prior to diagnosis.

Enter the platelets at diagnosis in $10^9$/L. If the platelet count is not known, check “unknown.”

**Question 18**  WBC:

Enter the white blood cell count (WBC) at diagnosis in $10^9$/L. If the WBC is not known, check “unknown.”

---

**NOTE:**

You cannot make the diagnosis of MDS without having the blood differential. Therefore, the percentage of neutrophils, monocytes and blasts should be available. If the blood data are not available, some effort may be necessary to produce these important values.

The blood differential is expressed as a percentage. In normal individuals, it includes the following categories: segs, bands, eosinophils, basophils, monocytes, and lymphocytes. In patients with MDS, the differential can also include: metamyelocytes, myelocytes, promyelocytes, and blasts.

The percentage of neutrophils is the sum of the percentages of segs, bands, metamyelocytes, myelocytes, and promyelocytes. In the great majority of patients, the total neutrophil count is made up of mostly segs and a few bands.
Question 19  Neutrophils:

Enter the percent of neutrophils at diagnosis. If the percent of neutrophils is not known, check “unknown.”

Question 20  Monocytes:

Enter the percent of monocytes at diagnosis. If the percent of monocytes is not known, check “unknown.”

Question 21  Blasts in blood:

NOTE:
If differential was performed and there were no blasts present in the peripheral blood, the lab may not display a column for blasts. In this case, it can be assumed that no blasts were present and “0” can be entered on the form.

Enter the percent of blasts in the blood at diagnosis. If the percent of blasts in the blood is not known, check “unknown.”

Bone Marrow Findings at Diagnosis

The responses to questions 22–25 must be obtained from a bone marrow examination that was performed at diagnosis of MDS/MPD and before any treatment (other than transfusions) was administered for MDS/MPD.

NOTE:
You cannot make the diagnosis of MDS without the bone marrow aspiration findings. However, sometimes no marrow tissue can be aspirated because of the presence of fibrosis or technical difficulties. The diagnosis of MDS in these cases is based upon the marrow biopsy, which cannot provide a differential (the percentage of different types of marrow cells). However, some institutions perform touch preparations with the biopsy so that a differential can be made. Differential findings are important to validate the diagnosis. Please make every effort to locate and report these data.
Question 22  Was a bone marrow examination done at first diagnosis of hematologic disorder?
If “yes,” continue with question 23.
If “no” or “unknown,” continue with question 26.

Question 23  Cellularity:

The best way to assess the cellularity is to examine the bone marrow biopsy so, when available, use the biopsy findings to report the cellularity.

Indicate if the cellularity of the bone marrow was “decreased,” “normal,” “increased,” or “unknown.”

Question 24  Fibrosis:

**NOTE:**

Fibrosis can only be assessed by a marrow biopsy. Although fibrosis can sometimes be seen in the HE or Giemsa preparations, it often requires special stains such as the reticulin stain and the trichrome stain.

Indicate if fibrosis in the bone marrow was “absent,” “mild,” “moderate,” “severe,” or “unknown.”

Question 25  Blasts in marrow:

**NOTE:**

The bone marrow blast count must be provided, as the MDS FAB classification cannot be defined without a marrow blast count. If the bone marrow pathology report states a range for blasts, enter the average of the range rounded to the nearest whole number (e.g., 0%–5%, enter 3%). If the report states > 90% blasts, packed marrow, or sheets of blasts, enter 91% on the form. If the report states < 5% blasts, enter 4% on the form.

Enter the percent of blasts.

Question 25a  Were Auer rods present?

Indicate if the bone marrow examination revealed the presence of Auer rods (bodies) in the cytoplasm of the bone marrow cells.
**Cytogenetics at Diagnosis**

**NOTE:**
Currently a marrow chromosome study is part of the standard evaluation of a patient with MDS.

**Question 26**  
Were tests done to detect a cytogenetic abnormality at first diagnosis of hematologic disorder?

See Appendix O for a list of cytogenetic abbreviations/terms and their definitions, and an explanation of how to read a cytogenetic report.

If “tests done,” continue with question 27.

If “tests attempted, but no evaluable metaphases obtained,” “no tests done,” or “unknown,” continue with question 30.

**Question 27**  
Number of metaphases:

**NOTE:**
Metaphase refers to the cell stage at which chromosomes are examined. The number of cells examined is equivalent to the number of metaphases examined.

Enter the number of metaphases.

**Question 28**  
Was the karyotype normal?

**NOTE:**
Karyotype refers to the designation of the results of the chromosome analysis. The karyotype may be defined at a cell level, a cell line or clone level, or at the level of the entire individual.

If “yes,” continue with question 30.

If “no,” continue with question 29.

**Question 29**  
Specify abnormality:

Indicate “yes” or “no” for each abnormality listed. If “other,” specify the abnormality. Do not leave any responses blank.
Treatment Prior to Conditioning

**Question 30** Did recipient receive treatment for myelodysplastic/myeloproliferative disorder prior to conditioning?

- If “yes,” continue with question 31.
- If “no” or “unknown,” continue with question 32.

**Question 31** Specify treatments:

- For each treatment given, enter the date the treatment was started, therapy indication code, agent code, and response code. If “Other,” specify the treatment that was given. Refer to the chart at the bottom of page 4 of the form for the indication, agent, and response codes.

Clinical Features Just Prior to Conditioning

Patients with MDS can progress from RA/RARS ⇒ RAEB ⇒ RAEB-t ⇒ AML, or from CMML ⇒ RAEB-t ⇒ AML. Certain treatments can revert the disease to an earlier stage. For instance, a patient could have evolved into RAEB-t and with therapy be in complete remission (which means practically normal counts) or in RA phase prior to conditioning (no blasts but still pancytopenic and dysplastic marrow.)

**Question 32** Did recipient transform to a different FAB classification or stage prior to conditioning?

- Answer this question “yes” if the recipient’s disease evolved to another FAB classification (including AML) after diagnosis. It is possible to report the same FAB classification in question 33 as in question 2, “FAB at diagnosis,” if the recipient’s disease transformed to a more severe form of the disease and then, after treatment, reverted to the FAB at diagnosis. Continue with question 33.
- Answer this question “yes, with subsequent complete remission” if the recipient’s disease transformed to another FAB classification after diagnosis and then, after treatment, went into complete remission. Continue with question 33.
- Answer this question “no” if the recipient’s disease did not transform to another FAB classification after diagnosis. Recipients with a myeloproliferative disorder generally will not change to another diagnosis during the course of the disease. Continue with question 36.
**NOTE:**

On Form 120, 520, 620 question 8, report the primary disease for which this transplant is being performed as the most serious form the disease transformed to (e.g., RA to RAEB to RA, report RAEB; or RAEB to AML to RA, report AML).

**Question 33**
Indicate FAB classification or stage at time of transplant, or if in complete remission, the most recent FAB stage:

**NOTE:**
See FAB classification criteria for MDS in the Note box for question 2 of these instructions.

Indicate the FAB classification or stage at time of transplant and continue with question 35.

If the recipient transformed to AML and is not in remission, check “Other myelodysplasia or myeloproliferative disorder,” and specify “AML.” If the recipient transformed to AML, but at the time of transplant is in RA, report “RA” as the FAB.

If stage is “Other myelofibrosis or myelosclerosis,” continue with question 34.

**Question 34**
Classification of myelofibrosis:

Indicate the classification of myelofibrosis. Refer to the appendix on page 7 of the form to determine the classification. If the classification is “Other,” specify the condition.

**Question 35**
Date of most recent transformation:

Enter the date the disease transformed to the FAB classification indicated in question 33.

**Question 36**
Did recipient have systemic symptoms (fever, sweats, weight loss > 10%) just prior to conditioning?

Indicate “yes,” “no,” or “unknown.”
Question 37 Did recipient have splenomegaly just prior to conditioning?
Indicate if the recipient had an enlarged spleen just prior to conditioning for transplant. If the recipient’s spleen was removed prior to conditioning, check “splenectomy.”

If “yes,” continue with question 38.
If “no,” “splenectomy,” or “unknown,” continue with question 39.

Question 38 cm below left costal margin:
Enter how many centimeters (cm) the spleen extends below the left costal margin.

Question 39 Did recipient have hepatomegaly just prior to conditioning?
Indicate if the recipient had an enlarged liver just prior to conditioning for transplant.

Check “yes,” “no,” or unknown.”

Hematologic Findings Just Prior to Conditioning

NOTE:
For questions 40–47 report the most recent lab values obtained prior to the onset of conditioning for the transplant. Lab values obtained on the first day of conditioning may be reported as long as the sample was drawn before any radiation or chemotherapy was given.

Question 40 Did the recipient receive a red cell transfusion within four weeks of conditioning?
This question should be answered “yes” if the recipient received either whole blood or packed red cells within four weeks prior to conditioning for transplant.

If “yes,” continue with question 42.
If “no,” continue with question 41.

Question 41 Hemoglobin:
Enter the hemoglobin concentration in grams per deciliter (g/dL).
Question 42  Did the recipient receive a platelet transfusion within four weeks of conditioning?

This question should be answered “yes” if the recipient received either single donor platelets or platelet concentrates within four weeks prior to conditioning for transplant.

If “yes,” continue with question 44.
If “no,” continue with question 43.

Question 43  Platelets:

Enter the platelet count in $10^9$/L.

Question 44  WBC:

Enter the white blood count (WBC) in $10^9$/L.

NOTE:

You cannot make the diagnosis of MDS without having the blood differential. Therefore, the percentage of neutrophils, monocytes, and blasts should be available. If the blood data are not available, some effort may be necessary to produce these important values.

The blood differential is expressed as percentage. In normal individuals, it includes the following categories: segs, bands, eosinophils, basophils, monocytes, and lymphocytes. In patients with MDS, the differential can also include: metamyelocytes, myelocytes, promyelocytes, and blasts.

The percentage of neutrophils is the sum of the percentages of segs, bands, metamyelocytes, myelocytes, and promyelocytes. In the great majority of patients, the total neutrophil count is made up of mostly segs and a few bands.

Question 45  Neutrophils:

Enter the percent of neutrophils.

Question 46  Monocytes:

Enter the percent of monocytes.
Question 47  Blasts in blood:

NOTE:
If a differential was performed and there were no blasts present in the peripheral blood, the lab report may not display a column for blasts. In this case, it can be assumed that no blasts were present and “0” can be entered on the form.

Enter the percent of blasts in the blood.

Bone Marrow Findings Just Prior to Conditioning

NOTE:
You cannot make the diagnosis of MDS without the bone marrow aspiration findings. However, sometimes no marrow tissue can be aspirated because of the presence of fibrosis or technical difficulties. The diagnosis of MDS in these cases is based upon the marrow biopsy, which cannot provide a differential (the percentage of different types of marrow cells). However, some institutions perform touch preparations with the biopsy so that a differential can be made. Differential findings are important to validate the diagnosis. Please make every effort to locate and report these data.

Question 48  Date of most recent bone marrow examination:

Enter the date of the most recent bone marrow examination.

Question 49  Cellularity:

The best way to assess the cellularity is to examine the bone marrow biopsy so, when available, use the biopsy findings to report the cellularity.

Indicate if the cellularity of the bone marrow was “decreased,” “normal,” “increased,” or “unknown.”
Question 50  Fibrosis:

NOTE:
Fibrosis can only be assessed by a marrow biopsy. Although fibrosis can sometimes be seen in the HE or Giemsa preparations, it often requires special stains such as the reticulin stain and the trichrome stain.

Indicate if fibrosis in the bone marrow was “absent,” “mild,” “moderate,” “severe,” or “unknown.”

Question 51  Blasts in marrow:

NOTE:
The bone marrow blast count must be provided, as the MDS FAB classification cannot be defined without a marrow blast count. If the bone marrow pathology report states a range for blasts, enter the average of the range rounded to the nearest whole number; e.g., 0%–5%, enter 3%. If the report states > 90% blasts, packed marrow, or sheets of blasts, enter 91% on the form. If the report states < 5% blasts, enter 4% on the form.

Enter the percent of blasts in the bone marrow.

Question 51a  Were Auer rods present?

Indicate if the bone marrow examination revealed the presence of Auer rods (bodies) in the cytoplasm of the bone marrow cells.

Question 52  Indication for bone marrow transplant:

Indicate the reason the bone marrow transplant is being performed. If “other,” specify the indication.

Cytogenetics After Treatment

Question 53  Were tests done to detect a cytogenetic abnormality after treatment?

See Appendix O for a list of cytogenetic abbreviations/terms and their definitions, and an explanation of how to read a cytogenetic report.

Indicate if cytogenetic tests were performed or attempted after the MDS/MPD was treated but prior to transplant. If question 53 is answered “tests done,” continue with question 54.
**Question 54** In all tests done, was the karyotype normal?

Indicate “yes” or “no.” If “no” continue with question 55.

**NOTE:**

Karyotype refers to the designation of the results of the chromosome analysis. The karyotype may be defined at a cell level, a cell line or clone level, or at the level of the entire individual.

**Question 55** Specify abnormality(ies):

Indicate “yes” or “no” for each abnormality listed. If “other,” specify the abnormality. Do not leave any responses blank.
Instructions
for
Form 120, 520, 620 – Insert VI
Multiple Myeloma

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert VI
Multiple Myeloma

This form is designed to capture more detailed data on the immunochemical type and stage of multiple myeloma, and laboratory findings just prior to conditioning.

This form must be completed for all recipients whose primary disease reported on Form 120, 520, 620 question 8 is multiple myeloma or plasma cell disorder. Form 120, 520, 620 is not considered complete until the appropriate disease-specific insert has been submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient ID: 

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: 

Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional) 

Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: 

Enter the date on which you are completing this form.

E. TC Code: 

Enter your Transplant Center’s three-digit Transplant Center.

F. Date of Transplant for which this form is being completed: 

Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type:  □ Marrow  □ PBSC  □ Cord blood

Check the box that corresponds to the transplant product type.
Question 1  What was the date of diagnosis of multiple myeloma?
Enter the date the recipient was diagnosed with multiple myeloma or another plasma cell disorder. Do not enter the date symptoms first appeared.

Question 2  What was the immunochemical type?
Indicate the immunochemical type. If the type was “Light chains only,” specify the type of light chain.

Question 3  What was the staging of the multiple myeloma at the time of the transplant?
According to the criteria listed on the form, indicate “Stage I,” “Stage II,” or “Stage III.”

Laboratory Findings Immediately Prior to Conditioning

NOTE:
For questions 4–7 report the most recent lab values obtained prior to the onset of conditioning for the transplant. Lab values obtained on the day of conditioning may be reported as long as the sample was drawn before any radiation or chemotherapy was given.

Question 4  Serum calcium:
Enter the serum calcium in milligrams per deciliter (mg/dL).

Question 5  Serum M component concentration:
Serum M component may be listed on the lab report as a paraprotein or a monoclonal protein. Serum M components are determined by immunoelectrophoresis.
Enter the serum M component concentration in grams per deciliter (g/dL).

Question 6  24 hour urine light chain excretion:
Enter the 24 hour urine light chain excretion in grams per 24 hours (g/24 hours).

Question 7  Serum beta 2 microglobulin:
Enter the serum beta 2 microglobulin in milligrams per deciliter (mg/dL).

Question 8  Was recipient refractory to chemotherapy prior to conditioning?
Indicate if the recipient was not responding to treatment prior to conditioning.
Instructions for
Form 120, 520, 620 – Insert VII
Other Malignancy

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert VII
Other Malignancy

This form is designed to obtain more detailed data on the recipient’s disease. This form must be completed for all recipients whose primary disease reported on the Form 120, 520, 620 question 8 is Other malignancy. Form 120, 520, 620 is not considered complete until the appropriate disease-specific insert has been submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient ID:  

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:  

Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional)  

Enter your center’s local ID for the recipient.

D. Today’s Date:  

Enter the date on which you are completing this form.

E. TC Code:  

Enter your center’s three-digit Transplant Center code.

F. Date of Transplant for which this form is being completed:  

Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type:  

☐ Marrow  
(Form 120)  
☐ PBSC  
(Form 520)  
☐ Cord blood  
(Form 620)

Check the box that corresponds to the transplant product type.
Question 1  What was the diagnosis?

Enter the diagnosis.

Question 2  What was the subtype?

Provide the subtype of the disease if there is one indicated. If a subtype was not described, write in “not described.”

Question 3  What was the stage (if appropriate)?

Provide the stage of the disease just prior to conditioning for transplant if it is appropriate for the diagnosis. If the stage is not indicated, write in “N/A.”

Question 4  What was the date of diagnosis?

Enter the date the malignancy was diagnosed. Do not enter the date the symptoms first appeared.
Instructions
for
Form 120, 520, 620 – Insert VIII
Aplastic Anemia
Form 120, 520, 620 – Insert VIII
Aplastic Anemia

This form is designed to obtain data on the etiology of the aplastic anemia, treatments the recipient received prior to transplant, and hematologic findings at diagnosis and just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520, 620 question 8 is severe aplastic anemia or Diamond-Blackfan anemia. It is also required for patients transplanted for Fanconi anemia if the disease has not transformed to acute leukemia or myelodysplastic syndrome. Form 120, 520, 620 is not considered complete until the appropriate disease-specific insert has been submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient ID:  
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:  
   Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional)  
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:  
   Enter the date on which you are completing this form.

E. TC Code:  
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:  
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type:  
   Check the box that corresponds to the transplant product type.
   - Marrow (Form 120)
   - PBSC (Form 520)
   - Cord blood (Form 620)
Question 1  What was the date of diagnosis of aplastic anemia?

Enter the date the recipient was diagnosed with aplastic anemia. The date of diagnosis will usually be the date the bone marrow was obtained for examination. Do not enter the date symptoms first appeared.

Question 2  What was the etiology?

The answer to this question must be the same as the answer to Form 120, 520, 620 question 8, “Primary Disease.”

Indicate the etiology (cause) of the severe aplastic anemia. If the cause is not known, check “Idiopathic.”

If etiology was “Hepatitis,” specify the type of hepatitis.

If etiology was “Drug induced,” specify the drug.

If “Other,” specify the known cause.

**NOTE:**
If the etiology is Fanconi anemia, and the disease has transformed to AML, ALL, or MDS, complete the corresponding disease insert instead of Insert VIII.

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**Hematologic Findings at Diagnosis of Aplastic Anemia**

Question 3  Hemoglobin (untransfused):

Enter the hemoglobin in grams per deciliter (g/dL) as determined at the time of diagnosis.

Leave this question blank if the recipient received either packed red cells or whole blood.

Question 4  Hematocrit:

Enter the percent of hematocrit as determined at the time of diagnosis. If the hematocrit at diagnosis is not known, check “unknown.”

Question 5  RBC:

Enter the red blood cell count (RBC) in $10^{12}$/L as determined at the time of diagnosis. If the RBC count at diagnosis is not known, check “unknown.”
Question 6  Uncorrected reticulocytes:

Enter the uncorrected percentage of reticulocytes as determined at the time of diagnosis. If the uncorrected reticulocyte percentage at diagnosis is not known, check “unknown.”

Question 7  WBC:

Enter the white blood cell count (WBC) in $10^9$/L as determined at time of diagnosis.

Question 8  Granulocytes:

Enter the percent of granulocytes as determined at time of diagnosis. Percent of granulocytes should equal the sum of the percent of neutrophils, basophils, and eosinophils.

Question 9  Platelets:

Enter the platelets in $10^9$/L as determined at time of diagnosis.

Question 10  Has recipient received prior treatment for aplastic anemia?

If “yes,” continue with question 11.

If “no,” continue with question 13.

Question 11  Please specify what treatments were given:

See Appendix M for a list of trade names under which generic drugs are manufactured.

Check “yes” or “no” for each treatment listed. Do not leave any responses blank.

If other immunosuppression was used, please specify the drug.

If cytokines were given, continue with question 12.

If other treatment was given, specify the treatment.

Question 12  What cytokines were given?

Check “yes” or “no” for each cytokine listed. Do not leave any responses blank. If “Other,” specify the cytokine.
Within Four Weeks Prior to Conditioning

Question 13 Did recipient receive red blood cell transfusions within four weeks prior to conditioning?

Indicate if the recipient received either packed red blood cells or whole blood within four weeks prior to conditioning. If “yes,” do not answer questions 15 and 16.

Question 14 Did recipient receive platelet transfusions within four weeks prior to conditioning?

Indicate if the recipient received either single donor platelets or pooled platelet concentrates within four weeks prior to conditioning. If “yes,” do not answer question 17.

Peripheral Blood Findings Immediately Prior to Conditioning

NOTE:
For questions 15–20 report the most recent lab values obtained prior to onset of conditioning for the transplant. Lab values obtained on the day of conditioning may be reported as long as the sample was drawn before any radiation or chemotherapy was given.

Question 15 Hemoglobin (only recipients untranfused within four weeks):

Leave this question blank if the recipient received packed red blood cells or whole blood within four weeks prior to conditioning.

Enter the hemoglobin concentration in gm/dL.

Question 16 Hematocrit (only recipients untranfused within four weeks):

Leave this question blank if the recipient received packed red blood cells or whole blood within four weeks prior to conditioning.

Enter the percent of hematocrit.
Question 17  Platelets (only recipients untransfused within four weeks):
Leave this question blank if the recipient received single donor platelets or pooled platelet concentrates within four weeks prior to conditioning.
Enter the platelets in 10⁹/L.

Question 18  WBC:
Enter the white blood cell count (WBC) in 10⁹/L.

Question 19  Granulocytes:
Enter the percent of granulocytes. Percent of granulocytes should equal the sum of the percentages of neutrophils, basophils, and eosinophils.

Question 20  Blasts:
Enter the percent of blasts found in the peripheral blood. Aplastic anemia patients should have 0% blasts.

NOTE:
If a differential was performed, and there were no blasts present in the peripheral blood, the lab report may not display a column for blasts. In this case, it can be assumed that no blasts were present and “0” can be entered on the form.
Instructions

for

Form 120, 520, 620 – Insert IX

Hodgkin and Non-Hodgkin Lymphoma

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert IX
Hodgkin and Non-Hodgkin Lymphoma

This form is designed to obtain data on the recipient’s hematologic and immunologic status just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease on Form 120, 520, 620 question 8 is Non-Hodgkin lymphoma or Hodgkin lymphoma. Form 120, 520, 620 is not considered complete until the appropriate disease-specific insert is submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient ID:  
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:  
   Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional)  
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:  
   Enter the date on which you are completing this form.

E. TC Code:  
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:  
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type:  
   □ Marrow (Form 120)  
   □ PBSC (Form 520)  
   □ Cord blood (Form 620)  
   Check the box that corresponds to the transplant product type.
Question 1  Date of diagnosis of lymphoma:
Enter the date the recipient was diagnosed with lymphoma.

Question 2  What was lymphoma histology at diagnosis?
Indicate the lymphoma histology using the 2-digit codes in the boxed list below the question. If the histology is “05 Other Hodgkin lymphoma,” “25 Composite,” “36 Other peripheral T-cell lymphoma,” or “38 Other non-Hodgkin lymphoma, unclassified,” complete the “Specify” line to record the diagnosis.

Question 3  Immune phenotype at diagnosis:
Indicate if the phenotype was “B-cell,” “T-cell,” “NK-cell,” “Null,” “Other,” or “Unknown.” If “Other,” use the “specify” line to record the phenotype.

Question 4  Did histologic transformation occur after diagnosis?
If “yes,” continue with question 5.
If “no,” continue with question 7.

Question 5  Date of transformation:
Enter the date of the histiologic transformation.

Question 6  New histology:
Indicate the new lymphoma histology using the 2-digit codes in the boxed list below question 2. If the histology is “05 Other Hodgkin lymphoma,” “25 Composite,” “36 Other peripheral T-cell lymphoma,” or “38 Other non-Hodgkin lymphoma, unclassified,” complete the “specify” line to record the diagnosis.

Stage at Time of Diagnosis

Question 7  Organ involvement at diagnosis:
Choose the level of organ involvement from the accompanying list. If “Other,” use the “specify” line to record the level of organ involvement.

Question 8  Symptoms at diagnosis:
If the recipient experienced unexplained weight loss > 10% body weight in six months before treatment, unexplained fever > 38°C, or night sweats, choose item “2–B” from the list. If none of the listed symptoms were present, choose item “1–A.” If “unknown,” choose item 3.
**Question 9**  Was there extranodal or splenic involvement at diagnosis?

If “yes,” continue with question 10.

If “no” or “unknown,” continue with question 11.

**Question 10**  Specify sites:

Indicate “yes” or “no” for each site listed. Do not leave any responses blank.

**Question 11**  LDH at diagnosis:

Record the recipient’s LDH level at diagnosis of lymphoma, then indicate the unit of measurement used to report the value.

**Question 12**  Upper limit of normal for LDH:

Enter your institution’s upper limit of normal for LDH level in the same unit of measurement reported in question 11.

**Question 13**  Was a mediastinal mass present at diagnosis?

Indicate “yes,” “no,” or “unknown.”

**Question 14**  Enter age-appropriate Karnofsky or Lansky score at diagnosis:

Two scales are used to report the functional status of the recipient prior to conditioning. The Karnofsky Scale is designed for recipients aged 16 years and older, and is not appropriate for children under the age of 16 years. The Lansky scale is designed for recipients less than 16 years old.

Based on the age of the recipient, choose either the Karnofsky or Lansky Scale. Record the number associated with the phrase that best indicates the recipient’s activity status at diagnosis.

A complete scale can be found associated with question 10 of the Baseline and Transplant Data Form 120, 520, 620.

**Question 15**  Was recipient treated for lymphoma prior to a high-dose therapy (conditioning)?

If “yes” continue with question 16.

If “no” continue with question 164.
Question 16  Chemotherapy:

If the recipient received chemotherapy, check “yes” and continue with question 17.

If the recipient did not receive chemotherapy, check “no” and continue with question 41.

Question 17  Number of cycles:

Record the number of chemotherapy cycles the recipient received during the first line of therapy, or check “unknown/not applicable.”

Question 18  Date started therapy:

Record the date the recipient began the first line of chemotherapy.

Question 19  Date stopped therapy:

Record the date the recipient ended the first line of chemotherapy.

Question 20  Treatment:

Question 21 to Question 39  Check “yes” or ”no” for each chemotherapy treatment listed for the first line of therapy. Do not leave any responses blank. If the recipient received a treatment not listed, check “yes” for other and specify the treatment in line 39.

Question 40  Given for stem cell priming?

Check “yes” if any of the chemotherapy treatments listed in questions 20 through 38 were administered for stem cell priming.

Question 41  Radiation therapy:

If the recipient received radiation therapy, check “yes” and continue with question 42.

If the recipient did not receive radiation therapy, check “no” and continue with question 47.

Question 42  Sites:

Question 43 to Question 44  Check “yes” or ”no” to indicate if the recipient received radiation to the mediastinum or other site. If the recipient received radiation to a site other than the mediastinum, specify the site(s) in line 44.
Question 45  Date started therapy:
Record the date the recipient began the first line of radiation therapy.

Question 46  Date stopped therapy:
Record the date the recipient ended the first line of radiation therapy.

Question 47  Surgery:
If the recipient received surgery as part of the first line of therapy, check “yes” and continue with question 48.
If the recipient did not receive surgery as part of the first line of therapy, check “no” and continue with question 49.

Question 48  Specify site:
Record the site at which the recipient had surgery as part of the first line of therapy.

Question 49  Best response to line of therapy:
Check only one box indicating whether the recipient’s best response to the first line of high-dose therapy was “continuous complete remission,” “complete remission,” “complete remission undetermined,” “partial response,” “no response/stable disease,” “progressive disease,” “not evaluable,” or “not tested/unknown.” If the response is “not evaluable,” use the “specify” line to record the reason.

Question 50  Date response established:
Record the date the best response to the first line of high-dose therapy was established.

Question 51  Did patient relapse/progress following this line of therapy?
Indicate “yes” or “no.”

Question 52  Date of relapse/progression:
Record the date the recipient relapsed or the disease progressed following the first line of high-dose therapy.
Question 53  2nd, 3rd, and 4th lines of therapy:

Question 163 If the recipient received more than 1 line of high-dose therapy, record the information for each subsequent line of therapy. If the recipient received more than 4 lines of therapy, make a copy of page 4 and continue to record each subsequent line of therapy.

Question 164 Did recipient have a splenectomy?

If “yes” continue with question 165; if “no” continue with question 166.

Question 165 Date:

Record the month and year in which the recipient received a splenectomy.

Question 166 Was the recipient restaged ≤ 2 months prior to high-dose therapy (conditioning)?

If “yes” continue with question 167; if “no, not completely restaged” continue with question 168.

Question 167 Stage of disease immediately prior to high-dose therapy (conditioning):

Choose the disease stage from the list provided. If none of the descriptions matches the disease stage, choose “other” and record the disease stage in the “specify” line.

Question 168 Evidence of disease prior to conditioning:

Check the box corresponding to the disease evidence known less than 2 months prior to conditioning for transplant.

Question 169 Did recipient have known nodal involvement immediately prior to conditioning?

If “yes” continue with question 170; if “no” continue with question 171.

Question 170 Specify sites:

Check “yes,” “no,” or “unknown” for each site listed. Do not leave any responses blank. If the recipient had nodal involvement at a site not listed, check “yes” for “other site” and use the “specify” line to record the site.

Question 171 Did recipient have known extranodal involvement immediately prior to conditioning?

Check “yes,” continue with question 172. If “no” or “unknown” continue with question 173.
Question 172  Specify sites:
Check “yes,” “no,” or “unknown” for each site listed. Do not leave any responses blank. If the recipient had extranodal involvement at a site not listed, check “yes” for “other site” and use the “specify” line to record the site.

Question 173  Did recipient have any mass immediately prior to conditioning?
If “yes” continue with question 174; if “no” continue with question 176.

Question 174  Size of largest mass (of any kind):
Report the size as measured in centimeters of the largest known mass.

Question 175  Site:
Report the site where the largest mass was detected.

Question 176  Was Gallium scan done ≤ 4 weeks prior to conditioning?
If “yes” continue with question 177; if “no” continue with question 179.

Question 177  Results:
Report whether the Gallium scan results were “negative,” “positive,” or “indeterminate/equivocal.”

Question 178  Sites:
Report the sites where the Gallium scan was conducted.

Question 179  What was sensitivity of lymphoma to chemotherapy prior to conditioning?
Report whether the response of the lymphoma to the last chemotherapy treatment given ≤ 6 months prior to transplant was “sensitive,” “resistant,” “untreated,” “not evaluable,” or “unknown.”

Question 180  Remission state immediately prior to conditioning:
Choose the disease remission state from the list provided.
Instructions for Form 120, 520, 620 – Insert X Severe Combined Immunodeficiency

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert X
Severe Combined Immunodeficiency (SCIDS)

This form is designed to obtain data on the recipient’s hematologic and immunologic status just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease on Form 120, 520, 620 question 8 is SCID, Omenn’s Syndrome, Reticular Dysgenesis, Bare Lymphocyte Syndrome or other SCID. Form 120, 520, 620 is not considered complete until the appropriate disease-specific insert is submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient ID: _______ - _______ - _______

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: ________________

Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional) _______ _______ _______ _______ _______ _______

Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: ___ ___ ___

Enter the date on which you are completing this form.

E. TC Code: _______

Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: ___ ___ ___

Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type: □ Marrow (Form 120) □ PBSC (Form 520) □ Cord blood (Form 620)

Check the box that corresponds to the transplant product type.
Question 1  What was the date of diagnosis of SCID?
Enter the date the recipient was diagnosed with SCIDS.

Question 2  What was the SCID phenotype?
Indicate the SCID phenotype. If phenotype was “Other,” specify the type.

<table>
<thead>
<tr>
<th>NOTE:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SCID Phenotype</strong></td>
</tr>
<tr>
<td>1. <em>ADA Deficiency</em> – markedly decreased or absent ADA enzyme activity in red blood cells (if recipient has not been transfused) or white blood cells. Inheritance of this disorder is always autosomal recessive.</td>
</tr>
<tr>
<td>2. <em>Absence of T cells with normal B cells</em> – T cell number (in the absence of maternal engraftment) is &lt; 100/mm³. B cells are SIg+ and normal in number, e.g., &gt; 200/mm³. This phenotype is usually inherited as x-linked recessive.</td>
</tr>
<tr>
<td>3. <em>Absence of T and B cells</em> – total absolute lymphocyte count &lt; 500/mm³. Recipients who have very low numbers of T and B cells, but have a greater proportion of NK cells, should be listed as “4. Other, specify: Absent T and B cells with NK cells.”</td>
</tr>
<tr>
<td>4. <em>Other</em> – specify the phenotype, e.g., Omenn syndrome, reticular dysgenesis, IL2 deficiency, etc.</td>
</tr>
</tbody>
</table>

Question 3  What was the inheritance of SCID?
Indicate if the inheritance was “X-linked,” “Autosomal recessive” or “Unknown.”

<table>
<thead>
<tr>
<th>NOTE:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inheritance</strong></td>
</tr>
<tr>
<td>1. <em>X-linked</em>: Mother’s family history is positive or recipient has been documented to have a defect of an x-linked gene causing SCID. Almost always males who are affected.</td>
</tr>
<tr>
<td>2. <em>Autosomal recessive</em>: No preceding family history; as likely to occur in females as males.</td>
</tr>
</tbody>
</table>
Hematologic Findings Pre-Transplant

Question 4  WBC:

Enter the white blood cell count (WBC) in $10^9$/L.

Question 5  Lymphocytes:

Enter the percent of lymphocytes.

Question 6  T cells (CD3 or equivalent):

Enter the percent of T cells.

Question 7  CD4+ cells:

Enter the percent of helper T cells (CD4+ cells).

Question 8  CD8+ cells:

Enter the percent of suppressor T cells (CD8+ cells).

Question 9  B cells (SIg+ or equivalent):

Enter the percent of B cells (surface immunoglobulin positive).

Question 10  NK cells (CD16+ or equivalent):

Enter the percent of natural killer (NK) cells.

Question 11  What was the mitogen proliferation response?

Indicate if the response was “absent,” “decreased,” “normal,” or “not tested.”

NOTE:

Mitogen Proliferation

Typically refers to PHA (Phytohemagglutinin) response; could also refer to Concanavalin A response.
Question 12  What was the natural killer cell function?
Indicate if NK cell function was “absent,” “decreased,” “normal,” or “not tested.”

NOTE:
Natural Killer Cell Function
Specific cytolysis (cell death) of NK sensitive target cells (e.g., K562).

Question 13  IgG:
Indicate if the IgG level was “absent,” “decreased,” “normal,” “increased,” or “not tested.”

Question 14  IgM:
Indicate if the IgM level was “absent,” “decreased,” “normal,” “increased,” or “not tested.”

Question 15  IgA:
Indicate if the IgA level was “absent,” “decreased,” “normal,” “increased,” or “not tested.”

Question 16  IgE:
Indicate if the IgE level was “absent,” “decreased,” “normal,” “increased,” or “not tested.”

Question 17  What was the specific antibody response?
Indicate if the specific antibody response was “absent,” “decreased,” “normal,” “increased,” or “not tested.”

NOTE:
Specific Antibody Response
Includes any antigen against which the recipient has been adequately immunized (e.g., > DPT for Diphtheria, Pertussis or Tetanus titres) or following natural exposure (e.g., CMV).
### Clinical Status of Recipient Pre-Transplant

**Question 18**  Was maternal engraftment present?

Indicate “yes,” “no,” or “unknown (not tested).”

**NOTE:**
*Maternal Engraftment*
Engraftment of the mother’s stem cells that were unintentionally transfused to the recipient either during gestation or delivery. Maternal engraftment may be determined by either HLA typing or discriminating RFLP analyses.

**Question 19**  Was graft vs. host disease present?

**NOTE:**
This question only refers to graft versus host disease (GVHD) that was present prior to transplant. Pre-transplant GVHD is usually caused by engraftment of maternal stem cells or from transfusions with blood products that were not irradiated.

If “yes,” continue with question 20.

If “no,” continue with question 21.

**Question 20**  Was GVHD caused by:

Indicate “yes” or “no” for each cause. Do not leave any responses blank.

**Question 21**  Did the recipient have failure to thrive?

Indicate “yes” or “no.”

**NOTE:**
*Failure to Thrive*
Weight < 5th percentile for age.
Question 22  Did the recipient have chronic (protracted) diarrhea?
Indicate “yes” or “no.”

NOTE:
Chronic or Protracted Diarrhea
Diarrhea greater than six weeks in duration.

Question 23  Did the recipient have respiratory impairment?
Indicate “yes” or “no.”

NOTE:
Respiratory Impairment at the Time of Transplant
Refers to the need for chronic or intermittent support with oxygen (O₂) or artificial ventilation, and/or the presence of persistent interstitial, nodular, or lobar pneumonia on X-ray.
Instructions
for
Form 120, 520, 620 – Insert XI
Wiskott Aldrich’s Syndrome

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert XI
Wiskott Aldrich Syndrome (WAS)

This form is designated to obtain data on the criteria used to determine the disease diagnosis and any complications prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease on Form 120, 520, 620 question 8 is WAS. Form 120, 520, 620 is not considered complete until the appropriate disease-specific insert is submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient ID:  

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:

Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID: (optional)

Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:

Month Day Year

Enter the date on which you are completing this form.

E. TC Code:

Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:

Month Day Year

Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type:  

- Marrow (Form 120)  
- PBSC (Form 520)  
- Cord blood (Form 620)

Check the box that corresponds to the transplant product type.
Question 1  What was the date of diagnosis of WAS?

Enter the date the recipient was diagnosed with WAS.

Question 2  What were the WAS defining (diagnostic) criteria?

Indicate “yes,” “no” or “unknown” for each criteria. Do not leave any responses blank.

**NOTE:**

X-linked inheritance demonstrated in the family refers to a family history that is positive for WAS.

Question 3  Was the diagnosis confirmed by molecular identification of the presence of a defect in the WAS gene?

Indicate “yes,” “no” or “unknown.”

### Clinical Status of Recipient Pre-Transplant

Question 4  Did the patient undergo splenectomy?

If “yes,” continue with question 5.

If “no” or “unknown,” continue with question 6.

Question 5  Was the platelet count normal immediately pre-transplant?

Indicate “yes,” “no,” or “unknown.”

Question 6  Did B cell lymphoproliferative disorder (BLPD) develop pre-transplant?

If “yes,” continue with question 7.

If “no” or “unknown,” continue with question 8.

**NOTE:**

If question 6 is answered “yes,” then Form 120, 520, 620 question 12r “history of other malignancy” must be answered “yes,” and “BLPD” specified.
Question 7  Was the BLPD associated with EBV?
Indicate “yes,” “no,” or “unknown.”

Question 8  Did the recipient develop any malignancy (non BLPD) pre-transplant?
Indicate “yes,” “no,” or “unknown.”

NOTE:
If question 8 is answered “yes,” then Form 120, 520, 620 question 12r “history of other malignancy” must be answered “yes,” and the type of malignancy specified.

Question 9  Did the recipient develop any autoimmune complications pre-transplant?
Indicate “yes,” “no,” or “unknown.”

NOTE:
If question 9 is answered “yes,” then Form 120, 520, 620 question 12z, “other co-existing disease” must be answered “yes,” and the autoimmune complications specified.
Instructions for
Form 120, 520, 620 – Insert XIII
Leukodystrophies

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert XIII
Leukodystrophies

This form is designed to obtain data on the recipient’s neurological, visual, and auditory status just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520, or 620 question 8, is globoid cell, metachromatic, or adrenoleukodystrophy. Form 120, 520, or 620 is not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

Form Key Fields:

All data reported in the key field section must be identical to the data reported in the key field section for the corresponding Form 120, 520, or 620.

A. Unrelated Recipient ID: __________ - __________ - __________
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: __________________________________________
   Print the recipient’s last name using capital letters.

C. Recipient Local ID (optional): __________________________________
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: __________ __________ __________
   Enter the date on which you are completing this form.

E. TC Code: __________
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: __________ __________ __________
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product type: □ Marrow (Form 120) □ PBSC (Form 520) □ Cord blood (Form 620)
   Check the box that corresponds to the transplant product type.
Question 1  For which type of leukodystrophy was the transplant performed?
Indicate the type of leukodystrophy for which the recipient was transplanted.
If “Globoid Cell Leukodystrophy,” continue with questions 2 and 3.
If “Metachromatic Leukodystrophy,” continue with questions 4 through 6.
If “Adrenoleukodystrophy,” continue with questions 7 through 13.

Questions 2  Report the enzyme activity at the time of the recipient’s diagnosis:
3  Enter the result and indicate if the enzyme was measured in nanomoles per hour per milligram protein (nmol/hr/mg protein) or in picomoles per hour per milligram protein (pmol/hr/mg protein).

NOTE: If the enzyme results for either the recipient or donor are reported in units other than those listed, attach a copy of the lab report and leave this question blank on the form. NMDP staff will determine if the lab result can be converted to nmol/hr/mg protein or pmol/hr/mg protein.

Enter the date the recipient’s enzyme activity was tested.

Question 5  Report the urinary sulfatides at diagnosis:
For recipients being transplanted for metachromatic leukodystrophy, report the level of urinary sulfatides in grams per milliliter (g/mL).

Question 7  Report the mean fasting plasma very-long-chain fatty acid (VLCFA) C26:0 as determined at diagnosis:
For recipients being transplanted for adrenoleukodystrophy, enter the plasma level as measured in micrograms per milliliter (µg/mL).

Question 8  Was the mean fasting plasma very-long-chain-fatty acid level measured pre-transplant (within two weeks prior to conditioning for transplant)?
If “yes,” continue with question 9.
If “no” or “unknown” continue with question 10.
Question 9  Specify:

Report the mean plasma level of very-long-chain-fatty acids as measured in micrograms per milliliter (µg/mL).

Enter the date that the mean fasting plasma very-long-chain-fatty acid level was measured. This date must be within two weeks prior to the date conditioning for transplant began.

Question 10  Was treatment given for adrenal insufficiency between diagnosis and transplant?

If “yes,” continue with question 11.

If “no” or “unknown” continue with question 12.

Question 11  Specify:

Indicate if glucocorticoid and mineralocorticoid were given to treat adrenal insufficiency.

Question 12  Was treatment given to lower plasma very-long-chain fatty acids at any time prior to transplant?

If “yes,” continue with question 13.

If “no” or “unknown” continue with question 14.

Question 13  Specify:

For each treatment listed, indicate whether it was given to lower plasma very-long-chain fatty acids. Do not leave any responses blank.

Clinical Status Pre-Transplant

Question 14  Is there a history of pre-transplant seizures?

Check “yes” or “no” to indicate if at any time from birth to time of transplant the recipient has had seizures.

Question 15  Was cerebrospinal fluid (CSF) testing done pre-transplant?

If “yes” continue with questions 16 and 17.

If “no” or “unknown” continue with question 18.
Question 16  Report results of most recent tests:

For each test listed, indicate whether the test was performed.

a. If opening pressure testing was performed, report the result in centimeters water (cm H₂O).

b. If total protein testing was performed, record the results and indicate whether the protein was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

c. If serum albumin testing was performed, record the results and indicate whether it was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

d. If serum IgG testing was performed, record the results and indicate whether it was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

Question 17  Date of most recent test:

Enter the date of the most recent cerebrospinal fluid test performed pre-transplant.

Question 18  Magnetic Resonance Imaging (MRI) pre-transplant:

If either “normal” or “abnormal” continue with question 19.

If “no” or “unknown” continue with question 20.

Question 19  Date of most recent report:

NOTE:
If possible, please attach a copy of the MRI report.

Enter the date of the most recent MRI performed pre-transplant.

Question 20  Magnetic Resonance Spectroscopy pre-transplant:

If either “normal” or “abnormal” continue with question 21.

If “no” or “unknown” continue with question 22.

Question 21  Date of most recent test prior to transplant:

NOTE:
If possible, please attach a copy of the Magnetic Resonance Spectroscopy report.

Enter the date of the most recent Magnetic Resonance Spectroscopy performed pre-transplant.
Question 22  Were nerve conduction velocities tested pre-transplant?
   If “yes,” continue with questions 23 and 24.
   If “no” or “unknown” continue with question 25.

Question 23  Specify nerve conduction velocities:
   Enter the result of the median nerve and peroneal nerve velocities in milliseconds (m/sec).

Question 24  Date of most recent test prior to transplant:
   Enter the date of the most recent nerve conduction velocity test performed pre-transplant.

Question 25  Was a Mental Development test done pre-transplant?
   If “yes,” continue with questions 26 through 30.
   If “no” or “unknown” continue with question 31.

Question 26  Indicate test instrument; report results of test done closest to transplant; report score, not percentile:
   Indicate which test instrument was used.

Question 27  Date of test:
   Enter the date of the test done closest to transplant.

Question 28  Full scale score:
   Enter the full scale score. Do not report as a percentile.

   NOTE:
   Depending on the test given, the full scale score may be referred to as a composite or standard score.

Question 29  Verbal score:
   Enter the verbal score. Do not report as a percentile.

   NOTE:
   Depending on the test given, the verbal score may be referred to as a verbal reasoning or verbal I.Q. score.
Question 30  Performance score:

NOTE:
Depending on the test given, the performance score may be referred to as the motor score.

Enter the performance score. Do not report as a percentile.

Question 31  Were the Vineland Adaptive Behavior Scales done pre-transplant?
If “yes,” continue with questions 32 and 33.
If “no” or “unknown” continue with question 34.

Question 32  Score results:
Report the score results for communication skills, daily living skills, and socialization skills.

Question 33  Date of test:
Enter the date of the test done closest to transplant.

Question 34  Was visual acuity tested pre-transplant?
If “yes,” continue with question 35.
If “no” or “unknown” continue with question 38.

Question 35  Is patient blind?
If “yes,” continue with question 38.
If “no,” continue with questions 36 and 37.

Question 36  Visual acuity:
Record the recipient’s visual acuity for both the right and left eyes.

Question 37  Date of test:
Enter the date of the most recent visual acuity test done pre-transplant.
**Question 38**  
Was an audiologic evaluation (auditory brain stem or conditioned response) done pre-transplant?  
If “yes,” continue with question 39.  
If “no” or “unknown” continue with question 40.

**Question 39**  
Tympanometry results:  
Check the box that corresponds to the test results for the right ear and the left ear.

**Question 40**  
Was the hearing loss (HL) in decibels (dB) assessed at the speech threshold for 500 hertz (HZ)?  
If “yes,” continue with question 41.  
If “no” or “unknown” continue with question 42.

**Question 41**  
Speech Threshold results at 500 HZ:  

<table>
<thead>
<tr>
<th>NOTE:</th>
<th>See the Degree of Hearing Loss chart for scale ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Check the box that corresponds to the test results for the right ear and the left ear.</td>
</tr>
</tbody>
</table>

**Question 42**  
Was the hearing loss (HL) in decibels (dB) assessed at the speech threshold for 2000 hertz (HZ)?  
If “yes,” continue with question 43.

**Question 43**  
Speech Threshold results at 2000 HZ:  

<table>
<thead>
<tr>
<th>NOTE:</th>
<th>See the Degree of Hearing Loss chart for scale ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Check the box that corresponds to the assessment at the speech threshold for the right ear and the left ear.</td>
</tr>
</tbody>
</table>
Instructions for
Form 120, 520, 620 – Insert XIV
Mucopolysaccharidoses and
Other Storage Diseases

NATIONAL MARROW DONOR PROGRAM®
Form 120, 520, 620 – Insert XIV
Mucopolysaccharidoses and Other Storage Diseases

This form is designed to obtain data on the recipient’s neurological, visual, and auditory status just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520, or 620 question 8, is a mucopolysaccharidosis or storage disease. Form 120, 520 or 620 is not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

Form Key Fields:

All data reported in the key field section must be identical to the data reported in the key field section for the corresponding Form 120, 520, or 620.

A. Unrelated Recipient NMDP ID: [Blank]
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: [Blank]
   Print the recipient’s last name using capital letters.

C. Recipient Local ID (optional): [Blank]
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: [Blank]
   Enter the date on which you are completing this form.

E. TC Code: [Blank]
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: [Blank]
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product type: □ Marrow □ PBSC □ Cord blood
   (Form 120)      (Form 520)      (Form 620)
   Check the box that corresponds to the transplant product type.
**Question 1**  Which enzyme deficiency was detected at diagnosis?

Indicate which enzyme deficiency was detected at diagnosis.

**Question 2**  Record the leukocyte enzyme levels at diagnosis:

<table>
<thead>
<tr>
<th>NOTE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the enzyme results for either the recipient or donor are reported in units other than those listed, attach a copy of the lab report and leave this question blank on the form. NMDP staff will determine if the lab result can be converted to nmol/hr/mg protein or pmol/hr/mg protein.</td>
</tr>
</tbody>
</table>

2a. Report the recipient’s enzyme level at diagnosis. Indicate whether the enzyme was reported in nanomoles per hour per milligram protein (nmol/hr/mg protein) or in picomoles per hour per milligram protein (pmol/hr/mg protein).

2b. Report the donor’s enzyme level. Indicate whether the enzyme was reported in nanomoles per hour per milligram protein (nmol/hr/mg protein) or in picomoles per hour per milligram protein (pmol/hr/mg protein).

**Question 3**  Was treatment given for the disease between diagnosis and transplant?

If “yes,” continue with question 4.

If “no” or “unknown” continue with question 5.

**Question 4**  Specify:

For each treatment listed, indicate whether or not it was given. Do not leave any responses blank.

**Clinical Status Pre-Transplant**

**Question 5**  Was cerebrospinal fluid (CSF) testing done pre-transplant?

If “yes,” continue with questions 6 and 7.

If “no” or “unknown” continue with question 20.
**Question 6** Report results of most recent tests:

For each test listed, indicate whether the test was performed.

a. If opening pressure testing was performed, report the result in centimeters water (cm H₂O).

b. If total protein testing was performed, record the results and indicate whether the protein was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

c. If serum albumin testing was performed, record the results and indicate whether it was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

d. If serum IgG testing was performed, record the results and indicate whether it was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

**Question 7** Date of most recent test:

Enter the date of the most recent cerebrospinal fluid test performed pre-transplant.

**Question 8** Magnetic Resonance Imaging (MRI) of the brain/spine pre-transplant:

If “yes” continue with questions 9 and 10.

If “no” or “unknown” continue with question 11.

**Question 9** Specify location of abnormalities:

**NOTE:**
If possible, please attach a copy of the MRI report.

a. Indicate if ventricular (hydrocephalus) abnormalities were detected. If hydrocephalus is not mentioned in the report, you may infer that it was not present on the MRI.

b. Indicate if odontoid hypoplasia abnormalities were detected. If odontoid (may also be referred to as dens or odontoid process) hypoplasia (erosion) is not mentioned in the report, you cannot infer its absence and must answer the question as “unknown.”

**Question 10** Date of test:

Enter the date of the most recent MRI performed pre-transplant.
Question 11  Was a Mental Development test done pre-transplant?

If “yes,” continue with questions 12 through 16.

If “no” or “unknown” continue with question 17.

Question 12  Indicate test instrument; report results of test done closest to transplant; report score, not percentile:

Indicate which test instrument was used.

Question 13  Date of test:

Enter the date of the test done closest to transplant.

Question 14  Full scale score:

NOTE: Depending on the test given, the full scale score may be referred to as a composite or standard score.

Enter the full scale score. Do not report as a percentile.

Question 15  Verbal score:

NOTE: Depending on the test given, the verbal score may be referred to as a verbal reasoning or verbal I.Q. score.

Enter the verbal score. Do not report as a percentile.

Question 16  Performance score:

NOTE: Depending on the test given, the performance score may be referred to as the motor score.

Enter the performance score. Do not report as a percentile.

Question 17  Were the Vineland Adaptive Behavior Scales done pre-transplant?

If “yes,” continue with questions 18 and 19.

If “no” or “unknown” continue with question 20.
Question 18  Score results:
Report the score results for communication skills, daily living skills, and socialization skills.

Question 19  Date of test:
Enter the date of the test done closest to transplant.

Question 20  Was an eye exam done pre-transplant?
If “yes” continue with questions 21 through 23.
If “no” or “unknown” continue with question 24.

Question 21  Visual acuity:
Record the recipient’s visual acuity for both the right and left eyes.

Question 22  Was corneal clouding present?
Indicate “yes” or “no” if the eye exam detected corneal clouding.

Question 23  Date of most recent test:
Enter the date of the eye exam done closest to transplant.

Question 24  Was an audiologic evaluation (auditory brain stem or conditioned response) done pre-transplant?
If “yes,” continue with question 25.
If “no” or “unknown” continue with question 26.

Question 25  Tympanometry results:
Check the box that corresponds to the test results for the right ear and the left ear.

Question 26  Was the hearing loss (HL) in decibels (dB) assessed at the speech threshold for 500 hertz (HZ)?
If “yes,” continue with question 27.
If “no” or “unknown” continue with question 28.
**Question 27**  Speech Threshold results at 500 HZ:

NOTE:

See the Degree of Hearing Loss chart for scale ranges

Check the box that corresponds to the test results for the right ear and the left ear.

**Question 28**  Was the hearing loss (HL) in decibels (dB) assessed at the speech threshold for 2000 hertz (HZ)?

If “yes,” continue with question 29.

If “no” or “unknown” continue with question 30.

**Question 29**  Speech Threshold results at 2000 HZ:

NOTE:

See the Degree of Hearing Loss chart for scale ranges

Check the box that corresponds to the assessment at the speech threshold for the right ear and the left ear.

**Question 30**  Was pulmonary function testing done pre-transplant?

If “yes,” continue with questions 31 and 32.

If “no” or “unknown” continue with question 33.

**Question 31**  Oxygen saturation on room air:

Enter the saturation as a percentile.

**Question 32**  Results of most recent pulmonary function test:

NOTE:

If possible, please attach a copy of the report.

Check the box that corresponds to the test result.
**Question 33** Was an echocardiogram done pre-transplant?

If “yes,” continue with questions 34 and 35.

If “no” or “unknown” continue with question 36.

**Question 34** Valvular insufficiency:

For each valve listed, check the box that corresponds to the degree of insufficiency.

**Question 35** Date of test:

Enter the date of the echocardiogram done closest to transplant.

**Question 36** Was the cardiac contractility tested pre-transplant?

If “yes,” continue with questions 37 and 38.

**Question 37** Ejection fraction:

**NOTE:**

You are not required to report both ejection and shortening fraction; only one is required. However, if results for both are known, please report both.

Enter the fraction as a percentile score.

**Question 38** Shortening fraction:

**NOTE:**

You are not required to report both ejection and shortening fraction; only one is required. However, if results for both are known, please report both.

Enter the fraction as a percentile score.
Instructions for
Form 580
Filgrastim Mobilized PBSC Protocol
Transplant Center PBSC Product Analysis

NATIONAL MARROW DONOR PROGRAM®
Form 580
Filgrastim Mobilized PBSC Protocol
Transplant Center PBSC Product Analysis

The Form 580 is designed to capture data on the laboratory analysis of the PBSC product. If two products are collected, a separate analysis must be performed on each product, and separate forms must be completed for each product. Do not pool products prior to analysis.

This form becomes due on the date of the first apheresis collection, and, if a second product is collected, a second Form 580 will become due on the date of the second apheresis collection.

Form Key Fields:

A. Donor NMDP ID: [ ] - [ ] - [ ]
   Enter the nine-digit NMDP Donor ID number.

B. Recipient NMDP ID: [ ] - [ ] - [ ]
   Enter the seven-digit NMDP Recipient ID number.

C. DC Code: [ ] [ ] [ ]
   Enter the 3-digit code of the Donor Center providing the product.

D. TC Code: [ ] [ ] [ ]
   Enter the 3-digit Transplant Center code.

E. Today’s Date: [ ] [ ] [ ]
   Enter the date on which you are completing this form.

F. Date of PBSC infusion for which this form is being completed:
   [ ] [ ] [ ]
   Enter the date the PBSC product was infused.

G. This form is being completed for: 1 [ ] Product One 2 [ ] Product Two
   (Form 580) (Form 581)

Check if this form is being completed for the first product or the second product.
Product Analysis

If two products are collected, do not pool products prior to analysis. A separate analysis must be performed on each product.

**Question 1**  
Date of receipt of PBSC product at your facility:

Enter the date the PBSC product was delivered to your center.

**Question 2**  
Time of receipt:

Enter the time (as measured using a 24-hour clock) the PBSC product was delivered to your center. See Appendix N for a table converting 12-hour clock times to 24-hour clock times.

**Question 3**  
Shipping temperature:

Check if the PBSC product was transported from the apheresis center to the transplant center on “wet ice 2º – 6º C (not in accordance with protocol),” “frozen gel pack 2º – 6º C,” or “other temperature (not in accordance with protocol).”

**Question 4**  
Total volume of PBSC product:

Enter in milliliters (mL) the total volume of the PBSC product. The total volume may be calculated using the following formula:

\[
\text{Calculating Total Volume:} \quad \frac{\text{Weight of PBSC product in grams}}{1.06} = \text{Volume of PBSC product in mL}
\]

* \(\text{Weight of PBSC product} = \text{Total weight (including bag)} - \text{weight of empty bag}\)

**Example:**

Weight of product: \(\frac{270 \text{ grams}}{1.06} = 254.7 \text{ mL}\)

Product Hematology

CBC and complete WBC differential must be performed on each PBSC product received at the transplant center. A separate Form 580 is completed for each product. See Appendix E for a list of validation ranges. If a value falls outside the valid range, write “verified” next to the value, and initial it.
**Question 5**  Date of CBC and differential:
Enter the date the CBC and WBC differential were performed.

**Question 6**  WBC:
Enter the white blood cell count (WBC) in $10^9/L$.

**Question 7**  Platelets:
Enter the platelet count in $10^9/L$.

**Question 8**  Hematocrit:
Enter the percent hematocrit.

---

**Product WBC Differential**

The differential may be determined either manually or by machine. Differentials determined by machine generally only report out values for neutrophils, lymphocytes, monocytes, and in some cases, eosinophils and basophils. If a cell type is not listed on the lab report, leave it blank on the form, do not enter zeroes. If the differential was determined manually, enter the values listed on the lab report, and enter zeroes for those cells not found on the report. The sum of all values reported for either machine or manual differential should be close to 100%. Attach a copy of the lab report to the form.

**Question 9**  Segmented neutrophils:
Enter the percent segmented neutrophils. If the differential was performed by machine, enter the percent neutrophils (this will include both segmented and band neutrophils.)

**Question 10**  Band neutrophils:
Enter the percent band neutrophils. If the differential was determined by machine and no value is reported, leave this question blank.

**Question 11**  Metamyelocytes:
Enter the percent metamyelocytes. If the differential was determined by machine and no value is reported, leave this question blank.
Question 12  Myelocytes:

Enter the percent myelocytes. If the differential was determined by machine and no value is reported, leave this question blank.

Question 13  Promyelocytes:

Enter the percent promyelocytes. If the differential was determined by machine and no value is reported, leave this question blank.

Question 14  Eosinophils:

Enter the percent eosinophils. If the differential was performed by machine and no value is reported, leave this question blank.

Question 15  Basophils:

Enter the percent basophils. If the differential was performed by machine and no value is reported, leave this question blank.

Question 16  Blasts:

Enter the percent blasts. If the differential was determined by machine and no value is reported, leave this question blank.

Question 17  Lymphocytes:

Enter the percent lymphocytes.

Question 18  Monocytes:

Enter the percent monocytes.
Question 19  Total mononuclear cells:

Enter the total number of mononuclear cells (lymphocytes plus monocytes) contained in the PBSC product.

Calculating Total Mononuclear Cell Count:

\[
\begin{align*}
\text{Percent of Lymphocytes} & + \text{Percent of Monocytes} \\
\times \text{White blood cell count} \times 10^9/L & = \text{Percent of Mononuclear cells} \\
\times \text{Volume of product in Liters (L)} & = \text{Mononuclear cell count} \times 10^9/L \\
\times \text{Volume of product in Liters (L)} & = \text{Total mononuclear cell count} \times 10^9 \\
\end{align*}
\]

Example:

\[
\begin{align*}
\text{Lymphocytes} & + \text{Monocytes} \\
\times \text{White blood cell count} \times 10^9/L & = \text{Mononuclear cells} \\
\times \text{Volume of product in Liters (L)} & = \text{Total mononuclear cell count} \times 10^9 \\
\end{align*}
\]

Question 20 Total CD34+ cells:

Enter the total number of CD34+ cells expressed in \(10^6\).

Question 21 Was the product manipulated at your center prior to infusion?

If the product was manipulated in any way prior to infusion, check “yes” and continue with question 22.

If the product was not manipulated, check “no” and continue with question 25.
Question 22  Indicate what the product was manipulated for:

Check the reason the product was manipulated. Only one reason may be checked. If the product was manipulated for both T-cell depletion and CD34+ cell selection, check “Other” and write, “T-cell depletion, CD34+ cell selection” on the specify line.

If the product was manipulated for T-cell depletion, or if both T-cell depletion and CD34+ cell selection were used, continue with question 23.

If any other product manipulation was done, continue with question 25.

Question 23  Specify method used:

Check the method used for T-cell depletion.

Question 24  If antibodies were used during manipulation, indicate which were used:

Indicate which antibodies were used during product manipulation. Check “yes” or “no” for each antibody listed. Do not leave any responses blank.

Question 25  Volume of infused product:

NOTE:
The total volume reported may be from pooled products. If products are pooled prior to infusion, report the total volume of the pooled product that was infused. In this case, the same value for question 25 will be reported on both the Form 580 for Product One and the Form 580 for Product Two.

Enter the total volume of PBSC product that was infused in milliliters (mL).

Question 26  Mononuclear cell count of infused product:

Enter the total mononuclear cell count of the infused product expressed as a cell concentration.

Tips for Reporting Mononuclear Cell Counts:

Report as a cell concentration (cells/volume). Example: 35 x 10^6 cells/mL
Do not report as a cell dose (cells/patient weight). Example: 2.5 x 10^8 cells/kg
Do not report as a total dose (cells). Example: 17.5 x 10^9 cells
Equivalent units for Mononuclear Cell Concentrations:
\[ n \times 10^9/L = n \times 10^6/mL = \frac{(n \times 1000) \text{cells/mm}^3}{1000} = n \times 10^3/\text{mm}^3 \]

**Example:**
\[ 4.6 \times 10^9/L = 4.6 \times 10^6/mL = \frac{4600 \text{cells/mm}^3}{1000} = 4.6 \times 10^3/\text{mm}^3 \]

**Question 27**  Time (24-hour clock) at start of infusion:
Enter the time (as measured using a 24-hour clock) the PBSC infusion began. See Appendix N for a table converting 12-hour clock times to 24-hour clock times.

**Question 28**  Was a fraction of the product cryopreserved for back-up infusion?

**NOTE:**
Only a portion of the PBSC product may be frozen prior to infusion unless prior approval has been obtained from the NMDP.

Answer this question “yes” if the product was cryopreserved at your facility. Continue with question 29.

Answer this question “no” if the product was not cryopreserved at your facility. Continue with question 31.

**Question 29**  Total volume of cryopreserved product:
Enter the total volume in milliliters (mL) of the product that was cryopreserved for back-up infusion.

**Question 30**  Nucleated cell count of cryopreserved product:
Enter the nucleated cell count in \(10^6\) per milliliter (mL) of the cryopreserved product.

**Question 31**  Were there any adverse events associated with the infusion?
If “yes” continue with question 32.
**Question 32**  Specify:

As accurately as possible, describe the adverse event(s) the recipient experienced as a result of the PBSC infusion.

<table>
<thead>
<tr>
<th>NOTE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse reactions that occur within 24 – 48 hours following an infusion that will be reported to the FDA include death, anaphylaxis, respiratory arrest, circulatory collapse, and new onset of bacteremia. If any of these events occurred, they must be reported to the NMDP by telephone or fax within 48 hours of occurrence.</td>
</tr>
</tbody>
</table>

**Signature**  The person completing the form must sign the form, print his/her name, and provide a phone number, fax number, and e-mail address where he/she can be reached.
Instructions for
Form 680
Cord Blood Unit Supplement

NATIONAL MARROW DONOR PROGRAM®

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Form 680 – Cord Blood Unit Supplement

This form must be completed for all recipients who receive a cord blood transplant facilitated by the National Marrow Donor Program. It must be accompanied by Form 620 – Recipient Baseline and Transplant Data. Form 620 is not considered complete until all required inserts or product analysis forms have been submitted to the Registry and are error free.

Form Key Fields:

All data reported in the key field section (excluding “Today’s Date) must be identical to the data reported in the key field section for the corresponding Form 620.

A. Unrelated Recipient NMDP ID: 

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: 

Print the recipient’s last name using capital letters.

C. Recipient Local ID (optional): 

Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: 

Enter the date on which you are completing this form.

E. TC Code: 

Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: 

Enter the date the transplant occurred. (Date of transplant is the date the cord blood infusion was started.)
Question 1  Cord blood unit (CBU) identification number:
Enter the 9-digit identification number.

Question 2  Date of receipt of CBU at your facility:
Enter the date the cord blood unit was delivered to the transplant center.

Question 3  Time of receipt of CBU:
Enter the time (as measured using a 24-hour clock) the cord blood unit was delivered to the transplant center. See Appendix N for a table converting 12-hour clock times to 24-hour clock times.

Question 4  Were the CBU secondary containers (e.g., insulated shipping containers and unit cassette) intact when they arrived at your center?
If “yes,” continue with question 5.
If “no,” complete an NMDP Adverse Event Reporting Form and fax it to the NMDP. Continue with question 5.

Question 5  Was the CBU completely frozen when it arrived at your center?
If “yes,” continue with question 6.
If “no,” complete an NMDP Adverse Event Reporting Form and fax it to the NMDP. Continue with question 6.

Question 6  Was the CBU stored at your center prior to thawing?
If “yes,” continue with question 7.
If “no,” continue with question 9.

Question 7  Temperature during storage:
Report the storage temperature in degrees Celsius.

Question 8  Date storage started:
Enter the date the transplant center began storing the cord blood unit.
Question 9  Date thawing initiated:

Enter the date the transplant center began to thaw the cord blood unit.

Question 10  Time at initiation of thawing process:

Enter the time (as measured using a 24-hour clock) the transplant center began to thaw the cord blood unit. See Appendix N for a table converting 12-hour clock times to 24-hour clock times.

Question 11  Time at completion of thawing process:

Enter the time (as measured using a 24-hour clock) the cord blood unit finished thawing. See Appendix N for a table converting 12-hour clock times to 24-hour clock times.

Question 12  Was the CBU primary container (e.g., CBU bag) intact upon thawing?

If “yes,” continue with question 13.

If “no,” complete an NMDP Adverse Event Reporting Form and fax it to the NMDP. Continue with question 13.

Question 13  Was the CBU washed in dextran-albumin?

If “yes,” continue with question 14.

If “no,” complete an NMDP Adverse Event Reporting Form and fax it to the NMDP. Continue with question 14.

Question 14  Nucleated cell count of CBU after thawing:

Enter the cell count in $10^6$ per milliliter ($10^6$/mL).

Question 15  Viability of nucleated cells:

Enter the percent of viable nucleated cells.

Question 16  Was the CBU manipulated prior to infusion?

If “yes,” continue with question 17.

If “no,” continue with question 20.
Question 17  Indicate the primary reason the CBU was manipulated:

Check if the cord blood was manipulated for “T-cells removed,” “ex-vivo expansion,” or “other.”

If the cord blood was manipulated to remove T cells, continue with question 18.

If the cord blood was manipulated for ex-vivo expansion, continue with question 20.

If the cord blood was manipulated for any other reason, use the “specify” line to describe the primary reason and continue with question 20.

Question 18  Specify method used:

Check which method was used to remove T-cells from the cord blood unit.

Question 19  If antibodies were used during marrow manipulation, indicate which antibodies were used:

If the answer to question 18 indicates that the method used to remove T-cells from the cord blood included an antibody, specify which were used. Do not leave any responses blank.

If no antibodies were used to remove the T-cells, answer “no” to items a–i, and check “yes” for only item j.

Question 20  Did any adverse events occur while thawing or manipulating the CBU?

If “yes,” complete an NMDP Adverse Event Reporting Form and fax it to the NMDP.

If “no,” continue with question 21.

Question 21  Time cord blood infusion initiated:

Enter the time (as measured using a 24-hour clock) the transplant center began to infuse the cord blood unit. See Appendix N for a table converting 12-hour clock times to 24-hour clock times.

Question 22  Time cord blood infusion completed:

Enter the time (as measured using a 24-hour clock) the cord blood unit finished infusion. See Appendix N for a table converting 12-hour clock times to 24-hour clock times.
Question 23  Volume of cord blood plus additives infused:
   Record the total volume infused in milliliters (mL).

Question 24  Does volume of infused CBU include any agents added to CBU?
   If “yes,” continue with question 25.
   If “no,” continue with question 26.

Question 25  What agents were added:
   Check the agents that were added to the cord blood unit. Do not leave any responses blank.

Question 26  Nucleated cell count of concentration of infused cord blood:
   Enter the cell count in $10^6$ per milliliter ($10^6$/mL).

Question 27  Was the entire volume of cord blood infused?
   If “yes,” continue with question 29.
   If “no,” continue with question 28.

Question 28  Explain:
   Use the area provided to describe the reason the entire volume of cord blood was not infused.

Question 29  Were there any adverse events associated with the infusion?
   If “yes,” complete an NMDP Adverse Event Reporting Form and fax it to the NMDP.
Instructions
for
Form 130, 530, 630
100-Day Follow-Up Visit of Recipient

NATIONAL MARROW DONOR PROGRAM®
FORM 130, 530, 630
100-Day Follow-Up Visit of Recipient

Form 130, 530, 630 is designed to obtain data on engraftment post-transplant and the acute complications following an unrelated stem cell transplant. The answers to all questions should reflect the clinical status of the recipient on the date of actual contact for follow-up evaluation. This should be approximately 100 days post-transplant.

If the recipient died prior to day 100, the Form 130, 530, 630 must be completed at the time of death. All responses should reflect the recipient’s clinical condition at the time of death.

Form 130, 530, 630 becomes due on the 100-day anniversary date of the transplant and is considered past due if not received within 120 days of the 100-day anniversary date.

**Form Key Fields:**

A. Unrelated Recipient NMDP ID:  
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:  
   Print the recipient’s last name using capital letters.

C. Recipient Local ID (optional):  
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:  
   Enter the date on which you are completing this form.

E. TC Code:  
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:  
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Product Type:  
   Check the box that corresponds to the transplant product type.
   - Marrow (Form 130)
   - PBSC (Form 530)
   - Cord blood (Form 630)
Question 1  Date of actual contact with recipient to determine medical status for this follow-up report:

Enter the date the recipient was evaluated to determine medical status post-transplant.

NOTE:
If this form reports the recipient’s death, the date of contact must be the same as the date of death reported on the Form 190, 590, 690. If this form reports a subsequent stem cell infusion from an unrelated donor (original stem cell donor or second unrelated donor) the date of contact must be the same as the date of the subsequent stem cell infusion reported in question 125.

Question 2  Did recipient receive a subsequent stem cell infusion (bone marrow, mobilized peripheral blood stem cells, cord blood) prior to day 100 after the transplant for which this form is being completed?

Indicate whether or not the recipient received a second (or third, etc.) stem cell infusion prior to 100 days post-transplant. Stem cells are defined as peripheral blood stem cells mobilized with Filgrastim (G-CSF), bone marrow, or cord blood. The source of the stem cells may be allogeneic unrelated, allogeneic related, or autologous.

NOTE:
If question 2 is answered “yes,” questions 125-127 “Subsequent Stem Cell Infusion” must be answered.

Question 3  Did recipient die prior to day 100 after the transplant for which this form is being completed?

If “yes,” answers to subsequent questions should reflect the recipient’s clinical status immediately prior to death.

If “no,” answers to subsequent questions should reflect the recipient’s clinical status on the day of actual contact for this follow-up evaluation.

NOTE:
If the recipient died, a Form 190, 590, 690 – Death Information, must be submitted. Subsequent follow-up forms will become due until both the Form 130, 530, 630 reporting death and Form 190, 590, 690 are submitted and error-free.
Question 4  Has recipient received an infusion of unstimulated peripheral blood mononuclear cells or lymphocytes from the original donor?

Answer this question “yes” if the recipient received a blood product that was not mobilized with Filgrastim (G-CSF). Continue with question 5.

Answer this question “no” if the recipient received a Filgrastim mobilized PBSC product. Report infusions with mobilized products in question 2. Continue with question 7.

Question 5  Date the first infusion was given:

Enter the date the first infusion of unstimulated peripheral blood mononuclear cells or lymphocytes was given.

NOTE:
The date of first infusion must be after the stem cell infusion date reported on the Form 120, 520, 620.

Question 6  Indication for the infusion(s) of donor cells:

Indicate the primary reason the recipient received donor mononuclear cells or lymphocytes.

NOTE:
If response 6.2, “treatment for B cell lymphoproliferative disorder” is checked, question 79.b, “B cell lymphoproliferative disorder” must be answered “yes.”

Hematopoietic Reconstitution Post-Transplant

Question 7  Has the recipient received hematopoietic, lymphoid growth factors or cytokines post-transplant?

See Appendix M for a list of growth factors and cytokines (biological response modifiers) and the trade names they are manufactured under.

If ”yes,” continue with question 8.

If “no,” continue with question 15.
Question 8  Specify agents given as planned therapy to promote engraftment, per protocol:

In question 8, only report growth factors that were specified in the transplant protocol as planned therapy to promote engraftment. If the transplant protocol did not include planned growth factor therapy, check “no” for each agent listed.

Question 9  Date therapy started:

Question 10  For each agent the recipient received, enter the date the first dose of the agent was administered.

Question 11  Specify agent:

Question 12  Report growth factors that were given as part of a blinded growth factor or cytokine trial.

Question 13  Report growth factors that were given as part of a blinded growth factor or cytokine trial.

Neutrophil Recovery

NOTE:

Engraftment as reported in this section does not distinguish between allogeneic engraftment (blood and stem cells of donor origin) and autologous engraftment (blood and stem cells of host origin). If the patient has auto-engrafted, report engraftment in this section and report results of chimerism tests in question 30.

Engraftment following a subsequent stem cell infusion should also be reported in this section. See Appendix P for a detailed explanation of how to complete this section for subsequent stem cell infusions.

Engraftment is defined as an absolute neutrophil count (ANC) of $\geq 500/mm^3$ for three consecutive lab values obtained on different days. Date of engraftment is the date of the first of three consecutive lab values where the ANC is $\geq 500/mm^3$. At some institutions, the lab reports display the ANC value; however, the ANC value will not be displayed until there are sufficient white blood cells to perform a differential count. At other institutions, the lab reports do not display the ANC and it must be calculated from the while blood cell count (WBC) and the percent of segmented and band neutrophils (if the differential was performed on a machine, the percent neutrophils will include both segmented and band neutrophils). If your institution’s lab reports do not display the ANC value, use the following calculation to determine the ANC:
Tracking the date of engraftment may not always be straightforward. In some cases the ANC may fluctuate for a period of time before the patient fully engrafts. In other cases the ANC may remain above 500/mm³ for several days immediately post-transplant and then fall below 500/mm³. This is most commonly seen in patients transplanted with a diagnosis of CML. Do not begin counting ANC values of ≥ 500/mm³ towards engraftment until the ANC has dropped below 500/mm³ post-transplant and then begins to increase. Recipients who receive a less intensive or non-myeloablative conditioning regimen most likely will have an ANC that remains at ≥ 500/mm³ immediately post-transplant and at no time post-transplant falls below 500/mm³. If this is the case, no date of ANC engraftment will be reported. Since the date of engraftment may be difficult to determine, it can be helpful to track the ANC values on a flow sheet.

**NOTE:**
Calculating Absolute Neutrophil Count (ANC)

\[
\begin{align*}
\text{% Segmented neutrophils} & + \text{% Band neutrophils} = \% \text{Neutrophils} \\
\times \text{White blood cell count/mm}^3 & = \text{Absolute neutrophil count/mm}^3
\end{align*}
\]

**EXAMPLE:**
(Percentage values are expressed as decimals)

\[
\begin{align*}
\text{Segmented neutrophils} & = 0.45 \\
\text{Band neutrophils} & = 0.05 \\
\text{Neutrophils} & = 0.50 \\
\text{White blood cell count} & = 1000/mm^3 \\
\text{Absolute neutrophil count} & = 500/mm^3^* \\
\end{align*}
\]

* ANC 500/mm³ = 0.5 x 10⁹/L = 0.5 x 10⁶/mL = 0.5 x 10³/mm³
NOTE:
Some data managers may find it helpful to create a flow sheet to help track engraftment.

If the ANC declines to < 500/mm³ for three consecutive lab values obtained on different days after engraftment, report the date the first ANC value of < 500/mm³ was recorded as the date of decline.

Question 15 Is (was) there evidence of hematopoietic recovery following this stem cell infusion?

Indicate whether or not there was evidence of hematopoietic recovery (engraftment) following this stem cell infusion.

Check only one response:

1) “Yes, ANC ≥ 500/mm³ achieved and sustained for 3 consecutive lab values obtained on different days with no subsequent decline.” If checked, continue with question 16.

2) “Yes, ANC ≥ 500/mm³ for 3 consecutive lab values obtained on different days with subsequent decline in ANC to < 500/mm³ for greater than 3 days.” If checked, continue with question 17.

3) “No, ANC ≥ 500/mm³ was not achieved and there was no evidence of recurrent disease in the bone marrow.” If checked, continue with question 25.
4) “No, ANC ≥ 500/mm³ was not achieved and there was documented persistent disease in the bone marrow post-transplant.” If checked, continue with question 29.

5) “ANC never dropped below 500/mm³ at any time post-stem cell infusion.” If checked, continue with question 25.

**Question 16** Date ANC ≥ 500/mm³ (first of three consecutive lab values on different days):

Enter the first date the ANC was greater than or equal to 500/mm³ for three consecutive lab values obtained on different days.

**Question 17** Date ANC ≥ 500/mm³ (first of three consecutive lab values on different days):

Enter the first date the ANC was greater than or equal to 500/mm³ for three consecutive lab values obtained on different days.

**Question 18** Date of decline in ANC to < 500/mm³ for greater than 3 days (first of 3 days that ANC declined):

Enter the first date the ANC declined to less than 500/mm³ for three or more consecutive days.

---

**Actual CBC on the First Day of Decline**

**Question 19** WBC:

Enter the white blood cell count (WBC) in 10⁹/L.

**Question 20** Neutrophils:

Enter the percent of neutrophils. This will include both segmented and band neutrophils.

**Question 21** Did recipient recover and maintain ANC ≥ 500/mm³ following the decline?

To answer this question “yes,” an ANC of ≥ 500/mm³ must have been maintained for at least three consecutive lab values obtained on different days.

If “yes,” continue with question 22.

If “no,” continue with question 25.
**Question 22**  Date of ANC recovery:

Enter the first date the recipient recovered an ANC ≥ 500/mm³ for three consecutive lab values obtained on different days.

---

**Actual CBC on the First Day of Recovery**

**Question 23**  WBC:

Enter the white blood cell count (WBC) in 10⁹/L.

**Question 24**  Neutrophils:

Enter the percent of neutrophils. This will include both segmented and band neutrophils.

---

**Platelet Recovery**

The following questions relate to *initial* platelet recovery following the transplant for which this form is being completed. All dates should reflect no transfusions in the previous seven days, and the first of three consecutive laboratory values obtained on different days.

<table>
<thead>
<tr>
<th>Transfusion</th>
<th>Reporting Dates for Platelet Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>10,000</td>
</tr>
<tr>
<td>Date</td>
<td>1-1-97</td>
</tr>
</tbody>
</table>

1st of 3
* Report 1-8-97 as date platelet count ≥ 20,000 x 10⁹/L was achieved.

If the recipient did not receive any platelet transfusions after the transplant, and the platelet count did not fall below 20,000 x 10⁹/L, then record the first day post-transplant that the platelet count was ≥ 20,000 x 10⁹/L.
**Question 25**  Was a platelet count of $\geq 20,000 \times 10^9$/L achieved?

If “yes,” continue with question 26.

If “no,” continue with question 29.

If “platelet count never dropped below $20,000 \times 10^9$/L,” continue with question 27.

**Question 26**  Date platelets $\geq 20,000 \times 10^9$/L:

Enter the date of the first of three consecutive lab values obtained on different days where the platelet count was $\geq 20,000 \times 10^9$/L.

**Question 27**  Was a platelet count of $\geq 50,000 \times 10^9$/L achieved?

If “yes,” continue with question 28.

If “no” or “platelet count never dropped below $50,000 \times 10^9$/L,” continue with question 29.

**Question 28**  Date platelets $\geq 50,000 \times 10^9$/L:

Enter the date of the first of three consecutive lab values obtained on different days where the platelet count was $\geq 50,000 \times 10^9$/L.

**Question 29**  Was the recipient transplanted on a protocol with a conditioning regimen intended to be non-myeloablative?

Indicate “yes” or “no,” and continue with question 30.

**Question 30**  Were chimerism studies performed?

If “yes,” continue with question 31.

If “no,” continue with question 32.
**Question 31** Are chimerism lab reports attached to this form?

Indicate “yes” or “no.” If “yes,” complete the Chimerism Studies chart on page 3 of the Form 130, 530, 630.

**NOTE:**

Chimerism studies are performed to determine the percent of blood cells post-transplant that are produced from donor stem cells and the percent that are produced from host (recipient) stem cells. Different types of blood cells and a variety of laboratory tests can be used to determine if a chimera (presence of both donor- and host-derived cells) exists. If cytogenetic testing was performed to look for disease markers, and the donor and recipient are different sexes, the test may also be used to determine if a chimera exists. If the donor and recipient are of the same sex, cytogenetic testing cannot be used to determine if there is a chimera. If chimerism studies were attempted, but no evaluable results were obtained, do not report the test.

<table>
<thead>
<tr>
<th><strong>Chimerism Table</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date</strong></td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
<tr>
<td><strong>Cell Type</strong></td>
</tr>
<tr>
<td><strong>Cytogenetics – Total Cells Examined</strong></td>
</tr>
<tr>
<td><strong>Cytogenetics – Number of Donor Cells</strong></td>
</tr>
<tr>
<td><strong>Molecular Studies – Percent Donor Cells, Quantitative Method</strong></td>
</tr>
<tr>
<td><strong>Molecular Studies – Percent Donor Cells, Non-Quantitative Method</strong></td>
</tr>
</tbody>
</table>
Acute Graft vs. Host-Disease (GVHD)

Questions 32-45 address the prevention and treatment of acute graft versus host disease (GVHD).

Question 32  Was specific therapy used post-transplant to prevent acute GVHD or graft rejection?

Indicate whether or not a specific immunosuppressive therapy was administered post-transplant to prevent acute GVHD or to immunosuppress host marrow, and thereby promote engraftment of donor stem cells. Most transplant centers have specific GVHD prophylaxis protocols and graft rejection protocols. Any agents a recipient received as a result of these protocols should be included in this section.

If “yes,” continue with question 33.
If “no,” continue with question 34.

NOTE:
Do not include in this section the use of hematopoietic growth factors or T cell depletion of the stem cell that was performed in the laboratory prior to infusing the stem cells.

Question 33  For each agent listed below, indicate whether or not it was used to prevent acute GVHD or graft rejection:

Check “yes” or “no” for each agent listed. Do not leave any responses blank.

Question 34  Did acute GVHD occur?

If “yes,” continue with question 35.
If “no,” continue with question 46.

Question 35  Maximum overall grade:

Check the maximum grade of acute GVHD.
**Question 36**  What was the diagnosis based on?

Indicate if the diagnosis of acute GVHD was based on “histiologic evidence,” “clinical evidence,” or “both.”

**Question 37**  Date of onset:

Enter the date of onset of acute GVHD.

**Question 38**  Is acute GVHD still present at the time of this report?

Indicate “yes,” “no,” “progressed to chronic GVHD,” or “unknown.”

**Question 39 to Question 43**

**Question 39**  Skin:

Check the stage that reflects the body surface area involved with a maculopapular rash.

Use the “Percent Body Surfaces” table below to determine the percent of body surface area involved with a rash.

<table>
<thead>
<tr>
<th>Percent Body Surfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Area</td>
</tr>
<tr>
<td>Each Arm</td>
</tr>
<tr>
<td>Each Leg</td>
</tr>
<tr>
<td>Chest &amp; Abdomen</td>
</tr>
<tr>
<td>Back</td>
</tr>
<tr>
<td>Head</td>
</tr>
<tr>
<td>Pubis</td>
</tr>
</tbody>
</table>

**Question 40**  Intestinal tract:

Check the stage that reflects the volume of diarrhea. Use mL/day for adult recipients and mL/m² body surface area (BSA)/day for pediatric recipients.
NOTE:

Diarrhea in pediatric recipients is assessed in mL/m² rather than mL/kg since the recipient’s weight may be fluctuating due to cardiac failure, renal failure, or severe diarrhea. See nomogram in Appendix Q for determining body surface area (m²).

**Question 41**  Liver:

Check the stage that reflects the bilirubin level.

**Question 42**  Other organ involvement?

If “yes,” continue with question 43.

If “no,” continue with question 44.

**Question 43**  Specify site:

Check “yes” or “no” for each site listed. Do not leave any responses blank.

**Question 44**  Was specific therapy used to treat acute GVHD?

If “yes,” continue with question 45.

If “no,” continue with question 46.

**Question 45**  For each agent listed below indicate whether or not it was used to treat acute GVHD:

See Appendix M for a list of trade names under which generic drugs are manufactured.

Check “yes, continued prophylaxis” if the agent was given for prophylaxis of acute GVHD and the dose was continued at the same level or increased after diagnosis, or if the drug was being tapered prior to diagnosis and then increased after diagnosis.

Check “yes, agent started” if the drug was first administered after acute GVHD was diagnosed.

Check “no, not used” if the agent was not administered.
Chronic Graft vs. Host Disease (GVHD)

Questions 46 through 60 are designed to evaluate the presence and extent of clinical chronic GVHD.

Question 46  Has recipient developed clinical chronic GVHD?

NOTE:

Do not answer question 46 as “yes” if the recipient had a positive lip biopsy or abnormal Schirmer’s test but did not have any clinical symptoms of chronic GVHD that were treated.

If “yes,” continue with question 47.
If “no,” continue with question 59.

Question 47  Onset of chronic GVHD was:

Indicate if the onset of chronic GVHD was “progressive (acute GVHD progressed directly to chronic GVHD),” “interrupted (acute GVHD resolved, then recipient developed chronic GVHD),” or “de novo (recipient never developed acute GVHD).”

Question 48  Date of onset:
Enter the date of onset of chronic GVHD.

NOTE:

If acute GVHD progressed into chronic GVHD, and a date of onset cannot be assigned, use day 100 as date of onset of chronic GVHD.

Question 49  Karnofsky/Lansky score at diagnosis of chronic GVHD:
Enter Karnofsky or Lansky score. Refer to page 10 of Form 130, 530, 630 for a complete scale.

Question 50  Platelet count at diagnosis of chronic GVHD:

If the recipient did not receive any platelet transfusions within seven days prior to the diagnosis of chronic GVHD, enter the platelet count at diagnosis of chronic GVHD. If the recipient received a platelet transfusion within seven days of the diagnosis, leave this question blank and write “not tested” next to the boxes.
Enter the platelet count in $10^9$/L.
Question 51  Total serum bilirubin at diagnosis of chronic GVHD:
Enter the total serum bilirubin in milligrams per deciliter (mg/dL) or micromoles per liter (µmol/L). Check the unit of measurement the value is reported in.

Question 52  Diagnosis was based on:
Indicate if the diagnosis was based on “histologic evidence” (biopsy), “clinical evidence” or “both.”

Question 53  Maximum grade of chronic GVHD:
Indicate the maximum grade of chronic GVHD.

NOTE:
At the present time chronic GVHD is graded as either limited or extensive. Indicate “limited” if the chronic GVHD only includes localized skin involvement and/or liver dysfunction. Indicate “extensive” chronic GVHD if the skin involvement is generalized; if there is liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; if there is involvement of the eye; if there is involvement of the salivary glands or oral mucous membranes; or if there is involvement of any other target organ.

Question 54  Overall severity of chronic GVHD as reported by the Transplant Center:
Indicate if the severity of chronic GVHD as determined by the Transplant Center is “mild,” “moderate,” or “severe.”

NOTE:
This question asks for very subjective data and will not be audited.

Question 55  Indicate if there was organ involvement with chronic GVHD from list below:
Check” yes” or “no” for each indication of organ involvement attributable to chronic GVHD. Do not leave any responses blank.

Question 56  Was specific therapy used to treat chronic GVHD?
If “yes,” continue with question 57.
If “no,” continue with question 58.
Question 57  For each agent listed below, indicate whether or not it was used to treat chronic GVHD:

See Appendix M for a list of trade names under which generic drugs are manufactured.

Check “yes, agent continued” if the agent was given for GVHD prophylaxis or treatment of acute GVHD and the dose was continued at the same level or increased after diagnosis of chronic GVHD, or if the drug was being tapered prior to diagnosis of chronic GVHD and then increased after diagnosis.

Check “yes, agent started” if the drug was first administered after diagnosis of chronic GVHD.

Check “no, not used” if the agent was not administered.

Question 58  Are symptoms of chronic GVHD still present?

Indicate “yes” or “no,” and continue with question 59.

Question 59  Is recipient still taking immunosuppressive agents (including PUVA) to treat or prevent GVHD?

If “yes,” continue with question 61.

If “no,” continue with question 60.

Question 60  Date final treatment administered:

Enter the month and year the final dose of immunosuppressive agent was given to treat or prevent either acute or chronic GVHD.

Organ Function

Pulmonary Function

Questions 61–74 are designed to collect information on pulmonary abnormalities. Report any pulmonary abnormalities that occurred after the start of conditioning up to the time of contact with the recipient.
**Question 61**  Did recipient develop interstitial pneumonitis or ARDS after the start of conditioning to present? (Interstitial pneumonitis is characterized by hypoxia and diffuse interstitial infiltrates on chest X-ray not caused by fluid overload.)

Interstitial pneumonitis may be caused by an infectious agent, usually either a virus or pneumocystis carinii, and occasionally aspergillus. Interstitial pneumonitis may also be idiopathic (no organism was isolated).

If “yes,” continue with question 62.

If “no,” continue with question 67.

**Question 62**  Date of onset:

Enter the date interstitial pneumonitis or ARDS began.

**Question 63**  Were diagnostic tests done?

If “yes,” continue with question 64.

If “no,” continue with question 67.

**Question 64**  Diagnosis was evaluated by:

Check “yes” or “no” for each evaluation method listed. Do not leave any responses blank.

**Question 65**  Was an organism isolated?

If “yes,” continue with question 66.

If “no,” continue with question 67. “No” should be checked if the etiology is idiopathic (no organism isolated).

**Question 66**  Etiology:

Check “yes” or “no” for each organism listed. Do not leave any responses blank.

**Question 67**  Did recipient develop bronchiolitis obliterans after the start of conditioning to present?

If “yes,” continue with question 68.

If “no,” continue with question 71.
NOTE:
In the medical record chart bronchiolitis obliterans may be documented as “BOOP” for Bronchiolitis Obliterans with Organizing Pneumonia.

NOTE:
Bronchiolitis obliterans is often a manifestation of chronic GVHD. Check to see if the recipient has either histological or clinical evidence of chronic GVHD of the lung. If bronchiolitis obliterans is a result of chronic GVHD, this form or a previous form must report that the recipient developed chronic GVHD.

Question 68 Date of onset:
Enter the date the recipient developed bronchiolitis obliterans.

Question 69 Were diagnostic tests done?
If “yes,” continue with question 70.
If “no,” continue with question 71.

Question 70 Diagnosis was evaluated by:
Check “yes” or “no” for each evaluation method. Do not leave any responses blank.

Liver Function

Question 71 Did recipient develop non-infectious liver toxicity after the start of conditioning to present (excluding GVHD)?

NOTE:
Questions 71–74 are designed to collect information on the level of liver dysfunction that is not related to acute or chronic GVHD (e.g., chemotoxicity, cyclosporin toxicity, venoocclusive disease (VOD)). Liver dysfunction secondary to causes other than GVHD may be determined by biopsy, viral culture, or suspected by the clinical picture.
If “yes,” continue with question 72.
If “no,” continue with question 75.

**Question 72**
Date of onset:
Enter the date of onset of liver toxicity.

**Question 73**
Etiology:
Check “yes” or “no” for each cause of liver toxicity listed. Do not leave any responses blank.

**Question 74**
Specify clinical signs and symptoms for diagnosis of liver toxicity:
Check “yes” or “no” for each symptom listed. Do not leave any responses blank.

**Other Organ Impairment / Disorder**

**Question 75**
Has the recipient developed any other clinically significant organ impairment or disorder since the start of conditioning?
If “yes,” continue with question 76.
If “no,” continue with question 78.

**Question 76**
Specify what organ impairment / disorder occurred:
Check “yes” or “no” for each impairment or disorder listed. Do not leave any responses blank.
If renal failure severe enough to warrant dialysis occurred, continue with question 77. Otherwise, continue with question 78.

**Question 77**
Did the recipient receive dialysis?
Indicate if the recipient received dialysis for renal failure since the last reported contact.
New Malignancy

**Question 78** Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear?

**NOTE:**

Only report new or secondary malignancies, lymphoproliferative disorders or myeloproliferative disorders in question 78. Do not report recurrence of the recipient’s primary disease (disease for which the transplant was performed) in this question. Report recurrent disease in questions 98–124, “Disease Status and Treatment Post-Transplant.”

If “yes,” continue with question 79.

If “no,” continue with question 82.

**Question 79** Diagnosis:

Check “yes” or “no” for each impairment or disorder listed. Do not leave any responses blank.

If a B-cell lymphoproliferative disorder occurred, continue with question 80. Otherwise, continue with question 81.

**Question 80** Is the recipient EBV positive?

Indicate if the recipient previously tested positive for Epstein-Barr virus.

**Question 81** Date of diagnosis:

Enter the date of diagnosis. If the recipient developed more than one secondary disease, enter the date the first secondary disease was diagnosed.
Survival and Functional Status

Question 82  Was recipient discharged from hospital after transplant?

**NOTE:**

Answer this question “no” if the recipient died without ever having been discharged from the hospital.

If “yes,” continue with question 83.
If “no” or “not applicable, high-dose therapy and stem cell infusion given as outpatient,” continue with question 84.

Question 83  Date of first discharge from hospital after transplant:
Enter the date of the first discharge from the hospital.

Question 84  Total number of inpatient days in first 100 days post-transplant:
Enter the total number of inpatient days. If the recipient was discharged and readmitted during the first 100 days, the total should include days hospitalized after being re-admitted.

Question 85  Was the recipient alive on the day of contact?
If “yes,” continue with question 86. (Question 3 must be answered “no.”)
If “no,” continue with question 87. (Question 3 must be answered “yes.”)

Question 86  If the recipient was alive on the day of contact, complete the Karnofsky Scale for recipients 16 years or older and the Lansky scale for recipients younger than 16.

Question 87  Was the recipient (age ≥ 6 and ≤ 18 years) attending school on the day of contact?
If “yes,” continue with question 88.
If “no,” “unknown,” or “not applicable, recipient age > 18,” continue with question 90.
If “not applicable, recipient age < 6,” continue with question 98.
**Question 88** Specify student attendance status:
Indicate if the recipient was attending school “part time,” “full time,” or “attendance status unknown.”

**Question 89** Date recipient returned to school:
Enter the date the recipient resumed classes, or check the “date unknown” box.

**Question 90** Was the recipient employed outside the home prior to current illness?
If “yes,” continue with question 91.
If “no,” continue with question 94.
If “unknown” or “not applicable, recipient age < 18 years,” continue with question 98.

**Question 91** Has the recipient returned to work?
If the recipient has returned to work on a part-time or full-time basis, continue with question 92.
If the recipient has not resumed work, continue with question 93.
If the recipient’s work status is “unknown,” continue with question 98.

**Question 92** Date recipient returned to work:
Enter the date the recipient returned to work.
If the date the recipient returned to work is unknown, check the “date unknown” box.

**Question 93** Is recipient able to work but not currently employed?
Indicate if the recipient is able to work, but is not currently employed outside the home.

**Question 94** Has the recipient resumed all usual household activities?
If “yes,” continue with question 95.
If “no” or “unknown,” continue with question 96.
Question 95  Date recipient resumed activities:

Enter the date the recipient resumed all usual household activities.

If the date the recipient resumed all usual household activities is unknown, check the “date unknown” box.

Question 96  Is the recipient currently employed outside the home?

If “yes,” continue with question 97.

If “no” or “unknown,” continue with question 98.

Question 97  Date recipient began work:

Enter the date the recipient began working outside the home on a part-time or full-time basis.

If the date the recipient began working outside the home on a part-time or full-time basis is unknown, check the “date unknown” box.

Disease Status and Treatment Post-Transplant

The questions in this section are disease-specific. Only answer the questions that pertain to the disease reported for this recipient on the Form 120, 520, 620. See Appendix R for a listing of disease-specific inserts.

Leukemia, MDS, Other Malignancy

NOTE:

If the primary disease reported on the Form 120, 520, 620 question 8 was lymphoma, complete Form 130, 530, 630 insert III – Post-Transplant Information for Hodgkin and Non-Hodgkin Lymphoma, and continue with question 125 on the Form 130, 530, 630. See Appendix R for a complete list of diseases that require an insert to report the recipient’s current disease status.
**Question 98**  What is (was) the status of the recipient’s disease at the time of this report or at the time of death?

**NOTE:**

*If the recipient died prior to being evaluated for recurring disease, and an autopsy was not performed, report the disease status as “first complete remission post-transplant.”*

If the status is “first complete remission post-transplant,” continue with question 125.

If the status is “therapy-induced complete remission after persistent disease or relapse post-transplant,” “relapse,” or “persistent disease,” continue with question 99.

**Question 99**  Date of first relapse or persistent disease:

Enter the date the first relapse occurred. If the relapse was detected only on autopsy, enter the date of death. If there was persistent disease, report the date of the test post-transplant that confirmed the presence of persistent disease.

**Question 100**  Site of relapse or persistent disease:

Check “yes” or “no” for each site listed. Do not leave any responses blank.

**Question 101**  Was recipient treated for post-transplant relapse or persistent disease?

If “yes,” continue with question 102.

If “no,” continue with question 125.

**Question 102**  Specify treatments given:

Check “yes” or “no” for each treatment listed. Do not leave any responses blank. Continue with question 125.
Chronic Myelogenous Leukemia (CML) Only

**Question 103** Did CML persist or recur (include clinical and/or cytogenetic relapse) post-transplant?

Answer “yes” if the recipient developed an extramedullary (outside the bone marrow), cytogenetic (Philadelphia chromosome positive or other chromosomal abnormality) or hematologic (blood or bone marrow) relapse. Continue with question 104.

If “no” or “unknown,” continue with question 111.

**Question 104** Date of relapse, or date of first clinical or cytogenetic evidence of disease post-transplant:

Enter the date the extramedullary, cytogenetic, or hematologic relapse was diagnosed.

If the date the extramedullary, cytogenetic, or hematologic relapse was diagnosed is unknown, check the “date unknown” box.

**Question 105** Was initial post-transplant relapse cytogenetic only?

If “yes,” continue with question 106.

If “no,” continue with question 109.

**Question 106** Did hematologic evidence of CML subsequently appear?

Answer “yes” if hematologic evidence of CML appeared after initial cytogenetic relapse. Continue with question 107.

If “no,” continue with question 111.

**Question 107** Date of relapse:

Enter the date of the hematologic relapse.

**Question 108** Phase of CML at initial hematologic relapse:

Indicate if the disease was in “chronic,” “accelerated,” or “blast” phase at relapse. Continue with question 111.
**Question 109** Phase of CML at relapse:

Indicate if the disease was in “chronic,” “accelerated,” or “blast” phase at relapse. Continue with question 110.

**Question 110** Site of relapse:

Indicate if the site of relapse was in the “bone marrow” or if it was “extramedullary,” and continue with question 111.

**Question 111** List all cytogenetic examinations of blood or bone marrow post-transplant:

Enter the date of the cytogenetic examination. Indicate if the source of cells used for the cytogenetic examination was blood or bone marrow.

Enter the number of metaphases examined.

Enter the percentage of cells that were Philadelphia chromosome positive (Ph+).

Indicate if any other cytogenetic abnormalities were found.

**Question 112** List all molecular (BCR / ABL) examinations of blood or bone marrow post-transplant:

Enter the date of the molecular examination.

Indicate if the source of cells used for the molecular examination was blood or bone marrow.

Indicate if the cells were positive for BCR / ABL.

**Question 113** Was treatment for CML given post-transplant?

If “yes,” continue with question 114.

If “no” or “unknown,” continue with question 121.

**Question 114** Was prophylaxis given as planned post-transplant therapy regardless of results of cytogenetic and/or molecular tests?

If “yes,” continue with question 115.

If “no,” continue with question 118.
Question 115  Specify treatments given:

Check “yes,” “no” or “unknown” for each treatment listed. Do not leave any responses blank.

If interferon was given as planned post-transplant therapy regardless of test results, continue with question 116.

If interferon was not given, or if it is unknown whether interferon was given, continue with question 118.

Question 116  Date started:

Enter the date interferon was started post-transplant.

Question 117  Date stopped:

Enter the date interferon was stopped post-transplant.

Question 118  Was treatment given for persistent or recurrent CML?

If “yes,” continue with question 119.

If “no,” continue with question 121.

Question 119  Specify treatments given:

Check “yes,” “no,” or “unknown” for each treatment listed. Do not leave any responses blank.

Question 120  Specify response:

Indicate the best response to treatment.

Question 121  Date current status of CML evaluated:

Enter the date of the most recent evaluation to determine the current status of CML.

Question 122  Was there evidence of CML?

If “yes,” continue with question 123.

If “no” or “unknown,” continue with question 125.
Question 123 Specify evidence of CML:

If “hematologic,” continue with question 124.

If “cytogenetic” or “molecular,” continue with question 125.

Question 124 Specify phase:

Indicate if CML was in “chronic,” “accelerated,” or “blast” phase, or if the phase of CML is “unknown.” Continue with question 125.

Subsequent Stem Cell Infusion

Complete this section if the recipient has received a subsequent stem cell infusion from marrow, mobilized peripheral blood stem cells, or cord blood.

Follow-up on recipients receiving a subsequent stem cell infusion (bone marrow, G-CSF stimulated peripheral blood stem cells, or cord blood) will be determined by the donor source of the stem cells for the subsequent infusion. See Appendix S for a list of follow-up forms due after a subsequent stem cell infusion.

<table>
<thead>
<tr>
<th>Stem Cell Source for Subsequent Infusion</th>
<th>Reporting Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original Unrelated Donor Stem Cell Infusion</td>
<td>Subsequent stem cell infusions from the original donor will be considered a second transplant, regardless of the indication for the infusion. A new Form 120, 520, 620 will be required, and follow-up will continue on the time schedule determined by the second infusion.</td>
</tr>
<tr>
<td>Second Unrelated Donor Stem Cell Infusion</td>
<td>Subsequent stem cell infusions from a second unrelated donor will be considered a second transplant, regardless of the indication for the infusion. A new Form 120, 520, 620 will be required, and follow-up will continue on the time schedule determined by the second infusion.</td>
</tr>
<tr>
<td>Related Donor or Autologous Stem Cell Infusion</td>
<td>Subsequent stem cell infusions from a related donor, or from cryopreserved autologous marrow or mobilized peripheral blood stem cells, will terminate the routine schedule for follow-up. Starting at the point the second infusion is reported, only yearly survival data will be collected on Form 150, 550, 650.</td>
</tr>
<tr>
<td>Cryopreserved Product</td>
<td>Subsequent stem cell infusions of cryopreserved autologous marrow or mobilized peripheral blood stem cells from the original donor will require follow-up based on the infusion date of the initial product.</td>
</tr>
<tr>
<td>Non-NMDP Donor</td>
<td>Subsequent stem cell infusions from non-NMDP donors (cooperative registry donors) will require follow-up based on the infusion date of the initial product.</td>
</tr>
</tbody>
</table>
Question 125  Date of subsequent stem cell infusion:

Enter the date of the stem cell infusion.

Question 126  What was the indication for subsequent stem cell infusion?

Indicate if the subsequent infusion was due to “no engraftment,” “partial engraftment,” “graft failure/rejection after achieving initial engraftment,” “persistent malignancy,” “recurrent malignancy,” “secondary malignancy,” “planned second transplant, per protocol,” or “other.” If “other,” specify the reason for the subsequent infusion.

Question 127  Source of stem cells:

Indicate if the source was “autologous,” “allogeneic, unrelated,” or “allogeneic, related.”

If the source was “allogeneic, unrelated,” specify whether the source was:
“fresh, original donor bone marrow”
“cryopreserved original donor bone marrow”
“fresh, second donor bone marrow” from an NMDP donor”
“non-NMDP bone marrow”
“fresh, original donor mobilized peripheral blood stem cells”
“cryopreserved original donor mobilized peripheral blood stem cells”
“fresh, second donor mobilized peripheral blood stem cells” from an NMDP donor”
“non-NMDP donor mobilized peripheral blood stem cells”
“NMDP cord blood”
“non-NDP cord blood”

Question 128  The person completing the form must also sign the form, print his/her name and provide a phone number, fax number, and e-mail address where he/she can be reached.
Instructions
for
Form 130, 530, 630/140, 540, 640
Post-Transplant Insert I
Severe Combined Immunodeficiency

NATIONAL MARROW DONOR PROGRAM®
Form 130, 530, 630/140, 540, 640 – Post-Transplant Insert I
Severe Combined Immunodeficiency (SCIDS)

This form is designed to obtain data on the recipient’s T cell, B cell, and myeloid engraftment post-transplant.

This form must be completed for all recipients whose primary disease on Form 120, 520, 620 question 8, is SCID, Omenn syndrome, Reticular dysgenesis, Bare lymphocyte syndrome, or other SCID. For these recipients, Form 130, 530, 630 – 100-day Follow-Up Visit of Recipient and Form 140, 540, 640 – Six Month to Two Year Follow-Up Visit of Recipient are not considered complete until this insert is submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient NMDP ID: 

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:

Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID (optional):

Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:

Enter the date on which you are completing this form.

E. TC Code:

Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:

Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Visit: □ 100 day □ 6 month □ 1 year □ 2 year

Check the box that identifies the time period being reported on this form.

H. Product Type: □ Marrow (Form 130/140) □ PBSC (Form 530/540) □ Cord blood (Form 630/640)

Check the box that corresponds to the transplant product type.
Status of Hematologic Engraftment

Question 1  What is the status of T-cell engraftment?

Indicate if the T cell population is “predominantly or completely donor,” “only host T-cells detected,” “mixed chimerism,” or “unknown.”

NOTE:
Status of T cell, B cell, and myeloid engraftment refers to quantitative tests using DNA markers. Prior to the test, peripheral blood cells must have been separated into T cell, B cell, or lymphoid versus myeloid cell populations. If RFLP analyses on unseparated cell populations indicate only donor cells, indicate that T cell, B cell, and myeloid engraftment is “predominantly or completely donor.”

Question 2  What is the status of B-cell engraftment?

Indicate if the B cell population is “predominantly or completely donor,” “only host T-cells detected,” “mixed chimerism,” or “unknown.”

Question 3  What is the status of myeloid engraftment?

Indicate if the myeloid engraftment is “completely donor,” “host only,” “mixed chimerism,” or “unknown.”

Question 4  Since the last report, has the recipient developed an EBV associated B-cell lymphoproliferative disorder?

Check “yes,” “no,” or “unknown.”

NOTE:
If the answer to question 4 is “yes,” then question 79b on Form 130, 530, 630 or question 77b on Form 140, 540, 640 must also be answered “yes.”

If “yes,” continue with question 5.

Question 5  Date of diagnosis:

Enter the date of diagnosis.
Instructions for Form 130, 530, 630/140, 540, 640
Post Transplant Insert II
Wiskott Adrich’s Syndrome

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Form 130, 530, 630/140, 540, 640 – Post-Transplant Insert II
Wiskott-Aldrich Syndrome (WAS)

This form is designed to obtain additional data on the recipient’s platelet count and platelet size post-transplant.

This form must be completed for all recipients whose primary disease on Form 120, 520, 620 question 8, is Wiskott-Aldrich syndrome. Form 130, 530, 630 – 100-day Follow-Up Visit of Recipient and Form 140, 540, 640 – Six Month to Two Year Follow-Up Visit of Recipient are not considered complete for WAS recipients until this insert is submitted to the Registry and is error free.

Form Key Fields:

A. Unrelated Recipient NMDP ID: [___] - [___] - [___]
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: [_______] [_______] [_______] [_______] [_______] [_______] [_______]
   Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID (optional): [___] [___] [___] [___] [___] [___] [___] [___] [___]
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: [___] [___] [___] [___] [___] [___] [___] [___]
   Enter the date on which you are completing this form.

E. TC Code: [___] [___] [___]
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: [___] [___] [___] [___] [___] [___] [___] [___]
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Visit:  □ 100 day  □ 6 month  □ 1 year  □ 2 year
   Check the box that identifies the time period being reported on this form.

H. Product Type:  □ Marrow  □ PBSC  □ Cord blood
   (Form 130/140)  (Form 530/540)  (Form 630/640)
   Check the box that corresponds to the transplant product type.
Question 1  What was the platelet count at most recent follow-up?
According to your laboratory’s criteria, indicate if the platelet count is “normal,” “decreased,” or “unknown.”

Question 2  What was the platelet size at most recent follow-up?
According to your laboratory’s criteria, indicate if the platelet count is “normal,” “decreased,” or “unknown.”

Question 3  Since the last report, has the recipient developed an EBV associated B-cell lymphoproliferative disorder?
Check “yes,” “no,” or “unknown.”

NOTE:
If the answer to question 3 is “yes,” then question 79b on Form 130, 530, 630 or question 77b on Form 140, 540, 640 must also be answered “yes.”

If “yes,” continue with question 4.

Question 4  Date of diagnosis:
Enter the date of diagnosis.
Instructions for
Form 130, 530, 630; 140, 540, 640
and 150, 550, 650 – Insert III
Post-Transplant Information for
Hodgkin and Non-Hodgkin Lymphoma

NATIONAL MARROW DONOR PROGRAM®
Form 130, 530, 630; 140, 540, 640; and 150, 550, 650 – Insert III
Post-Transplant Information for Hodgkin and Non-Hodgkin Lymphoma

This form is designed to obtain data on the recipient’s disease status post-transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520, or 620 question 8, is a type of Hodgkin or non-Hodgkin lymphoma. Form 130, 530 630; 140, 540, 640; or 150, 550, 650 is not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

**Form Key Fields:**

All data reported in the key field section must be identical to the data reported in the key field section for the corresponding Form 130, 530 630; 140, 540, 640; or 150, 550, 650.

A. **Unrelated Recipient NMDP ID:**  
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. **Recipient Last Name:**  
   Print the recipient’s last name using capital letters.

C. **Recipient Local ID (optional):**  
   Enter your Transplant Center’s local ID for the recipient.

D. **Today’s Date:**  
   Enter the date on which you are completing this form.

E. **TC Code:**  
   Enter your Transplant Center’s three-digit code.

F. **Date of Transplant for which this form is being completed:**  
   Enter the date the transplant occurred. (Date of transplant is the date the infusion was started.)
G. Visit:  
- □ Form 130, 530, 630 – 100 day
- □ Form 140, 540, 640 – □ 6 month □ 1 year □ 2 year
- □ Form 150, 550, 650 – □ □ year

Check the box that corresponds to the follow-up form being completed.

If the follow-up form being completed is the Form 140, 540 or 640, check the box that identifies the time period being reported on this form. If the follow-up form being completed is the Form 150, 550 or 650, write in the annual visit number in years (3 or higher).

H. Product type:  
- □ Marrow  
  (Form 130/140/150)  
- □ PBSC  
  (Form 530/540/550)  
- □ Cord blood  
  (Form 630/640/650)

Check the box that corresponds to the transplant product type.
**Question 1**  What was the recipient’s best response to transplant not including planned post-transplant treatment?

Indicate if the best response was “continued complete remission,” “complete remission,” “complete remission undetermined,” “partial remission,” “no response/progressive disease,” or “not evaluable.”

**Question 2**  Was planned treatment (not for progressive disease) given post-transplant?

This question refers only to planned post-transplant treatments reported for the recipient’s 100-day, 6 month and first annual visits.

If “yes,” continue with question 3.

If “no,” continue with question 11.

**Question 3**  Chemotherapy

If “yes,” use the box provided to specify the chemotherapy treatment given.

**Question 4**  Radiation

If “yes,” use the box provided to specify the site(s) where radiation was applied.

**Question 5**  Immune therapy

If “yes,” continue with question 6.

If “no,” continue with question 9.

**Question 6**  IL-2

Indicate whether IL-2 was given as planned immune therapy.

**Question 7**  Linomide

Indicate whether Linomide was given as planned immune therapy.

**Question 8**  Other immune therapy

If “yes,” use the box provided to specify the immune therapy treatment given.

**Question 9**  Other treatment

If “yes,” use the box provided to specify any additional planned treatment given.
**Question 10**  What was the recipient’s best response to transplant including planned post-transplant treatment?

Indicate if the best response was “continued complete remission,” “complete remission,” “complete remission undetermined,” “partial remission,” “no response/progressive disease,” or “not evaluable.”

**Question 11**  Was a Gallium scan done post-transplant?

If “yes,” continue with question 12.

If “no,” continue with question 15.

**Question 12**  Date of scan:

Enter the date the Gallium scan was performed.

**Question 13**  Results:

Indicate whether the results of the Gallium scan were “negative,” “positive,” or “indeterminate / equivocal.”

**Question 14**  Sites:

List the site(s) where the Gallium scan was performed.

**Question 15**  What is the status of lymphoma at the time of last contact or at time of death?

If the status of the lymphoma was “progressive disease,” “recurrent disease,” or “free of lymphoma after post-transplant relapse” continue with question 16.

If the status of the lymphoma was “free of lymphoma with no recurrence post-transplant,” “free of lymphoma except for persistent scan abnormalities of unknown significance, no recurrence post-transplant,” “persistent lymphoma without progression ,” or “not evaluable” continue with question 18.

**Question 16**  Date of recurrence/progression:

Enter the date the lymphoma recurred or progressed. If the date of recurrence or progression has been previously reported, check the box and leave the date blank.
**Question 17** Specify site(s) of first progression:

If the sites of progression have not been previously reported, check “yes,” “no,” or “unknown” for each nodal and extranodal site listed. Do not leave any responses blank.

If the sites have been previously reported, check the box and leave the rest of this question blank.

**Question 18** Date status established:

Enter the date the status of the lymphoma was established.
Instructions for
Form 130, 530, 630 – Insert V
Leukodystrophies
100-day Follow-up Visit of Recipient

NATIONAL MARROW DONOR PROGRAM®
Form 130, 530, 630 – Insert V
Leukodystrophies – 100-day Follow-up Visit of Recipient

This form is designed to obtain data on the recipient’s enzyme level 100 days post-transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520, or 620 question 8, is a type of globoid cell, metachromatic, or adrenoleukodysrophy. Form 130, 530 or 630 is not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

Form Key Fields:

All data reported in the key field section must be identical to the data reported in the key field section for the corresponding Form 130, 530 or 630.

A. Unrelated Recipient NMDP ID: Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: Print the recipient’s last name using capital letters.

C. Recipient Local ID (optional): Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: Enter the date on which you are completing this form.

E. TC Code: Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: Enter the date the transplant occurred. (Date of transplant is the date the infusion was started.)

G. Product type: Check the box that corresponds to the transplant product type.

☐ Marrow (Form 130) ☐ PBSC (Form 530) ☐ Cord blood (Form 630)
Question 1  
For which type of leukodystrophy was the transplant performed?  
Indicate the type of leukodystrophy for which the recipient was transplanted.  
If “Globoid Cell Leukodystrophy,” continue with question 2.  
If “Metachromatic Leukodystrophy,” continue with question 3.  
If “Adrenoleukodystrophy,” continue with question 4.

Questions 2  
Report the enzyme activity as determined 100 days post-transplant:  
Enter the result and indicate if the enzyme was measured in nanomoles per hour per milligram protein (nmol/hr/mg protein) or in picomoles per hour per milligram protein (pmol/hr/mg protein).  

NOTE:
If the enzyme results are reported in units other than those listed, attach a copy of the lab report and leave this question blank on the form. NMDP staff will determine if the lab result can be converted to nmol/hr/mg protein or pmol/hr/mg protein.

Enter the date the recipient’s enzyme activity was tested.

Question 4  
Report the mean fasting plasma very-long-chain fatty acid (VLCFA) C26:0 as determined 100 days post-transplant:  
For recipients transplanted for adrenoleukodystrophy, enter the plasma level as measured in micrograms per milliliter (µg/mL).  
Enter the date that the mean fasting plasma very-long-chain-fatty acid level was measured.
Instructions for
Form 130, 530, 630 – Insert VI
Mucopolysaccharidoses
100-day Follow-up Visit of Recipient

NATIONAL MARROW DONOR PROGRAM®
Form 130, 530, 630 – Insert VI
Mucopolysaccharidoses – 100-day Follow-up Visit of Recipient

This form is designed to obtain data on the recipient’s enzyme level 100 days post-transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520 or 620 question 8, is a mucopolysaccharidosis or storage disease. Form 130, 530 or 630 is not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

Form Key Fields:

All data reported in the key field section must be identical to the data reported in the key field section for the corresponding Form 130, 530 or 630.

A. Unrelated Recipient NMDP ID:  □□□□□ - □□□□ - □
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:  □□□□□□□□□□□□□□□□□□□□□□□□□□□
   Print the recipient’s last name using capital letters.

C. Recipient Local ID (optional):  □□□□□□□□□□□□□□□□□□□□□□□□□□□
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:  □□ □□ □□
   Month  Day  Year
   Enter the date on which you are completing this form.

E. TC Code:  □□□
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:  □□ □□ □□
   Month  Day  Year
   Enter the date the transplant occurred. (Date of transplant is the date the infusion was started.)

G. Product type:  □ Marrow  □ PBSC  □ Cord blood
   (Form 130)  (Form 530)  (Form 630)
   Check the box that corresponds to the transplant product type.
Question 1  Indicate the enzyme that was evaluated for activity level in the first 100 days post-transplant. The enzyme reported on this form must correspond to the enzyme found deficient at diagnosis.

Indicate the enzyme that was evaluated.

Question 2  Enzyme level:

**NOTE:**
If the enzyme results are reported in units other than those listed, attach a copy of the lab report and leave this question blank on the form. NMDP staff will determine if the lab result can be converted to nmol/hr/mg protein or pmol/hr/mg protein.

Report the recipient’s enzyme level and indicate whether the enzyme was reported in nanomoles per hour per milligram protein (nmol/hr/mg protein) or in picomoles per hour per milligram protein (pmol/hr/mg protein).

Question 3  Date of test:

Enter the date the enzyme activity level was evaluated.
Instructions
for
Form 140, 540, 640
Six Month to Two Year Follow-Up
Visit of Recipient

NATIONAL MARROW DONOR PROGRAM®
FORM 140, 540, 640
Six Month to Two Year Follow-Up Visit of Recipient

Form 140, 540, 640 is designed to obtain data on engraftment post-transplant and the acute and chronic complications following an unrelated stem cell transplant. The answers to all questions should reflect the clinical status of the recipient on the date of actual contact for follow-up evaluation. These medical evaluations should be at approximately six months, one year, and two years post-transplant.

If the recipient died after day 100, then Form 140, 540, 640 must be completed at the time of death. All responses should reflect the recipient’s clinical condition at the time of death.

Form 140, 540, 640 becomes due on the six-month, one-year, and two-year anniversary date of the transplant and is considered past due if not received within 90 days of the transplant anniversary date.

Form Key Fields:

A. Unrelated Recipient NMDP ID: __________ - ________ - ________
   Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: ______________________________
   Print the recipient's last name using capital letters.

C. Recipient Local ID (optional): ________________________
   Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: ________ ________ ________
   Enter the date on which you are completing this form.

E. TC Code: ________
   Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: ________ ________ ________
   Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion was started.)

G. Visit:  □ 6 month  □ 1 year  □ 2 year
   Check the box that identifies the time period being reported on this form.

H. Product type:  □ Marrow  □ PBSC  □ Cord blood
   (Form 140) (Form 540) (Form 640)
   Check the box that corresponds to the transplant product type.
**Question 1**  
Date of actual contact with recipient to determine medical status for this follow-up report:

Enter the date the recipient was evaluated to determine medical status post-transplant.

**NOTE:**
If this form reports the recipient’s death, the date of contact must be the same as the date of death reported on the Form 190, 590, 690. If this form reports a subsequent stem cell infusion from a second unrelated donor (donor other than the original stem cell donor), the date of contact must be the same as the date of the subsequent stem cell infusion reported in question 120.

**Question 2**  
Did recipient receive a subsequent stem cell infusion (bone marrow, mobilized peripheral blood stem cells, cord blood, autologous cells) since last report?

Indicate whether or not the recipient received a second (or third, etc.) stem cell infusion since the last report. Stem cells are defined as peripheral blood stem cells mobilized with Filgrastim (G-CSF), bone marrow, or cord blood.

**NOTE:**
If question 2 is answered “yes,” questions 120–122, “Subsequent Stem Cell Infusion” must be answered.

**Question 3**  
Did recipient die since last report?

If “yes,” answers to subsequent questions should reflect the recipient’s clinical status immediately prior to death.

If “no,” answers to subsequent questions should reflect the recipient’s clinical status on day of actual contact for this follow-up evaluation.

**NOTE:**
If the recipient died, a Form 190, 590, 690 – Death Information must be submitted. Subsequent follow-up forms will become due until both the Form 140, 540, 640 reporting death and Form 190, 590, 690 are submitted and error free.
Question 4  Has recipient received an infusion of unstimulated peripheral blood mononuclear cells or lymphocytes from the donor since last report?

Answer this question “yes” if the recipient received a blood product from the original donor that was not mobilized with Filgrastim (G-CSF). Continue with question 5.

Answer this question “no” of the recipient received a Filgrastim mobilized PBSC product. Report infusions with mobilized products in question 2. Continue with question 7.

Question 5  Date the first infusion was given:

Enter the date the first infusion of unstimulated peripheral blood mononuclear cells or lymphocytes was given.

NOTE:
The date of first infusion must be after the stem cell infusion date reported on the Form 120, 520, 620.

Question 6  Indication for the infusion(s) of donor cells:

Indicate the primary reason the recipient received donor mononuclear cells.

NOTE:
If response 6.2, “treatment for B cell lymphoproliferative disorder” is checked, question 77b, “B cell lymphoproliferative disorder” must be answered “yes.”

Hematopoietic Reconstitution Post-Transplant

Question 7  Has recipient received hematopoietic, lymphoid growth factors or cytokines since last report?

See Appendix M for a list of growth factors and cytokines (biological response modifiers), and the trade names under which they are manufactured.

If ”yes,” continue with question 8.

If “no,” continue with question 15.
Question 8 Specify agents given:

In question 8, only report growth factors that were specified in the transplant protocol as planned therapy to promote engraftment. If the transplant protocol did not include planned growth factor therapy, check “no” for each agent listed.

Question 9 Code for indication of therapy (from list below):

Question 10

Question 12

Question 14

For each agent the recipient received, enter the reason the agent was administered by entering the appropriate number from the Codes for Indication of Therapy list. If the code is 7 – “Other intervention therapy,” use the line provided to specify the reason the agent was given.

Question 11 Specify agent:

Question 13

Report growth factors that were given as part of a blinded growth factor or cytokine trial.

Neutrophil Recovery

NOTE:

Engraftment as reported in this section does not distinguish between allogeneic engraftment (blood and stem cells of donor origin) and autologous engraftment (blood and stem cells of host origin). If the patient has auto-engrafted, report engraftment in this section and report results of chimerism tests in question 29.

Engraftment following a subsequent stem cell infusion should also be reported in this section. See Appendix P for a detailed explanation of how to complete this section for subsequent stem cell infusions.

Engraftment is defined as an absolute neutrophil count (ANC) of ≥ 500/mm³ for three consecutive lab values obtained on different days. Date of engraftment is the date of the first of three consecutive lab values where the ANC is ≥ 500/mm³. At some institutions, the lab reports display the ANC value; however, the ANC value will not be displayed until there are sufficient white blood cells to perform a differential count. At other institutions, the lab reports do not display the ANC, and it must be calculated from the while blood cell count (WBC) and the percent of segmented and band neutrophils (if the differential was performed on a machine, the percent neutrophils will include both segmented and band neutrophils.) If your institution’s lab reports do not display the ANC value, use the following calculation to determine the ANC:

\[
ANC = \frac{WBC \times \text{segmented neutrophils} + \text{band neutrophils}}{100}
\]
Tracking the date of engraftment may not always be straightforward. In some cases the ANC may fluctuate for a period of time before the patient fully engrafts. In other cases the ANC may remain above 500/mm³ for several days immediately post-transplant and then fall below 500/mm³. This is most commonly seen in patients transplanted with a diagnosis of CML. Do not begin counting ANC values of ≥ 500/mm³ towards engraftment until the ANC has dropped below 500/mm³ post-transplant and then begins to increase. Recipients who receive a less intensive or non-myeloablative conditioning regimen most likely will have an ANC that remains at ≥ 500/mm³ immediately post-transplant and at no time post-transplant falls below 500/mm³. If this is the case, no date of ANC engraftment will be reported. Since the date of engraftment may be difficult to determine, it can be helpful to track the ANC values on a flow sheet.

### NOTE:

**Calculating Absolute Neutrophil Count (ANC)**

\[
\begin{align*}
\text{% Segmented neutrophils} + \text{% Band neutrophils} &= \text{% Neutrophils} \\
\text{x White blood cell count/mm}^3 &= \text{Absolute neutrophil count/mm}^3
\end{align*}
\]

### EXAMPLE:

(Percentage values are expressed as decimals)

\[
\begin{align*}
\text{Segmented neutrophils} + \text{Band neutrophils} &= \text{Neutrophils} \\
\text{x White blood cell count x 1000/mm}^3 &= \text{Absolute neutrophil count 500/mm}^3^* \\
\text{ANC 500/mm}^3 &= 0.5 \times 10^9/L = 0.5 \times 10^6/mL = 0.5 \times 10^3/mm^3
\end{align*}
\]
If the ANC declines to < 500/mm³ for three consecutive lab values obtained on different days after engraftment, report the date the first ANC value of < 500/mm³ was recorded as the date of decline.

**Question 15**  Did the recipient achieve an initial hematopoietic recovery (ANC ≥ 500/mm³ for three consecutive lab values obtained on different days) since last report?

Indicate whether or not there was evidence of hematopoietic recovery (engraftment) following the initial stem cell infusion or a subsequent stem cell infusion. Check only one response.

Check “Yes” if an ANC ≥ 500/mm³ was achieved and sustained for three consecutive lab values with no subsequent decline and initial engraftment post-transplant has not been reported on a previous report. Continue with question 16.

Check “No, recipient’s initial hematopoietic recovery was recorded on a previous report” if the recipient engrafted and it was reported on a previous follow-up form. Continue with question 17.

### Transplant Date May 6

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<th>ANC</th>
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**NOTE:** Some data managers may find it helpful to create a flow sheet to help track engraftment.

![Flow sheet](image-url)
If “No, recipient’s ANC never dropped below 500/mm³,” continue with question 17.

If “No, recipient has never achieved an ANC ≥ 500/mm³ for three consecutive lab values obtained on different days and there is no evidence of recurrent disease,” continue with question 25.

If “No, recipient has never achieved an ANC ≥ 500/mm³ for three consecutive lab values obtained on different days and there was documented persistent malignant disease post-transplant,” continue with question 31.

**Question 16** Date ANC ≥ 500/mm³ (first of 3 consecutive lab values taken on different days):

Enter the first date the ANC was greater than or equal to 500/mm³ for three consecutive lab values obtained on different days.

**Question 17** Following initial hematopoietic recovery (ANC ≥ 500/mm³ for three consecutive lab values obtained on different days) did the recipient experience a subsequent decline in ANC to < 500/mm³ for greater than three days since last report?

If “yes,” continue with question 18.

If “no,” continue with question 25.

**Question 18** Date of decline in ANC to < 500/mm³ for greater than 3 days:

Enter the first date the ANC declined to less than 500/mm³ for three consecutive days.

---

### Actual CBC on the First Day of Decline

**Question 19** WBC:

Enter the white blood cell count (WBC) in 10⁹/L.

**Question 20** Neutrophils:

Enter the percent of neutrophils. This will include both segmented and band neutrophils.
**Question 21** Did recipient recover and maintain ANC ≥ 500/mm³ following the decline?

To answer this question “yes,” an ANC of ≥ 500/mm³ must have been maintained for at least three consecutive lab values obtained on different days.

If “yes,” continue with question 22.

If “no,” continue with question 25.

**Question 22** Date of ANC recovery:

Enter the first date the recipient recovered an ANC ≥ 500/mm³ for three consecutive lab values obtained on different days.

---

### Actual CBC on the First Day of Recovery

**Question 23** WBC:

Enter the white blood cell count (WBC) in 10⁹/L.

**Question 24** Neutrophils:

Enter the percent of neutrophils. This will include both segmented and band neutrophils.

---

### Platelet Recovery

The following questions relate to initial platelet recovery. All dates should reflect no transfusions in the previous seven days, and the first of three consecutive laboratory values obtained on different days.

**Reporting Dates for Platelet Counts**

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<th>Day</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet Count</td>
<td>10,000</td>
<td>35,000</td>
<td>30,000</td>
<td>25,000</td>
<td>10,000</td>
<td>15,000</td>
<td>19,000</td>
<td>23,000</td>
<td>25,000</td>
<td>40,000</td>
<td>50,000</td>
</tr>
<tr>
<td>Date</td>
<td>1-1-97</td>
<td>1-2-97</td>
<td>1-3-97</td>
<td>1-4-97</td>
<td>1-5-97</td>
<td>1-6-97</td>
<td>1-7-97</td>
<td>1-8-97</td>
<td>1-9-97</td>
<td>1-10-97</td>
<td>1-11-97</td>
</tr>
</tbody>
</table>

If the recipient did not receive any platelet transfusions after the transplant, and the platelet count did not fall below 20,000 x 10⁹/L, then record the first day post-transplant that the platelet count was ≥ 20,000 x 10⁹/L.

Report 1-8-97 as date platelet count ≥ 20,000 x 10⁹/L was achieved.

Transfusion 1st of 3

---

---
Question 25  Was a platelet count of $\geq 20,000 \times 10^9/L$ achieved?

If “yes,” continue with question 26.

If “no,” continue with question 29.

If “platelet count never dropped below 20,000 x $10^9/L$” or “platelet count of $\geq 20,000 \times 10^9/L$ previously reported,” continue with question 27.

Question 26  Date platelets $\geq 20,000 \times 10^9/L$:

Enter the date of the first of three consecutive lab values where the platelet count was $\geq 20,000 \times 10^9/L$.

Question 27  Was a platelet count of $\geq 50,000 \times 10^9/L$ achieved:

If “yes,” continue with question 28.

If “no,” “platelet count never dropped below 50,000 x $10^9/L$” or “platelet count of $\geq 50,000 \times 10^9/L$ previously reported,” continue with question 29.

Question 28  Date platelets $\geq 50,000 \times 10^9/L$:

Enter the date of the first of three consecutive lab values obtained on different days where the platelet count was $\geq 50,000 \times 10^9/L$.

Question 29  Were chimerism studies performed?

If “yes,” continue with question 30.

If “no,” continue with question 31.

NOTE:

Chimerism studies are performed to determine the percent of blood cells post-transplant that are produced from donor stem cells and the percent that are produced from host (recipient) stem cells. Different types of blood cells and a variety of laboratory tests can be used to determine if a chimera (presence of both donor and host derived cells) exists. If cytogenetic testing was performed to look for disease markers, and the donor and recipient are different sexes, the test may also be used to determine if a chimera exists.

If the donor and recipient are of the same sex, cytogenetic testing cannot be used to determine if there is a chimera. If chimerism studies were attempted, but no evaluable results were obtained, do not report the test.
Question 30  Are chimerism lab reports attached to this form?

Indicate “yes” or “no.” Complete the Chimerism Studies chart on page 4 of the Form 140, 540, 640.

<table>
<thead>
<tr>
<th>Chimerism Table</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date</strong></td>
</tr>
<tr>
<td><strong>Method</strong></td>
</tr>
<tr>
<td><strong>Cell Type</strong></td>
</tr>
<tr>
<td><strong>Cytogenetics – Total Cells Examined</strong></td>
</tr>
<tr>
<td><strong>Cytogenetics – Number of Donor Cells</strong></td>
</tr>
<tr>
<td><strong>Molecular Studies – Percent Donor Cells, Quantitative Method</strong></td>
</tr>
<tr>
<td><strong>Molecular Studies – Percent Donor Cells, Non-Quantitative Method</strong></td>
</tr>
</tbody>
</table>

Acute Graft vs. Host Disease (GVHD)

Questions 31 – 42 address the onset or flare-up and treatment of acute graft versus host disease (GVHD).
**Question 31** Did acute GVHD occur for the first time (or a flare-up that was more severe) after the 100-day post-transplant report or since previous report?

If “yes,” continue with question 32.
If “no,” continue with question 43.
If “not known,” continue with question 43.

**Question 32** Maximum overall grade:
Check the maximum grade of acute GVHD.

**Question 33** What was the diagnosis based on?
Indicate if the diagnosis was based on “histologic evidence” (biopsy of skin, liver, intestine, or other organ), “clinical evidence” (non-biopsy evidence), or “both.”

**Question 34** Date of onset or flare-up:
Enter the date of onset of acute GVHD. If a flare-up of acute GVHD that was more severe than the initial episode is being reported, enter the date the flare-up was documented. If multiple flare-ups occurred during the reporting period, enter the date of the first flare-up.

**Question 35** Is acute GVHD still present at time of this report?
Check “yes,” “no,” “progressed to chronic GVHD,” or “unknown.”

**Question 36** List the maximum severity of organ involvement:

**Question 37** Skin:
Check the stage that reflects the body surface area involved with a maculopapular rash.
Use the “Percent Body Surfaces” table below to determine the percent of body surface area involved with a rash.

<table>
<thead>
<tr>
<th>Body Area</th>
<th>Percent</th>
<th>Total Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each Arm</td>
<td>9%</td>
<td>18%</td>
</tr>
<tr>
<td>Each Leg</td>
<td>18%</td>
<td>36%</td>
</tr>
<tr>
<td>Chest &amp; Abdomen</td>
<td>18%</td>
<td>18%</td>
</tr>
<tr>
<td>Back</td>
<td>18%</td>
<td>18%</td>
</tr>
<tr>
<td>Head</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Pubis</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Question 37 Intestinal tract:

Check the stage that reflects the volume of diarrhea. Use mL/day for adult recipients and mL/m² body surface area (BSA)/day for pediatric recipients.

**NOTE:**
Diarrhea in pediatric recipients is assessed in mL/m² rather than mL/kg, since the recipient’s weight may be fluctuating due to cardiac failure, renal failure or severe diarrhea. See nomogram in Appendix Q for determining body surface area (m².)

Question 38 Liver:

Check the stage that reflects the bilirubin level.

Question 39 Other organ involvement?

If “yes,” continue with question 40.
If “no,” continue with question 41.

Question 40 Specify site:

Indicate “yes” or “no” for each site listed. Do not leave any responses blank.

Question 41 Was specific therapy used to treat acute GVHD?

If “yes,” continue with question 42.
If “no,” continue with question 43.
**Question 42**

For each agent listed below indicate whether or not it was used to treat AGVHD:

See Appendix M for a list of trade names under which generic drugs are manufactured.

Check “yes, continued prophylaxis” if the agent was given for prophylaxis of acute GVHD and the dose was continued at the same level or increased after diagnosis, or if the drug was being tapered prior to diagnosis and then increased after diagnosis.

Check “yes, agent started” if the drug was first administered post-stem cell transplant.

Check “no, not used” if the agent was not administered.

---

**Chronic Graft vs. Host Disease (GVHD)**

Questions 43 through 58 are designed to evaluate the presence and extent of chronic GVHD.

**Question 43**

Did the recipient have chronic GVHD at the time of the last report?

---

**NOTE:**

The answer to question 43 on Form 140, 540, 640 must correspond to question 58 on the Form 130, 530, 630 or question 56 on the Form 140, 540, 640 (the form submitted just prior to this current report).

If “yes” or “no,” continue with question 44.

If “no symptoms, but receiving treatment,” continue with question 54.

**Question 44**

Has the recipient developed clinical chronic GVHD since the last report?

---

**NOTE:**

Do not answer question 44 as “yes” if the recipient had a positive lip biopsy or abnormal Schirmer’s test but did not have any clinical symptoms of chronic GVHD that were treated.

If “yes,” continue with question 45.

If “no,” continue with question 57.
Question 45  Onset of chronic GVHD was:
Indicate if the onset of chronic GVHD was “progressive (acute GVHD progressed directly to chronic GVHD),” “interrupted (acute GVHD resolved, then recipient developed chronic GVHD),” or “de novo (recipient never developed acute GVHD).”

Question 46  Date of onset:
Enter the date of onset of chronic GVHD.

Question 47  Karnofsky/Lansky score at diagnosis of chronic GVHD:
Enter Karnofsky or Lansky score. Refer to page 10 of Form 140, 540, 640 for a complete scale.

Question 48  Platelet count at diagnosis of chronic GVHD:
If the recipient did not receive any platelet transfusions within seven days prior to the diagnosis of chronic GVHD, enter the platelet count at diagnosis of chronic GVHD. If the recipient received a platelet transfusion within seven days of the diagnosis, leave this question blank and write “not tested” next to the boxes.
Enter the platelet count in $10^9$/L.

Question 49  Total serum bilirubin at diagnosis of chronic GVHD:
Enter the total serum bilirubin in milligrams per deciliter (mg/dL) or micromoles per liter ($\mu$mol/L). Check the unit of measurement the value is reported in.

Question 50  Diagnosis was based on:
Indicate if the diagnosis was based on “histologic evidence” (biopsy), “clinical evidence,” or “both.”
**Question 51**  Overall severity of chronic GVHD as reported by the Transplant Center:

Indicate if the severity of chronic GVHD as defined by the Transplant Center is “mild,” “moderate,” or “severe.”

**NOTE:**
This question asks for very subjective data and will not be audited.

**Question 52**  Maximum grade of chronic GVHD:

Indicate the maximum grade of chronic GVHD.

**NOTE:**
At the present time chronic GVHD is graded as either limited or extensive. Indicate “limited” if the chronic GVHD only includes localized skin involvement and/or liver dysfunction. Indicate “extensive” chronic GVHD if the skin involvement is generalized; if there is liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; if there is involvement of the eye; if there is involvement of the salivary glands or oral mucous membranes; or if there is involvement of any other target organ.

**Question 53**  Indicate if there was organ involvement with chronic GVHD from list below:

Check “yes” or “no” for each indication of organ involvement attributable to chronic GVHD. Do not leave any responses blank.

**Question 54**  Was specific therapy used to treat chronic GVHD?

If “yes,” continue with question 55.

If “no,” continue with question 56.
Question 55  For each agent listed below, indicate whether or not it was used to treat chronic GVHD:

See Appendix M for a list of trade names under which generic drugs are manufactured.

Check “yes, agent continued” if the agent was given for prophylaxis of chronic GVHD or treatment of acute GVHD and the dose was continued at the same level or increased after diagnosis, or if the drug was being tapered prior to diagnosis and then increased after diagnosis.

Check “yes, agent started” if the drug was first administered post-stem cell transplant for treatment of chronic GVHD.

Check “no, not used” if the agent was not administered.

Question 56 Are symptoms of chronic GVHD still present?

Indicate “yes” or “no,” and continue with question 57.

Question 57 Is recipient still taking immunosuppressive agents (including PUVA) to treat or prevent GVHD?

If “yes,” continue with question 59.

If “no,” continue with question 58.

Question 58 Date final treatment administered:

Enter the month and year the final dose of immunosuppressive agent was given to treat or prevent either acute or chronic GVHD.

Organ Function

Pulmonary Function

Questions 59–68 are designed to collect information on pulmonary abnormalities. Report any pulmonary abnormalities that occurred after the start of conditioning up to the time of contact with the recipient.
**Question 59** Has recipient developed interstitial pneumonitis since last report? (Interstitial pneumonitis is characterized by hypoxia and diffuse interstitial infiltrates on chest X-ray not caused by fluid overload.)

Interstitial pneumonitis may be caused by an infectious agent, usually either a virus or pneumoncystis carinii, and occasionally aspergillus. Interstitial pneumonitis may also be idiopathic (no organism was isolated).

If “yes,” continue with question 60.
If “no,” continue with question 65.

**Question 60** Date of onset:
Enter the date interstitial pneumonitis began.

**Question 61** Were diagnostic tests done?
If “yes,” continue with question 62.
If “no,” continue with question 65.

**Question 62** Diagnosis was evaluated by:
Check “yes” or “no” for each evaluation method listed. Do not leave any responses blank.

**Question 63** Was an organism isolated?
If “yes,” continue with question 64.
If “no,” continue with question 65. “No” should be checked if the etiology is idiopathic (no organism isolated).

**Question 64** Etiology:
Check “yes” or “no” for each organism listed. Do not leave any responses blank.
**Question 65**  
Did recipient develop bronchiolitis obliterans since last report?  
If “yes,” continue with question 66.  
If “no,” continue with question 69.

**NOTE:**  
Bronchiolitis obliterans is often a manifestation of chronic GVHD. Check to see if the recipient has either histological or clinical evidence of chronic GVHD of the lung. If bronchiolitis obliterans is a result of chronic GVHD, this form or a previous form must report that the recipient developed chronic GVHD. In the medical record chart this may appear as “BOOP” for Bronchiolitis Obliterans with Organizing Pneumonia.

**Question 66**  
Date of onset:  
Enter the date the recipient developed bronchiolitis obliterans.

**Question 67**  
Were diagnostic tests done?  
If “yes,” continue with question 68.  
If “no,” continue with question 69.

**Question 68**  
Diagnosis was evaluated by:  
Check “yes” or “no” for each evaluation method. Do not leave any responses blank.

**Reproductive Function**

**Question 69**  
Since the last report, has the recipient:  
If the recipient has “become pregnant,” continue with question 70.  
If the recipient has “fathered a child,” continue with question 71.  
If the question is “not applicable” or if the recipient’s reproductive status is “unknown,” continue with question 72.
Question 70  Specify birth status:

Check if the status of the recipient’s pregnancy is “live birth,” “birth pending,” or “miscarriage.”

Question 71  Specify:

Check if the recipient fathered a child “using cryopreserved sperm” or “fathered a child naturally.”

Other Organ Impairment / Disorder

Question 72  Since the last reported contact, has the recipient developed any other clinically significant organ impairment or disorder?

If “yes,” continue with question 73.

If “no,” continue with question 76.

Question 73  Specify what organ impairment / disorder occurred:

Check “yes” or “no” for each impairment or disorder listed. Do not leave any responses blank.

If renal failure severe enough to warrant dialysis occurred, continue with question 74. Otherwise, continue with question 76.

If gonadal dysfunction occurred, continue with question 75. Otherwise, continue with question 76.

Question 74  Did the recipient receive dialysis?

Indicate if the recipient received dialysis for renal failure since the last reported contact.

Question 75  Specify:

Check “yes” or “no” for each gonadal dysfunction listed. Do not leave any responses blank.
New Malignancy

**Question 76** Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear since the last report?

### NOTE:
Only report new or secondary malignancies, lymphoproliferative disorders or myeloproliferative disorders in question 76. Do not report recurrence of the recipient’s primary disease (disease for which the transplant was performed) in this question. Report recurrent disease in questions 93–119, “Disease Status and Treatment Post-Transplant.”

If “yes,” continue with question 77.
If “no,” continue with question 80.

**Question 77** Diagnosis:
Check “yes” or “no” for each impairment or disorder listed. Do not leave any responses blank.

If a B-cell lymphoproliferative disorder occurred, continue with question 78. Otherwise, continue with question 79.

**Question 78** Is the recipient EBV positive?
Indicate if the recipient previously tested positive for Epstein-Barr virus.

**Question 79** Date of diagnosis:
Enter the date of diagnosis. If the recipient developed more than one secondary disease, enter the date the first secondary disease was diagnosed.
Survival and Functional Status

Question 80  Was the recipient alive on the day of contact?

If “yes,” continue with question 81. (Question 3 must be answered “no.”)

If “no,” continue with question 82. (Question 3 must be answered “yes.”)

Question 81  If the recipient was alive on the day of contact, complete the Karnofsky Scale for recipients 16 years or older and the Lansky scale for recipients younger than 16.

Question 82  Was the recipient (age ≥ 6 and ≤ 18 years) attending school on the day of contact?

If “yes,” continue with question 83.

If “no,” “unknown,” or “not applicable, recipient age > 18,” continue with question 85.

If “not applicable, recipient age < 6,” continue with question 93.

Question 83  Specify student attendance status:

Indicate if the recipient was attending school on the date of contact “part time,” “full time,” or “attendance status unknown.”

Question 84  Date recipient returned to school:

Enter the date the recipient resumed classes, or check the “date unknown” box.

Question 85  Was the recipient employed outside the home prior to current illness?

If “yes,” continue with question 86.

If “no,” continue with question 89.

If “unknown” or “not applicable, recipient age < 18 years,” continue with question 93.
**Question 86**  Has the recipient returned to work?

If the recipient has returned to work on a part-time or full-time basis, continue with question 87.

If the recipient has not resumed work, continue with question 88.

If the recipient’s work status is “unknown,” continue with question 93.

**Question 87**  Date recipient returned to work:

Enter the date the recipient resumed work, or check the “date unknown” box.

**Question 88**  Is recipient able to work but not currently employed?

Indicate if the recipient is able to work, but is not currently employed outside the home.

**Question 89**  Has the recipient resumed all usual household activities?

If “yes,” continue with question 90.

If “no” or “unknown,” continue with question 93.

**Question 90**  Date recipient resumed activities:

Enter the date the recipient resumed all usual household activities, or check the “date unknown” box.

**Question 91**  Is the recipient currently employed outside the home?

If “yes,” continue with question 92.

If “no” or “unknown,” continue with question 93.

**Question 92**  Date recipient began work:

Enter the date the recipient began working outside the home on a part-time or full-time basis, or check the “date unknown” box.
Disease Status and Treatment Post-Transplant

The questions in this section are disease-specific. Only answer the questions that pertain to the disease reported for this recipient on the Form 120, 520, 620.

Leukemia, MDS, Other Malignancy

NOTE:
If the primary disease reported on the Form 120, 520, 620 question 8 was lymphoma, complete Form 140, 540, 640 insert III – Post-Transplant Information for Hodgkin and Non-Hodgkin Lymphoma, and continue with question 120 on the Form 140, 540, 640. See Appendix R for a complete list of diseases that require an insert to report the recipient’s current disease status.

Question 93  What is (was) the status of the recipient’s disease at the time of this report or at the time of death?

NOTE:
If the recipient died prior to being evaluated for recurring disease, and an autopsy was not performed, report the disease status as “first complete remission post-transplant.”

If the status is “first complete remission post-transplant,” continue with question 120.

If the status is “therapy-induced complete remission after persistent disease or relapse post-transplant,” “relapse,” or “persistent disease,” continue with question 94.

Question 94  Date of first relapse or persistent disease:

Enter the date the first relapse occurred. If the relapse was detected only on autopsy, enter the date of death. If there was persistent disease, report the date of the test post-transplant that confirmed the presence of persistent disease.
Question 95  Site of relapse or persistent disease:
Check “yes” or “no” for each site listed. Do not leave any responses blank.

Question 96  Was recipient treated for post-transplant relapse or persistent disease?
If “yes,” continue with question 97.
If “no,” continue with question 120.

Question 97  Specify treatments given:
Check “yes” or “no” for each treatment listed. Do not leave any responses blank.
Continue with question 120.

**Chronic Myelogenous Leukemia (CML) Only**

Question 98  Did CML persist or recur (including clinical and/or cytogenetic relapse) since last report?
Answer “yes” if the recipient developed an extramedullary (outside the bone marrow), cytogenetic (Philadelphia chromosome positive or other chromosomal abnormality) or hematologic (blood or bone marrow) relapse. Continue with question 99.
If “no” or “unknown,” continue with question 106.

Question 99  Date of relapse, or date of first clinical or cytogenetic evidence of disease post-transplant:
Enter the date the extramedullary, cytogenetic, or hematologic relapse was diagnosed, or check the “date unknown” box.

Question 100  Was initial post-transplant relapse cytogenetic only?
If “yes,” continue with question 101.
If “no,” continue with question 104.
**Question 101** Did hematologic evidence of CML subsequently appear?

Answer “yes” if hematologic evidence of CML appeared after initial cytogenetic relapse. Continue with question 102.

If “no,” continue with question 106.

**Question 102** Date of hematologic relapse:

Enter the date of the hematologic relapse.

**Question 103** Phase of CML at initial hematologic relapse:

Indicate if the disease was in “chronic,” “accelerated,” or “blast” phase at relapse. Continue with question 106.

**Question 104** Phase of CML at relapse:

Indicate if the disease was in “chronic,” “accelerated,” or “blast” phase at relapse.

**Question 105** Site of relapse:

Indicate if the site of relapse was in the “bone marrow” or if it was “extramedullary,” and continue with question 106.

**Question 106** List all cytogenetic examinations of blood or bone marrow performed since the last reporting period:

Enter the date of the cytogenetic examination. Indicate if the source of cells used for the cytogenetic examination was blood or bone marrow.

Enter the number of metaphases examined.

Enter the percentage of cells that were Philadelphia chromosome positive (Ph+). Indicate if any other cytogenetic abnormalities were found.

**Question 107** List all molecular (BCR / ABL) examinations of blood or bone marrow performed since the last reporting period:

Enter the date of the molecular examination.

Indicate if the source of cells used for the molecular examination was blood or bone marrow.

Indicate if the cells were positive for BCR / ABL.
**Question 108**  Was treatment for CML given post-transplant?

If “yes,” continue with question 109.

If “no” or “unknown,” continue with question 116.

**Question 109**  Was prophylaxis given as planned post-transplant therapy regardless of results of cytogenetic and/or molecular tests?

If “yes,” continue with question 110.

If “no,” continue with question 113.

**Question 110**  Specify treatments given:

Check “yes,” “no” or “unknown” for each treatment listed. Do not leave any responses blank.

If interferon was given as planned post-transplant therapy regardless of test results, continue with question 111.

**Question 111**  Date started:

Enter the date interferon was started post-transplant.

**Question 112**  Date stopped:

Enter the date interferon was stopped post-transplant.

**Question 113**  Was treatment given for persistent or recurrent CML?

If “yes,” continue with question 114.

If “no,” continue with question 116.

**Question 114**  Specify treatments given:

Check “yes,” “no,” or “unknown” for each treatment listed. Do not leave any responses blank.

**Question 115**  Specify response:

Indicate the best response to treatment of the persistent or recurrent CML.
**Question 116**  Date current status of CML evaluated:

Enter the date of the most recent evaluation to determine the current status of CML.

**Question 117**  Was there evidence of CML?

If “yes,” continue with question 118.
If “no” or “unknown,” continue with question 120.

**Question 118**  Specify evidence of CML:

If “hematologic,” continue with question 119.
If “cytogenetic” or “molecular,” continue with question 120.

**Question 119**  Specify phase:

Indicate if CML was in “chronic,” “accelerated,” or “blast” phase, or if the phase of CML is “unknown.”

---

**Subsequent Stem Cell Infusion**

Complete this section if the recipient has received a subsequent stem cell infusion from marrow, mobilized peripheral blood stem cells, or cord blood.

Follow-up on recipients receiving a subsequent stem cell infusion (bone marrow, G-CSF stimulated peripheral blood stem cells, or cord blood) will be determined by the donor source of the stem cells for the subsequent infusion. See Appendix S for a list of follow-up forms due after a subsequent stem cell infusion.

<table>
<thead>
<tr>
<th>Stem Cell Source for Subsequent Infusion</th>
<th>Reporting Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original Unrelated Donor Stem Cell Infusion</td>
<td>Subsequent stem cell infusions from the original donor will be considered a second transplant, regardless of the indication for the infusion. A new Form 120, 520, 620 will be required, and follow-up will continue on the time schedule determined by the second infusion.</td>
</tr>
<tr>
<td>Second Unrelated Donor Stem Cell Infusion</td>
<td>Subsequent stem cell infusions from a second unrelated donor will be considered a second transplant, regardless of the indication for the infusion. A new Form 120, 520, 620 will be required, and follow-up will continue on the time schedule determined by the second infusion.</td>
</tr>
</tbody>
</table>
Stem Cell Source for Subsequent Infusion | Reporting Requirements
--- | ---
Related Donor or Autologous Stem Cell Infusion | Subsequent stem cell infusions from a related donor, or from cryopreserved autologous marrow or mobilized peripheral blood stem cells, will terminate the routine schedule for follow-up. Starting at the point the second infusion is reported, only yearly survival data will be collected on Form 150, 550, 650.
Cryopreserved Product | Subsequent stem cell infusions of cryopreserved autologous marrow or mobilized peripheral blood stem cells from the original donor will require follow-up based on the infusion date of the initial product.
Non-NMDP Donor | Subsequent stem cell infusions from non-NMDP donors (cooperative registry donors) will require follow-up based on the infusion date of the initial product.

**Question 120** Date of subsequent stem cell infusion:

Enter the date of the stem cell infusion.

**Question 121** What was the indication for subsequent stem cell infusion?

Indicate if the subsequent infusion was due to “no engraftment,” “partial engraftment,” “graft failure/rejection after achieving initial engraftment,” “persistent malignancy,” “recurrent malignancy,” “secondary malignancy,” “planned second transplant, per protocol,” or “other.” If “other,” specify the reason for the subsequent infusion.

**Question 122** Source of stem cells:

Indicate if the source was “autologous,” “allogeneic, unrelated,” or “allogeneic, related.”

If the source was “allogeneic, unrelated,” specify whether the source was:

- “fresh, original donor bone marrow”
- “cryopreserved original donor bone marrow”
- “fresh, second donor bone marrow” from an NMDP donor”
- “non-NMDP bone marrow”
- “fresh, original donor mobilized peripheral blood stem cells”
- “cryopreserved original donor mobilized peripheral blood stem cells”
- “fresh, second donor mobilized peripheral blood stem cells” from an NMDP donor”
- “non-NMDP donor mobilized peripheral blood stem cells”
- “NMDP cord blood”
- “non-NDP cord blood”
**Question 123**  The person completing the form must also sign the form, print his/her name and provide a phone number, fax number, and e-mail address where he/she can be reached.
Instructions for
Form 140, 540, 640 and 150, 550, 650 – Insert V
Leukodystrophies
Annual Follow-up Visit of Recipient

NATIONAL MARROW DONOR PROGRAM®
Form 140, 540, 640 and 150, 550, 650 – Insert V
Leukodystrophies – Annual Follow-up Visit of Recipient

This form is designed to obtain data on the recipient’s disease status post-transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520 or 620 question 8, is globoid cell, metachromatic, or adrenoleukodystrophy. The follow-up Forms 140, 540 or 640 and 150, 550, or 650 are not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

Form Key Fields:

All data reported in the key field section must be identical to the data reported in the key field section for the corresponding Form 140, 540 or 640 or Form 150, 540 or 650.

A. Unrelated Recipient NMDP ID: [ ] - [ ] - [ ]

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Print the recipient’s last name using capital letters.

C. Recipient Local ID (optional): [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: [ ] [ ] [ ]

Enter the date on which you are completing this form.

E. TC Code: [ ] [ ] [ ]

Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed: [ ] [ ] [ ]

Enter the date the transplant occurred. (Date of transplant is the date the infusion was started.)
G. Visit:  Form 140, 540, 640 – □ 1 year  □ 2 year

Form 150, 550, 650 – □ □ year

If the follow-up form being completed is the Form 140, 540 or 640, check the box that identifies the time period being reported on this form. If the follow-up form being completed is the Form 150, 550 or 650, write in the annual visit number in years (3 or higher).

H. Product type:  □ Marrow  □ PBSC  □ Cord blood

(Form 140/150)  (Form 540/550)  (Form 640/650)

Check the box that corresponds to the transplant product type.
Question 1  For which type of leukodystrophy was the transplant performed?

Indicate the type of leukodystrophy the recipient was transplanted for.

If “Globoid Cell Leukodystrophy,” continue with question 2.

If “Metachromatic Leukodystrophy,” continue with question 3.

If “Adrenoleukodystrophy,” continue with question 4.

Questions 2  Report the enzyme activity as determined at the most recent follow-up evaluation:

Enter the result and indicate if the enzyme was measured in nanomoles per hour per milligram protein (nmol/hr/mg protein) or in picomoles per hour per milligram protein (pmol/hr/mg protein).

NOTE: If the enzyme results are reported in units other than those listed, attach a copy of the lab report and leave this question blank on the form. NMDP staff will determine if the lab result can be converted to nmol/hr/mg protein or pmol/hr/mg protein.

Enter the date the recipient’s enzyme activity was tested.

Question 4  Report the mean fasting plasma very-long-chain fatty acid (VLCFA) C26:0 as determined at the most recent follow-up evaluation:

For recipients transplanted for adrenoleukodystrophy, enter the plasma level as measured in micrograms per milliliter (µg/mL).

Enter the date that the mean fasting plasma very-long-chain-fatty acid level was measured.

Clinical Status Post-Transplant

Question 5  Is there a history of post-transplant seizures attributed to the underlying disease since the last report?

Check “yes” or “no” to indicate whether at any time since the last report the recipient has had seizures.
Question 6  Was cerebrospinal fluid (CSF) testing done since the last report?
If “yes” continue with questions 7 and 8.
If “no” or “unknown” continue with question 9.

Question 7  Report results of most recent tests:
For each test listed, indicate whether the test was performed.
  a. If opening pressure testing was performed, report the result in centimeters water (cm H2O).
  b. If total protein testing was performed, record the results and indicate whether the protein was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).
  c. If serum albumin testing was performed, record the results and indicate whether it was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).
  d. If serum IgG testing was performed, record the results and indicate whether it was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

Question 8  Date of most recent test:
Enter the date of the most recent cerebrospinal fluid test performed post-transplant.

Question 9  Was Magnetic Resonance Imaging (MRI) done since the last report?
If either “normal” or “abnormal” continue with question 10.
If “unknown” or “not done” continue with question 11.

Question 10  Date of most recent report:

NOTE:
If possible, please attach a copy of the MRI report.

Enter the date of the most recent MRI performed post-transplant.

Question 11  Magnetic Resonance Spectroscopy results since the last report:
If either “normal” or “abnormal” continue with question 12.
If “unknown” or “not done” continue with question 13.
**Question 12** Date of most recent test:

```
NOTE:
If possible, please attach a copy of the Magnetic Resonance Spectroscopy report.
```

Enter the date of the most recent Magnetic Resonance Spectroscopy performed post-transplant.

**Question 13** Were nerve conduction velocities tested since the last report?

- If “yes,” continue with questions 14 and 15.
- If “no” or “unknown” continue with question 16.

**Question 14** Specify nerve conduction velocities:

Enter the result of the median nerve and peroneal nerve velocities in milliseconds (m/sec).

**Question 15** Date of most recent test:

Enter the date of the most recent nerve conduction velocity test performed post-transplant.

**Question 16** Was a Mental Development test done since the last report?

- If “yes,” continue with questions 17 through 21.
- If “no” or “unknown” continue with question 22.

**Question 17** Indicate test instrument; report results of most recent test; report score, not percentile:

Indicate which test instrument was used.

**Question 18** Date of most recent test:

Enter the date of the test done since the last report.
Question 19  Full scale score:

**NOTE:**
Depending on the test given, the full scale score may be referred to as a composite or standard score.

Enter the full scale score. Do not report as a percentile.

Question 20  Verbal score:

**NOTE:**
Depending on the test given, the verbal score may be referred to as a verbal reasoning or verbal I.Q. score.

Enter the verbal score. Do not report as a percentile.

Question 21  Performance score:

**NOTE:**
Depending on the test given, the performance score may be referred to as the motor score.

Enter the performance score. Do not report as a percentile.

Question 22  Were the Vineland Adaptive Behavior Scales done since the last report?

If “yes,” continue with questions 23 and 24.

If “no” or “unknown” continue with question 25.

Question 23  Score results:

Report the score results for communication skills, daily living skills, and socialization skills.

Question 24  Date of most recent test:

Enter the date of the test done since either the transplant or the last report.

Question 25  Was visual acuity tested since the last report?

If “yes,” continue with question 26.

If “no” or “unknown” continue with question 29.
**Question 26**  Is patient blind?

If “yes,” continue with question 29.
If “no,” continue with questions 27 and 28.

**Question 27**  Visual acuity:

Record the recipient’s visual acuity for both the right and left eyes.

**Question 28**  Date of most recent test:

Enter the date of the most recent visual acuity test done since either the transplant or the last report.

**Question 29**  Was an audiologic evaluation (auditory brain stem or conditioned response) done since the last report?

If “yes,” continue with question 30.
If “no” or “unknown” continue with question 31.

**Question 30**  Tympanometry results:

Check the box that corresponds to the test results for the right ear and the left ear.

**Question 31**  Was the hearing loss (HL) in decibels (dB) assessed at the speech threshold for 500 hertz (HZ) since the last report?

If “yes,” continue with question 32.
If “no” or “unknown” continue with question 33.

**Question 32**  Speech Threshold results at 500 HZ:

- **NOTE:** See the Degree of Hearing Loss chart for scale ranges.

Check the box that corresponds to the test results for the right ear and the left ear.
**Question 33** Was the hearing loss (HL) in decibels (dB) assessed at the speech threshold for 2000 hertz (HZ) since the last report?

If “yes,” continue with question 34.

If “no” or “unknown” continue with question 35.

**Question 34** Speech Threshold results at 2000 HZ:

<table>
<thead>
<tr>
<th>NOTE:</th>
</tr>
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<tbody>
<tr>
<td>See the Degree of Hearing Loss chart for scale ranges.</td>
</tr>
</tbody>
</table>

Check the box that corresponds to the assessment at the speech threshold for the right ear and the left ear.

**Question 35** Has there been a change in the neurologic status since the last report? (Clinical status, not neuro-psych status.)

<table>
<thead>
<tr>
<th>NOTE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>These questions refer to the clinical neurologic status, not the neuro-psych status.</td>
</tr>
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</table>

If “yes,” continue with question 36.

**Question 36** Status is:

<table>
<thead>
<tr>
<th>NOTE:</th>
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</thead>
<tbody>
<tr>
<td>To report improvement, the report must specifically state improved neurological status, not just status improved. Attach documentation of neurological status (e.g., physical examination, neurological examination, etc).</td>
</tr>
</tbody>
</table>

Check the box that corresponds to the recipient’s current neurologic status.
Instructions for
Form 140, 540, 640 and 150, 550, 650 – Insert VI
Mucopolysaccharidoses
Annual Follow-up Visit of Recipient

NATIONAL MARROW DONOR PROGRAM®
Form 140, 540, 640 and 150, 550, 650 – Insert VI
Mucopolysaccharidoses – Annual Follow-up Visit of Recipient

This form is designed to obtain data on the recipient’s neurological, visual, and auditory status just prior to conditioning for transplant.

This form must be completed for all recipients whose primary disease reported on Form 120, 520 or 620 question 8, is a mucopolysaccharidosis or storage disease. The follow-up Forms 140, 540 or 640 and 150, 550, or 650 are not considered complete until all required disease-specific inserts have been submitted to the Registry and are error free.

Form Key Fields:

All data reported in the key field section must be identical to the data reported in the key field section for the corresponding Form 140, 540, or 640 or Form 150, 550, or 650.

A. Unrelated Recipient NMDP ID:  [ ] - [ ] - [ ]

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name:  [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Print the recipient’s last name using capital letters.

C. Recipient Local ID (optional):  [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date:  [ ] [ ] [ ]  [ ] [ ] [ ]

Enter the date on which you are completing this form.

E. TC Code:  [ ] [ ] [ ]

Enter your Transplant Center’s three-digit code.

F. Date of Transplant for which this form is being completed:  [ ] [ ] [ ]  [ ] [ ] [ ]

Enter the date the transplant occurred. (Date of transplant is the date the infusion was started.)
G. Visit: Form 140, 540, 640 – ☐ 1 year ☐ 2 year

Form 150, 550, 650 – ☐ ☐ year

If the follow-up form being completed is the Form 140, 540 or 640, check the box that identifies the time period being reported on this form. If the follow-up form being completed is the Form 150, 550 or 650, write in the annual visit number in years (3 or higher).

H. Product type: ☐ Marrow (Form 140/150) ☐ PBSC (Form 540/550) ☐ Cord blood (Form 640/650)

Check the box that corresponds to the transplant product type.
Question 1  Indicate the enzyme that was evaluated for activity level since the last follow-up. The enzyme reported on this form must correspond to the enzyme found deficient at diagnosis.

Indicate the enzyme that was evaluated since the last follow-up.

Question 2  Record the enzyme levels:

**NOTE:**

If the enzyme results are reported in units other than those listed, attach a copy of the lab report and leave this question blank on the form. NMDP staff will determine if the lab result can be converted to nmol/hr/mg protein or pmol/hr/mg protein.

Report the recipient’s enzyme levels and indicate whether the enzyme was measured in nanomoles per hour per milligram protein (nmol/hr/mg protein) or in picomoles per hour per milligram protein (pmol/hr/mg protein).

Question 3  Was treatment given for the disease since the last report?

If “yes” continue with question 4.

If “no” or “unknown” continue with question 5.

Question 4  Specify:

For each treatment listed, indicate whether or not it was given. Do not leave and responses blank.

**Clinical Status Post-Transplant**

Question 5  Was cerebrospinal fluid (CSF) testing done since the last report?

If “yes” continue with questions 6 and 7.

If “no” or “unknown” continue with question 8.
**Question 6**  Report results of most recent tests:

For each test listed, indicate whether the test was performed.

a. If opening pressure testing was performed, report the result in centimeters water (cm H₂O).

b. If total protein testing was performed, record the results and indicate whether the protein was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

c. If serum albumin testing was performed, record the results and indicate whether it was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

d. If serum IgG testing was performed, record the results and indicate whether it was measured in milligrams per deciliter (mg/dL) or in grams per liter (g/L).

**Question 7**  Date of most recent test:

Enter the date of the most recent cerebrospinal fluid test performed post-transplant.

**Question 8**  Was Magnetic Resonance Imaging (MRI) of the brain/spine done since the last report?

If “yes” continue with question 9 and 10.

If “no” or “unknown” continue with question 11.

**Question 9**  Specify location of abnormalities:

<table>
<thead>
<tr>
<th>NOTE: If possible, please attach a copy of the MRI report.</th>
</tr>
</thead>
</table>

a. Indicate if ventricular (hydrocephalus) abnormalities were detected. If hydrocephalus is not mentioned in the report, you may infer that it was not present on the MRI.

b. Indicate if odontoid hypoplasia abnormalities were detected. If odontoid (may also be referred to as dens or odontoid process) hypoplasia (erosion) is not mentioned in the report, you cannot infer its absence and must answer the question as “unknown.”

**Question 10**  Date of most recent test:

Enter the date of the most recent MRI performed since either the transplant or the last report.
**Question 11**  Was a Mental Development test done since the last report?
If “yes,” continue with questions 12 through 16.
If “no” or “unknown” continue with question 17.

**Question 12**  Indicate test instrument; report results of most recent test; report score, not percentile:
Indicate which test instrument was used.

**Question 13**  Date of test:
Enter the date of the test done since either the transplant or the last report.

**Question 14**  Full scale score:

**NOTE:**
Depending on the test given, the full scale score may be referred to as a composite or standard score.
Enter the full scale score. Do not report as a percentile.

**Question 15**  Verbal score:

**NOTE:**
Depending on the test given, the verbal score may be referred to as a verbal reasoning or verbal I.Q. score.
Enter the verbal score. Do not report as a percentile.

**Question 16**  Performance score:

**NOTE:**
Depending on the test given, the performance score may be referred to as the motor score.
Enter the performance score. Do not report as a percentile.

**Question 17**  Were the Vineland Adaptive Behavior Scales done since the last report?
If “yes,” continue with questions 18 and 19.
If “no” or “unknown” continue with question 20.
**Question 18**  Score results:

Report the score results for communication skills, daily living skills, and socialization skills.

**Question 19**  Date of test:

Enter the date of the test done since either the transplant or the last report.

**Question 20**  Was an eye exam done since the last report?

If “yes” continue with questions 21 through 23.

If “no” or “unknown” continue with question 24.

**Question 21**  Visual acuity:

Record the recipient’s visual acuity for both the right and left eyes.

**Question 22**  Was corneal clouding present?

Indicate “yes” or “no” if the eye exam detected corneal clouding.

**Question 23**  Date of test:

Enter the date of the eye exam done since the last report.

**Question 24**  Was an audiologic evaluation (auditory brain stem or conditioned response) done since the last report?

If “yes,” continue with question 25.

If “no” or “unknown” continue with question 26.

**Question 25**  Tympanometry results:

Check the box that corresponds to the test results for the right ear and the left ear.

**Question 26**  Was the hearing loss (HL) in decibels (dB) assessed at the speech threshold for 500 hertz (HZ) since the last report?

If “yes,” continue with question 27.

If “no” or “unknown” continue with question 28.
Question 27  Speech Threshold results at 500 HZ:

**NOTE:**
See the Degree of Hearing Loss chart for scale ranges.

Check the box that corresponds to the test results for the right ear and the left ear.

Question 28  Was the hearing loss (HL) in decibels (dB) assessed at the speech threshold for 2000 hertz (HZ) since the last report?

If “yes,” continue with question 29.
If “no” or “unknown” continue with question 30.

Question 29  Speech Threshold results at 2000 HZ:

**NOTE:**
See the Degree of Hearing Loss chart for scale ranges.

Check the box that corresponds to the assessment at the speech threshold for the right ear and the left ear.

Question 30  Has there been a change in the neurologic status since the last report? (Clinical status, not neuro-psych status.)

**NOTE:**
These questions refer to the clinical neurologic status, *not* the neuro-psych status.

If “yes,” continue with question 31.
If “no” or “unknown” continue with question 32.

Question 31  Status is:

**NOTE:**
To report improvement, the report must specifically state improved *neurological* status, *not* just status improved. Attach documentation of neurological status (e.g., physical examination, neurologic examination, etc.).

Check the box that corresponds to the recipient’s current neurologic status.
Question 32  Was pulmonary function testing done since the last report?
If “yes,” continue with questions 33 and 34.
If “no” or “unknown” continue with question 35.

Question 33  Oxygen saturation on room air:
Enter the saturation as a percentile.

Question 34  Results of most recent pulmonary function test:

| NOTE: If possible, attach a copy of the report. |
| Check the box that corresponds to the test result. |

Question 35  Was an echocardiogram done since the last report?
If “yes,” continue with questions 36 and 37.
If “no” or “unknown” continue with question 38.

Question 36  Valvular insufficiency:
For each valve listed, check the box that corresponds to the degree of insufficiency.

Question 37  Date of test:
Enter the date of the most recent echocardiogram.

Question 38  Was the cardiac contractility tested since the last report?
If “yes,” continue with questions 39 and 40.
If “no” or “unknown” continue with question 41.

Question 39  Ejection fraction:

| NOTE: You are not required to report both ejection and shortening fraction; only one is required. However, if results for both are known, please report both. |
Enter the fraction as a percentile score.
**Question 40** Shortening fraction:

<table>
<thead>
<tr>
<th>NOTE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>You are not required to report both ejection and shortening fraction; only one is required. However, if results for both are known, please report both.</td>
</tr>
</tbody>
</table>

Enter the fraction as a percentile score.

**Question 41** Was orthopedic surgery performed since the last report?

If “yes,” continue with question 42.

**Question 42** Specify site(s):

For each site listed, indicate whether orthopedic surgery has been performed since either the transplant or the last report. Do not leave any responses blank.
Instructions
for
Form 150, 550, 650
Yearly Follow-Up for Greater Than Two Years Post-Transplant

NATIONAL MARROW DONOR PROGRAM®
FORM 150, 550, 650
Yearly Follow-Up for Greater Than Two Years Post-Transplant

Form 150, 550, 650 is designed to obtain data on late complications post-transplant, and on functional and survival status. If this form reports the recipient’s death, the answers should reflect the recipient’s clinical status just prior to death.

Form 150, 550, 650 first becomes due on the third anniversary of the transplant and annually thereafter. If a Form 130, 530, 630 or Form 140, 540, 640 reports that the recipient received an autologous or allogeneic related transplant, a Form 150, 550, 650 will be due annually on the transplant anniversary from that point forward. The Form 150, 550, 650 is considered past due if it is not received within 45 days of the anniversary date.

Form Key Fields:

A. Unrelated Recipient NMDP ID: [ ] [ ] - [ ] [ ] - [ ]

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Print the recipient’s last name in all capital letters.

C. Unrelated Recipient Local ID (optional): [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Enter the your Transplant Center’s local ID for the recipient.

D. Today’s Date: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Enter the date on which you are completing this form.

E. TC Code: [ ] [ ] [ ]

Enter the your Transplant Center’s three-digit code.

F. Follow-up Visit for which this form is being completed: [ ] [ ]

Enter which follow-up visit this is (e.g., 03 for third annual follow-up visit).

G. Date of Transplant for which this form is being completed: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Enter the date the transplant occurred. (Date of transplant is the date the stem cell infusion began.)

H. Product Type: [ ] Marrow (Form 150) [ ] PBSC (Form 550) [ ] Cord blood (Form 650)

Check the box that corresponds to the transplant product type.
**Survival Status**

**Question 1** Is the recipient alive?

**NOTE:**
If this form reports the recipient’s death, the date of contact must be the same as the date of death reported on the Form 190, 590, 690.

If “yes,” answers to subsequent questions should reflect clinical status on day of actual contact for this follow-up evaluation. Continue with question 2.

If “no,” answers to subsequent questions should reflect clinical status immediately prior to death. Continue with question 3.

**Question 2** Give date of most recent contact:

Enter the date of the most recent contact with the recipient, and continue with question 4.

**Question 3** Give date of death:

If the recipient has died, enter the date of death and complete a Form 190, 590, 690, “Recipient Death Information.” Answers to all subsequent questions should reflect the recipient’s clinical status just prior to death. Continue with question 16.

**Functional Status**

Two scales are used to report the functional status of the recipient. The Karnofsky Scale is designed for recipients aged 16 years and older and is not appropriate for children under the age of 16 years. The Lansky scale is designed for recipients less than 16 years old.

**Question 4** Complete the Karnofsky Scale for recipients 16 years or older and the Lansky Scale for recipients younger than 16.

**Question 5** Was the recipient (age ≥ 6 and ≤ 18 years) attending school on the day of contact?

If “yes,” continue with question 6.

If “no,” “unknown,” or “not applicable, recipient age > 18,” continue with question 8.

If “not applicable, recipient age < 6,” continue with question 16.
Question 6 Specify student attendance status:

Indicate if the recipient was attending school on the day of contact “part-time,” “full-time,” or “attendance status unknown.”

Question 7 Date recipient returned to school:

Enter the date the recipient returned to school.

Question 8 Was the recipient employed outside the home prior to current illness?

If “yes,” continue with question 9.

If “no,” continue with question 12.

If there has been no change in the recipient’s employment status since the last report, the recipient’s employment status is unknown, or the recipient is less than 18 years old, continue with question 16.

Question 9 Has the recipient returned to work?

If “yes,” continue with question 10.

If “no,” continue with question 11.

If there has been no change in the recipient’s work status since the last report, or the recipient’s work status is unknown, continue with question 16.

Question 10 Date recipient returned to work:

Enter the date the recipient returned to work.

Question 11 Is recipient able to work but not currently employed?

Indicate if the recipient is able to work but is not employed as of the date of contact. Continue with question 16.

Question 12 Has the recipient resumed all usual household activities?

If “yes,” continue with question 13.

If “no,” continue with question 14.

If there has been no change in the recipient’s activities since the last report, or the recipient’s activity is unknown, continue with question 14.
**Question 13**  
Date recipient resumed activities:  
Enter the date the recipient resumed his or her usual household activities.

**Question 14**  
Is the recipient currently employed outside the home?  
If “yes,” continue with question 15.  
If “no,” continue with question 16.  
If there has been no change in the recipient’s employment status since the last report, or the recipient’s employment status is unknown, continue with question 16.

**Question 15**  
Date recipient began work:  
Enter the date the recipient began work outside the home.

### Chronic Graft Versus Host Disease

**Question 16**  
Did the recipient have chronic GVHD at the time of the last report?

**NOTE:**  
The answer to question 16 on Form 150, 550, 650 must correspond to the answer to “Is chronic GVHD still present?” (Form 140, 540, 640 question 56, or Form 150, 550, 650 question 24) on the form submitted just prior to this current report.

If “yes,” continue with question 19.  
If “no,” continue with question 17.

**Question 17**  
Did the recipient develop chronic GVHD since the last report?  
If “yes,” continue with question 18.  
If “no,” continue with question 25.

**Question 18**  
Date of onset:  
Enter the date of onset of chronic GVHD. Continue with question 19.
**Question 19**
Indicate the maximum grade of GVHD since the last report:

**NOTE:**
At the present time chronic GVHD is graded as either limited or extensive. Indicate “limited” if the chronic GVHD only includes localized skin involvement and/or liver dysfunction. Indicate “extensive” chronic GVHD if the skin involvement is generalized; if there is liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; if there is involvement of the eye; if there is involvement of the salivary glands or oral mucous membranes; or if there is involvement of any other target organ.

Indicate if the grade of GVHD is “limited” (localized skin involvement), or “extensive” (generalized skin involvement).

**Question 20**
Overall severity of chronic GVHD as reported by the Transplant Center:
Indicate if the severity of chronic GVHD is “mild,” “moderate,” or “severe” based on the criteria at your center.

**NOTE:**
This question asks for very subjective data and will not be audited.

**Question 21**
Indicate if there was organ involvement with chronic GVHD from list below:
Indicate “yes” or “no” for each organ listed. Do not leave any responses blank.

**Question 22**
Was specific therapy used to treat chronic GVHD?
If “yes,” continue with question 23.
If “no,” continue with question 24.

**Question 23**
For each agent listed below, indicate whether or not it was used to treat chronic GVHD:
Indicate “yes, agent continued,” “yes, agent started,” or “no, not used” for each therapy listed. Do not leave any responses blank.
Question 24  Is chronic GVHD still present at the time of this report?
Check “yes” or “no.”

Question 25  Is recipient still taking immunosuppressive agents (including PUVA) to treat or prevent GVHD?
If “yes,” continue with question 27.
If “no,” continue with question 26.

Question 26  Date final treatment administered:
Enter the date the final treatment of immunosuppressive agent was administered.

New Malignancies

NOTE:
Only report new or secondary malignancies, or lymphoproliferative or myeloproliferative disorders, in question 27. Do not report recurrence of the recipient’s primary disease (disease for which the transplant was performed) in this question. Report recurrent disease in the “Disease Status Post-Transplant” section.

Question 27  Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear?
If “yes,” continue with question 28.
If “no,” continue with question 31.

Question 28  Diagnosis:
Indicate “yes” or “no” for each diagnosis listed. Do not leave any responses blank.
If the new malignancy is a B-cell lymphoproliferative disorder, continue with question 29.

Question 29  Is the recipient EBV positive?
Check “yes” or “no.”

Question 30  Date of diagnosis:
Enter the date of diagnosis. If the recipient developed more than one secondary disease, enter the date the first secondary disease was diagnosed.
Other Organ Impairment/Disorder

Question 31  Since the last reported contact has the recipient developed any other clinically significant organ impairment or disorder?

If “yes,” continue with question 32.

If “no,” continue with “Disease Status Post-Transplant” section.

Question 32  From the list below, indicate what organ impairment/disorder occurred:

Indicate “yes” or “no” for each item listed. Do not leave any responses blank. If the recipient developed gonadal dysfunction, continue with question 33.

Question 33  Specify:

Indicate “yes” or “no” for each gonadal function listed. Do not leave any responses blank.

Disease Status Post-Transplant

NOTE:

Question 34 is disease specific. Only answer the question if the diagnosis listed on the Form 120, 520, 620 is an acute or chronic leukemia, or other malignancy.

Question 34  What is the recipient’s current disease status?

At the time of this report, indicate if the malignancy is in “complete remission,” “therapy induced remission after persistent disease or relapse post-transplant,” “hematologic relapse,” “cytogenetic relapse,” “extramedullary relapse,” or “BCR/ABL positive.”

If the disease status is “complete remission,” continue with question 36.

If the disease status is anything other than “complete remission,” continue with question 35.

See Appendix R for a list of diseases that require an insert to report the recipient’s current disease status.
**Question 35**  
Date of first relapse for this type of relapse:

If the recipient had a post-transplant, hematologic, cytogenetic, or extramedullary relapse, enter the date of first relapse. If the date of relapse was reported on a previous form, check the box for “first relapse date for this type of relapse previously reported.”

---

**Subsequent Stem Cell Infusion**

Complete this section if the recipient has received a subsequent stem cell infusion of marrow, mobilized peripheral blood stem cells, or cord blood.

Follow-up on recipients receiving a subsequent stem cell infusion (bone marrow, G-CSF stimulated peripheral blood stem cells, or cord blood) will be determined by the donor source of the stem cells for the subsequent infusion. See Appendix S for a list of follow-up forms due after a subsequent stem cell infusion.

<table>
<thead>
<tr>
<th>Stem Cell Source for Subsequent Infusion</th>
<th>Reporting Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original Unrelated Donor Stem Cell Infusion</td>
<td>Subsequent stem cell infusions from the original donor will be considered a second transplant, regardless of the indication for the infusion. A new Form 120, 520, 620 will be required, and follow-up will continue on the time schedule determined by the second infusion.</td>
</tr>
<tr>
<td>Second Unrelated Donor Stem Cell Infusion</td>
<td>Subsequent stem cell infusions from a second unrelated donor will be considered a second transplant, regardless of the indication for the infusion. A new Form 120, 520, 620 will be required, and follow-up will continue on the time schedule determined by the second infusion.</td>
</tr>
<tr>
<td>Related Donor or Autologous Stem Cell Infusion</td>
<td>Subsequent stem cell infusions from a related donor, or from cryopreserved autologous marrow or mobilized peripheral blood stem cells, will terminate the routine schedule for follow-up. Starting at the point the second infusion is reported, only yearly survival data will be collected on Form 150, 550, 650.</td>
</tr>
<tr>
<td>Cryopreserved Product</td>
<td>Subsequent stem cell infusions of cryopreserved autologous marrow or mobilized peripheral blood stem cells from the original donor will require follow-up based on the infusion date of the initial product.</td>
</tr>
<tr>
<td>Non-NMDP Donor</td>
<td>Subsequent stem cell infusions from non-NMDP donors (cooperative registry donors) will require follow-up based on the infusion date of the initial product.</td>
</tr>
</tbody>
</table>
**Question 36**  
Date of subsequent stem cell infusion:  
Enter the date of the stem cell infusion.

**Question 37**  
What was the indication for the subsequent stem cell infusion?  
Indicate if the subsequent infusion was due to “no engraftment,” “partial engraftment,” “graft failure/rejection after achieving initial engraftment,” “persistent malignancy,” “recurrent malignancy,” “secondary malignancy,” “planned second transplant, per protocol,” or “other.” If “other,” specify the reason for the subsequent infusion.

**Question 38**  
Source of stem cells:  
Indicate if the source was “autologous,” “allogeneic, unrelated,” or “allogeneic, related.”  
If the source was “allogeneic, unrelated,” specify whether the source was:  
“fresh, original donor bone marrow”  
“cryopreserved original donor bone marrow”  
“fresh, second donor bone marrow” from an NMDP donor”  
“non-NMDP bone marrow”  
“fresh, original donor mobilized peripheral blood stem cells”  
“cryopreserved original donor mobilized peripheral blood stem cells”  
“fresh, second donor mobilized peripheral blood stem cells” from an NMDP donor”  
“non-NMDP donor mobilized peripheral blood stem cells”  
“NMDP cord blood”  
“non-NDP cord blood”

**Question 39**  
The person completing the form must sign the form, print his/her name, and provide a phone number, fax number, and e-mail address where he/she can be reached.
Instructions
for
Form 190, 590, 690
Recipient Death Information

NATIONAL MARROW DONOR PROGRAM®
FORM 190, 590, 690
Recipient Death Information

Form 190, 590, 690 is designed to obtain data on the recipient’s primary cause of death and contributing factors.

Form 190, 590, 690 should be completed as soon as possible after the recipient has died. When a recipient dies, both the Form 190, 590, 690 and the next follow-up form that would have been due (Form 130, 530, 630; 140, 540, 640; or 150, 550, 650) must be completed. Forms will continue to become due for the recipient until both the Form 190, 590, 690 and the next follow-up form that would have been due have been submitted to the Registry and are error free.

Form Key Fields:

A. Unrelated Recipient NMDP ID: 

Enter the seven-digit NMDP Unrelated Recipient ID.

B. Recipient Last Name: 

Print the recipient’s last name in all capital letters.

C. Recipient Local ID (optional): 

Enter your Transplant Center’s local ID for the recipient.

D. Today’s Date: 

Enter the date on which you are completing this form.

E. TC Code: 

Enter your Transplant Center’s three-digit code.

F. Product type for first transplant: 

- Marrow (Form 190) 
- PBSC (Form 590) 
- Cord blood (Form 690)

Check the box that corresponds to the transplant product type. If the recipient had more than one transplant with different product types, check the product type that was used for the first transplant.
Question 1  Date of death:

Enter the date the recipient died.

NOTE:
Form 190, 590, 690 should be submitted as soon as possible after the recipient dies. If an autopsy was performed but results are not yet available, report the cause of death as determined by clinical assessment and in question 2 indicate that autopsy results are pending. A second Form 190, 590, 690 will then become due six months from the date of death. The cause of death as confirmed by autopsy will be reported on this second Form 190, 590, 690. The second Form 190, 590, 690 overwrites the first Form 190, 590, 690. All pertinent information must be included on the second Form 190, 590, 690.

Question 2  Was cause of death confirmed by autopsy?

Indicate if an autopsy was performed to confirm the cause of death. If an autopsy was performed but results are still pending, check “pending.” If “pending” is checked, a second Form 190, 590, 690 will become due six months from the date of death.

Question 3  Cause of death:

Using the Cause of Death Codes provided, report the diseases, complications, or injuries that led to death. Don’t report the mode of death (e.g., cardiopulmonary arrest).

Indicate the primary and contributing causes of death. The primary cause of death should be listed first and contributing causes of death listed in order of decreasing severity. Please see the following “Definitions of Cause of Death Codes” in these instructions for complete descriptions of the cause of death codes and instructions on reporting the primary cause of death.

Question 4  The person completing the form must also sign the form, print his/her name, and provide a phone number, fax number, and/or e-mail address where he/she can be reached.
DEFINITIONS OF CAUSE OF DEATH CODES

1.0 Graft rejection or failure
Report graft failure or rejection as the primary cause of death if one of the following conditions is met and the patient has not relapsed. Infection, hemorrhage, etc. should be listed as contributing causes of death.

Failure: ANC < 500/mm³ after day 28 post-transplant and bone marrow biopsy with < 5% cellularity.
Rejection: ANC sustained > 500/mm³ more than three days consecutive days with subsequent decrease to < 500/mm³ and bone marrow examination with < 5% cellularity.

2.0 Infection (other than interstitial pneumonia)
If a patient with graft failure or rejection dies of infection, the infection should be listed as a contributing cause of death. Report fungal or bacterial pneumonia under this code.

3.0 Interstitial pneumonia
Report viral pneumonia and viral infection of other organs under this code. Interstitial pneumonia in the absence of viral infection or pneumocystis should be coded as non-infectious organ failure – pulmonary (8.3).

4.0 Adult Respiratory Distress Syndrome
It is expected that this diagnosis will be used infrequently. Patients who develop pulmonary failure soon after transplant will usually be coded as non-infectious organ failure – pulmonary (8.3). ARDS should clearly follow a precipitating event such as bacterial sepsis, severe transfusion reaction or other systemic insult.

5.0 Acute Graft vs. Host Disease
This should be considered the primary cause of death for patients who have severe, progressive acute GVHD.

Acute GVHD should be indicated as a contributing cause of death, even if the patient has no acute GVHD symptoms, if the patient dies of an opportunistic infection or EBV lymphoma while on immunosuppression. Because of the effect of the acute GVHD treatment, this should be listed as a contributing cause of death even if the autopsy indicates no acute GVHD.

6.0 Chronic Graft vs. Host Disease
This should be considered the primary cause of death for patients dying with severe, symptomatic chronic GVHD. Infection or other complications should be indicated as contributing causes of death.

Chronic GVHD should be indicated as a contributing cause of death, even if the patient has no chronic GVHD symptoms, if the patient dies of an opportunistic infection or EBV lymphoma while on immunosuppression. Because of the effect of the chronic GVHD treatment, this should be listed as a contributing cause of death even if the autopsy indicates no chronic GVHD.
7.0 **Recurrence or persistence of leukemia/malignancy/MDS**
This should be considered the primary cause of death for patients who relapse after bone marrow transplantation. Report relapse as a contributing cause of death if recurrent disease was only discovered by autopsy. Other complications should be listed as contributing causes of death. Report death from recurrent or persistent non-malignant disease such as adrenoleukodystrophy, Hurler’s, Hunter’s, etc. under 13.0.

8.0 **Organ failure (not due to GVHD or infection)**
Report in this section any organ failure that is not due to graft versus host disease (GVHD) or infection. Sections 8.1 – 8.7 list some of the possible conditions that could be reported here, but the list is not exhaustive.

8.1 **Liver**
Veno-occlusive disease, drug toxicities, non-infectious hepatitis, idiopathic hyperammonemic syndrome.

8.2 **Cardiac (Cardiomyopathy)**
Heart failure, congestive heart failure, non-infectious pericarditis, cardiac tamponade.

8.3 **Pulmonary**
Organizing alveolitis, pulmonary hypertension, pneumothorax, pulmonary fibrosis, aspiration pneumonia, non-infectious acute respiratory failure occurring < 28 days after transplantation, non-infectious acute respiratory failure occurring one month or more post-transplant that does not meet the criteria for ARDS.

8.4 **CNS**
Radiation-induced brain atrophy, strokes or infarcts, brain stem dysfunction, encephalitis of unknown origin, cerebritis.

8.5 **Renal**
Uremic coma, chronic or acute renal failure.

8.6 **Multiple organ failure, specify**
Multiorgan failure (MOF), specify organs involved.

8.7 **Other, specify**
Hepatorenal syndrome, hemorrhagic cystitis, gastrointestinal injuries, acute or chronic pancreatitis.

9.0 **Secondary malignancy**

10.0 **Hemorrhage**
Hemorrhage refers to excessive bleeding typically from the gastrointestinal tract or a ruptured blood vessel. CNS bleeding is recorded under 8.4. Sections 10.1 – 10.5 list some of the possible conditions that could be reported here, but the list is not exhaustive.
10.1 **Pulmonary**  
Diffuse alveolar hemorrhage (DAH).

10.2 **Intracranial**  
Aneurysm, strokes.

10.3 **Gastrointestinal**

10.4 **Hemorrhage not specified**

10.5 **Other, specify**

11.0 **Vascular**  
Sections 11.1 – 11.6 list some of the possible conditions that could be reported here, but the list is not exhaustive.

11.1 **Thromboembolic**

11.2 **Disseminated intravascular coagulation (DIC)**

11.3 **Gastrointestinal**

11.4 **Thrombotic thrombocytopenic purpura**

11.5 **Vascular not specified**

11.6 **Other, specify**

12.0 **Accidental death**  
This refers to accidents that are unrelated to the medical treatment of the patient. These include motor vehicle accidents, falls, drownings, natural disasters, etc. Suicide should not be reported here but under 13.0, “other,” and specified as “suicide.”
13.0 Other, specify
This should be listed as primary or contributing cause of death, and the cause specified, only when categories 1.0 to 12.0 do not describe the cause of death. Some of the causes of death included in this category are suicide, heart attack, cardiac arrest, ventricular tachyarrhythmia, malignant arrhythmia, cardiopulmonary arrest, sudden death. Report in this section death from progressive nonmalignant disease, e.g., a persistent or recurrent metabolic disorder, such as Hurler Syndrome.
### Example of Monthly Forms Due Report

**NATIONAL MARROW DONOR PROGRAM**  
**FORMS DUE REPORT**  
**FOR TRANSPLANT CENTER 000**  
**TRANSPLANT CENTER**

<table>
<thead>
<tr>
<th>PD</th>
<th>DUE</th>
<th>STS</th>
<th>FORM</th>
<th>NATL DONOR ID</th>
<th>NATL RECIP ID</th>
<th>RECIPIENT LAST NAME</th>
<th>EARLIEST CMPLT DTE</th>
<th>DUE DATE</th>
<th>REFERRING PHYSICIAN</th>
<th>REFERRING PHYS PHONE NUMBER</th>
<th>DONOR CNTR ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td>ERR</td>
<td>120</td>
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<td></td>
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<td>DUE</td>
<td>130</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DUE</td>
<td>140 – 6 Month</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DUE</td>
<td>650</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DUE</td>
<td>22</td>
<td>0081-4995-7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Y DUE</td>
<td>540 – One Year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Key**

1. Date report was generated.
2. "Y" in this column means the form is past due.
3. This column indicates if the form is due ("DUE"), or if the form has been submitted, but has errors ("ERR"). Any form with errors will also appear on the monthly Form Error Report. The Form Error Report will detail the specific error(s) for each form.
4. This column indicates which form is due. Marrow forms are 100 series numbers, PBSC forms are 500 series numbers, and cord blood forms are 600 series numbers.
5. Donor’s NMDP identification number.
6. Donor’s local donor center identification number.
7. Recipient’s NMDP identification number.
8. Date the form first becomes due.
9. Date the form becomes past due.
Appendix B

Appendix B is Chapter 11 from the NMDP’s TransLink™ Software User Guide.

11 Forms Due

The NMDP requires transplant centers to complete many forms during the search process. The TRANS Link™ application helps transplant centers organize and manage their forms in the Forms Due screen.

Forms Due Screen

The Forms Due screen organizes forms by type of form, specific form numbers and a variety of date ranges. The screen displays the form’s status at the transplant center and its status at the NMDP. It also displays the Complete Date and Earliest Complete Date along with several other optional fields.
Selection Criteria

The Form Types field offers a list of options used to filter the number of forms displayed. To see this list click on the down arrow, then select the needed form type. To display the forms that match this form type, click on the List Forms button. The system filters the forms displayed based on the selection criteria.

This table describes the different types of forms.

<table>
<thead>
<tr>
<th>Form Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Forms Due</td>
<td>Forms that are still due to the NMDP or contain errors</td>
</tr>
<tr>
<td>CPI Forms</td>
<td>Forms required for Continuous Process Improvement (i.e. form 130 and 120)</td>
</tr>
<tr>
<td>All Completed Forms</td>
<td>Displays all forms keyed into the Registry at the NMDP complete and error-free</td>
</tr>
<tr>
<td>Reimbursed Forms</td>
<td>If your center uses the Reimbursed indicator, the system selects all forms where this indicator is “Yes”</td>
</tr>
<tr>
<td>Unreimbursed Completed Forms</td>
<td>If your center uses the Reimbursed indicator, the system selects all forms where this indicator is “No”</td>
</tr>
</tbody>
</table>

Table 11.1

Another option is to select forms by form numbers. In the Specific Forms box, highlight the form number needed and click on the List Forms button.
Two options exist for displaying more than one form number. The <Shift> key allows you to highlight a group of form numbers contiguous in the list. Highlight number 22, hold down the <Shift> key, and then highlight number 118. All forms between and including 22 and 118 are highlighted. The system displays these forms after clicking the List Forms button.

To highlight form numbers that are not contiguous in the list, hold down the <Ctrl> key while clicking on the forms needed. Use the List Forms button to display the forms.

The Forms List screen offers form selection by multiple types of date ranges. First, select the date type to search by in the *Date to search on* field.

The system filters the forms displayed by the different date types chosen. Make this selection in the *Date to search on* field. The table below describes what each date type displays.

<table>
<thead>
<tr>
<th>Form Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form Due</td>
<td>The date that the form is due for completion by the NMDP.</td>
</tr>
<tr>
<td>Earliest Complete Date</td>
<td>The earliest date that the form could be completed.</td>
</tr>
<tr>
<td>Complete Date</td>
<td>The date that the form was keyed by the NMDP complete and error free into the STAR® system.</td>
</tr>
</tbody>
</table>

Table 11.2

Enter the start and end date range into the appropriate fields. The date must be entered in a European format. First, type in the four-digit year, then a two digit month and then the two-digit day. The system displays the date in a U. S. format of a three-letter abbreviation for month, then the day, and then a four-digit year.
Selecting the form type of **CPI Forms** in the Selection Criteria box produces three radio dials in the Date Range box. The radio buttons move the date ranges by trimester increments, which is every four months. Select the date type to filter the number of forms displayed. Click on the arrow in the *Date to search on* field to display this list.

<table>
<thead>
<tr>
<th>Date Range</th>
</tr>
</thead>
</table>
| **Date to search on:** | Form Due  
| **Start Date:** CCYY/MM/DD | Jan 1, 2001  
| **End Date:** CCYY/MM/DD | Apr 30, 2001  

Selecting one of the radio buttons displays a different four-month date range. The table below describes what each radio button displays.

<table>
<thead>
<tr>
<th>Radio Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>Displays the current trimester's forms.</td>
</tr>
<tr>
<td>Previous</td>
<td>Displays the previous trimester's forms.</td>
</tr>
<tr>
<td>Next</td>
<td>Displays the next trimester's forms.</td>
</tr>
</tbody>
</table>

Table 11.3

Another option in filtering the form selection criteria is by entering an NMDP ID to list the forms for a specific patient or entering a Secondary Transplant Center Code.

<table>
<thead>
<tr>
<th>NMDP ID:</th>
<th>Sec TC Code</th>
</tr>
</thead>
</table>

**Editing the Forms List Screen**

After choosing the appropriate selection criterion and displaying the forms, you can edit information about a form. The system sets some fields such as the *Past Due, Form Complete Dte, NMDP Status, and Earliest Cmplt Dte* fields. The user sets other fields, which are optional and for the transplant center’s use only.
The table below lists the fields shown in the forms display box. It also offers a description for each field and whether the user or the system enters the data.

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Entered by...</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frm ID</td>
<td>System</td>
<td>NMDP’s form identification number.</td>
</tr>
<tr>
<td>NMDP ID</td>
<td>System</td>
<td>NMDP’s unique identification number for the patient.</td>
</tr>
<tr>
<td>Local ID</td>
<td>System</td>
<td>The transplant center’s unique identification number for the patient.</td>
</tr>
<tr>
<td>First Name</td>
<td>System</td>
<td>Patient’s first name that was entered into the patient folder.</td>
</tr>
<tr>
<td>Last Name</td>
<td>System</td>
<td>Patient’s last name that was entered into the patient folder.</td>
</tr>
<tr>
<td>Donor ID</td>
<td>System</td>
<td>NMDP’s unique identification number for the donor.</td>
</tr>
<tr>
<td>Past Due</td>
<td>System</td>
<td>Displays whether the form is past due with a Yes or No indicator.</td>
</tr>
<tr>
<td>Due Date</td>
<td>System</td>
<td>The due date for the form by the NMDP.</td>
</tr>
<tr>
<td>Earliest Cmplt Dte</td>
<td>System</td>
<td>The earliest date that the form could have been completed.</td>
</tr>
<tr>
<td>Form Complete Dte</td>
<td>System</td>
<td>The date that the NMDP keyed in a complete and error-free form in the STAR system.</td>
</tr>
<tr>
<td>NMDP Status</td>
<td>System</td>
<td>The form’s status at the NMDP. Complete indicates that the form was keyed into the STAR system complete and error-free. Not Started indicates that the NMDP received the form but has not keyed it. Error indicates that form was keyed in the STAR system with errors.</td>
</tr>
<tr>
<td>TC Status</td>
<td>User</td>
<td>WIP (Work in progress) indicates that someone is completing this form. Forms Sent indicates that the TC sent the form to the NMDP. Corr Sent (Correction Sent) indicates that a correction was sent to the NMDP on this form.</td>
</tr>
<tr>
<td>Review Status</td>
<td>User</td>
<td>Review Completed indicates that a supervisor or doctor has reviewed this form. Review Cancelled indicates that the review process has been cancelled. In Review indicates that this form is currently being reviewed by a supervisor or doctor.</td>
</tr>
<tr>
<td>Sec TC Code</td>
<td>System</td>
<td>Secondary transplant center code.</td>
</tr>
<tr>
<td>Protocol</td>
<td>User</td>
<td>The user enters the protocol into the patient’s folder, which is displayed in the forms screen.</td>
</tr>
<tr>
<td>Responsibility</td>
<td>User</td>
<td>Type in the responsible person’s name into this field.</td>
</tr>
<tr>
<td>Reimb</td>
<td>User</td>
<td>Reimbursed allows the TC to track those forms that the NMDP has reimbursed. Choose from Yes, No, and NA (not applicable)</td>
</tr>
</tbody>
</table>

Table 11.4
Printing a Forms Report

The TRANS Link system allows you to print a report of forms information. First, select the criteria and edit any information necessary. These steps are listed in the Selection Criteria and Editing sections.

To print all the forms due, do not select a specific report. If a form has already been selected, then click the Reset button and then click the List Forms button.

Now select File from the menu and then select Print. A dialog box appears allowing the user to enter notes, which appears on the Forms Report.

Click on the OK button to accept the report footer in the box.

If you need a different footer, then type it into this box. Next, click the OK button.

The report prints automatically. It shows the print date, print time and includes up to three lines of information about each form in a column format. A sample form is included at the end of this chapter.
Form 580 Due Exercise

From the Welcome screen open the Forms Due screen by one of the two methods. Either click on the Forms button or select Forms Due from the TC Tasks menu.

1. Keep the default setting in the Forms Types field to Current Forms Due.

2. In the Specific Forms field, select 580 and click the List Forms button.
3. Notice that the Form Count field displays a count of forms. Highlight the second line.

4. Select File from the menu and then select Edit.

5. Use the slide rule bar to locate the TC Status column. Click on the arrow in that field to display a list. Select Forms Sent from this list.

6. In the Review Status field, click on the arrow and select Review Cmplt from the list.

For this exercise, DO NOT save your changes.

At your transplant center you can save your changes by selecting File from the menu and then select Save.
You want to view your center’s Form 22’s for the month of December 1999.

1. In the Form Types field, select *All Completed Forms* from the list. In the Specific Forms section, select 22 from the list.

2. In the start date range field, enter “19991201.” Remember that the date format is entered as a four-digit year, two-digit month then a two-digit day. When you move off the field, the system displays the date as “Dec 1 1999.”

3. Click the List Forms button and the system displays a count of forms at the bottom of screen.

4. Select File from the menu and then Select Edit.

5. Highlight the first line.

6. Use the slide rule to find the reimbursement field labeled “Reimb.” Click on the arrow in that field and select Yes.

7. For this exercise, DO NOT save your changes.

8. In the Date Range section, go to the Date to Search on field and change your selection from Form Complete to Form Due.

9. Click on the List Forms button.
The system will display a text box “Updates pending – Information has been modified and not been saved would you like to save your changes now?” Click on the No button. This is caused by not saving the changes for this exercise.

The system now displays a count of forms found.

Click on the Reset button.
1. In the Form Types, select CPI Forms.

2. In the Specific Forms field, select 140, 1 Year.

3. Click on the List Forms button. The system now displays a count of forms.

4. Click on the Previous button in the Date Range; notice the Start and End Date.

5. Click on the Next button in the Date Range; notice the Start and End Date.
<table>
<thead>
<tr>
<th>Form ID</th>
<th>NMDP ID</th>
<th>First Name</th>
<th>Early Cmplt Dte</th>
<th>Protocol</th>
<th>TC Status</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>942-417-7</td>
<td>NILE8LP</td>
<td>Apr 14 2002</td>
<td></td>
<td>YES</td>
<td>IN REVIEW N</td>
</tr>
<tr>
<td>YES</td>
<td>0308-9660-</td>
<td>EB38BD</td>
<td>Jul 13 2002</td>
<td></td>
<td></td>
<td>Not Started</td>
</tr>
<tr>
<td>22</td>
<td>953-206-7</td>
<td>MLCCH8</td>
<td>Dec 29 2001</td>
<td>FORM SENT</td>
<td>YES</td>
<td>REVIEW Y</td>
</tr>
<tr>
<td>YES</td>
<td>5009-7353-</td>
<td>ILC92</td>
<td>Mar 29 2002</td>
<td>CMPLT</td>
<td></td>
<td>Not Started</td>
</tr>
</tbody>
</table>

Current Forms Due for forms: 22 for Start Date: Jan 1 2002 for End Date: Dec 31 2002
Example of Daily Error Report

To: Donor Center/MCI Number
Subject: DAILY FOLLOW-UP ERROR REPORT

RUN DATE: 03 Mar 02
RUN TIME: 21:32:41
NATIONAL MARROW DONOR PROGRAM
REPORT: MDPR0012
REQUEST: CXXXA009

FORM ERROR REPORT
FOLLOW-UP FORMS
TRANSPLANT CENTER XXX
NAME OF TRANSPLANT CENTER

===========================================================================
Form 140 Version 6 – 1 Year

Brown, Joe

Sequence Number: 224143
NATL RID: 936-073-5
Local RID: 3E9002

ERROR 1:
Quest ID and Name
---------------------------------------------- ---------------------
19 - WBC
The Field’s value is outside of the acceptable range.

Key

1 Date the report was generated.
2 Form number that is in error.
3 Sequence number given to the form at the NMDP’s Registry. The sequence number is required to track the form in the database and must be entered on the error correction form.
4 Recipient’s NMDP identification number.
5 Recipient’s local transplant center identification number.
6 The “Today’s Date” from the form.
7 Date the form was received at the NMDP’s Registry.
8 The question number and a description of the question that is in error.
9 Description of error.
10 Answer that did not pass edit check.
Example of Monthly Error Report

RUN DATE: 01 June 02
RUN TIME: 01:42:22
NATIONAL MARROW DONOR PROGRAM
REPORT: MDPR0016
REQUEST: NM999A570

FORM ERROR MONTHLY SUMMARY REPORT
FOLLOW-UP FORMS
TRANSPLANT CENTER XXX
NAME OF TRANSPLANT CENTER

<table>
<thead>
<tr>
<th>Days Since Err</th>
<th>Recipient/Donor Info</th>
<th>Fill Dte</th>
<th>Question ID and Name</th>
<th>Answer</th>
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</thead>
<tbody>
<tr>
<td>100 Brown, Joe</td>
<td>Seq Num: 146806</td>
<td>28 Feb 02</td>
<td>16A - Ast known</td>
<td>Form 120 - Version 8</td>
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<tr>
<td>3 Natl RID: 933-333-3</td>
<td>01 Mar 02</td>
<td>8</td>
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</tr>
<tr>
<td>4 Locl RID: a4d4555</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>44 Doe, Jane</td>
<td>Seq Num: 146111</td>
<td>01 Apr 02</td>
<td>516 - Blst mrrw prcdtn</td>
<td>Form 120 ins 5 - Version 2</td>
</tr>
<tr>
<td>5 Natl RID: 944-444-4</td>
<td>15 Apr 02</td>
<td>80.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Locl RID: a4d4556</td>
<td>10 Blank</td>
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<td></td>
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<tr>
<td>01 Brown, Rose</td>
<td>Seq Num: 146115</td>
<td>15 May 02</td>
<td>41 - Acute GVHD treatment</td>
<td>Form 140 - 1 year Version 6</td>
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<tr>
<td>5 Natl RID: 955-555-5</td>
<td>31 May 02</td>
<td>1 - yes</td>
<td></td>
<td></td>
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<tr>
<td>5 Locl RID: a4d4557</td>
<td>1 - no</td>
<td></td>
<td></td>
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</tbody>
</table>

Key

① Date the report was generated
② Number of days since the error was first identified and reported to the transplant center.
③ Sequence number given to the form at the Registry. The sequence number is required to track the form in the data base and must be entered on the error correction form.
④ Recipient’s NMDP identification number.
⑤ Recipient’s local donor center identification number.
⑥ The “Today’s Date” from the form.
⑦ Date the form was received at the Registry.
⑧ The question number and description of question that is in error.
⑨ Form that is in error.
⑩ Answer that did not pass edit check.
⑪ Description of error.
Appendix D

Example of Error Correction Form

ERROR CORRECTION FORM

1. Sequence Number: ________________
2. Recipient NMDP ID: ________________
3. Unique Patient Number (UPN): ________________
4. TC Code: ________________
5. Product type: □ Marrow □ PBSC □ Cord blood
6. Initials: ________________

Unrelated Recipient NMDP ID: ________________
Recipient Last Name: ________________
Recipient Local ID (optional): ________________
Donor NMDP ID: ________________
Today’s Date: ________________
Date of Transplant for which this form is being completed: ________________
Product type: □ Marrow (Form 120) □ PBSC (Form 520) □ Cord blood (Form 620)
TC Code: ________________

National Marrow Donor Program®
Recipient Baseline and Transplant Data

Registry Use Only

Sequence Number: ________________
Date Received: ________________

Research blood samples should be collected before initiation of preparative regimen and sent to Blood Centers of the Pacific, Irwin Center. See Transplant Center Manual of Operations for instructions.

1. Recipient name: ____________________________________________________________________________ (please print) Reg Use Only
2. a. State of residence of recipient (for residents of USA): __________________________________________
   b. Zip or postal code for place of recipient’s residence (USA recipients only): ________________
   c. Country if non-resident of USA: ____________________________________________________________________________
3. Does the recipient have a U.S. Social Security Number (or Canadian Social Insurance Number)? (optional)
   1 ☒ yes  4. Social Security Number/Social Insurance Number: ________________
   2 ☐ no
   3 ☐ Transplant Center is not allowed to report this information

Key

① Enter the sequence number of the form to be corrected. The sequence number is listed on both the Daily Follow-Up Error Report and the Form Error Monthly Summary Report. If the Transplant Center wants to correct data that did not generate an error, write “Transplant Center initiated.” In these cases, the sequence number can be left blank.
② Enter the recipient’s seven-digit NMDP identification number.
③ Enter the recipient’s unique patient number assigned at the Transplant Center. This field is optional.
④ Enter the Transplant Center code assigned to your center.
⑤ Check the box corresponding to the type of stem cell product the recipient received.
⑥ Write your initials in the box provided.
⑦ Enter the corrected data. If data should be deleted, circle the question on the error form that contains the data to be deleted and write “Delete value.”
### Appendix E  FOLLOW-UP FORMS RANGE VALIDATION

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Valid Range</th>
</tr>
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<tbody>
<tr>
<td>16</td>
<td>AST (SGOT)</td>
<td>&gt;0 - 200</td>
</tr>
<tr>
<td>18</td>
<td>AST upper limit of normal</td>
<td>3 - 70</td>
</tr>
<tr>
<td>19</td>
<td>Serum creatinine</td>
<td>0.1 - 4 mg/dL or 8.8 - 353.9 µmol/L</td>
</tr>
<tr>
<td>18</td>
<td>Serum creatinine upper limit of normal</td>
<td>0.2 - 15 mg/dL or 3.5 - 263 µmol/L</td>
</tr>
<tr>
<td>22</td>
<td>Total serum bilirubin</td>
<td>2 - 12</td>
</tr>
<tr>
<td>24</td>
<td>Total serum bilirubin upper limit of normal</td>
<td>2 - 12</td>
</tr>
<tr>
<td>25</td>
<td>LDH</td>
<td>30 - 1400</td>
</tr>
<tr>
<td>27</td>
<td>LDH upper limit of normal</td>
<td>30 - 1250</td>
</tr>
<tr>
<td>42</td>
<td>Height</td>
<td>30 - 200</td>
</tr>
<tr>
<td>43</td>
<td>Weight</td>
<td>1 - 200</td>
</tr>
<tr>
<td>48</td>
<td>Total dose</td>
<td>100 - 1600</td>
</tr>
<tr>
<td>51</td>
<td>Dose per fraction</td>
<td>10 - 350</td>
</tr>
<tr>
<td>52</td>
<td>Number of days</td>
<td>2 - 6</td>
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<tr>
<td>53</td>
<td>Total number of fractions</td>
<td>2 - 12</td>
</tr>
<tr>
<td>54</td>
<td>Total dose:</td>
<td>100 - 1600</td>
</tr>
<tr>
<td>57</td>
<td>Dose per fraction</td>
<td>10 - 250</td>
</tr>
<tr>
<td>58</td>
<td>Number of days</td>
<td>2 - 6</td>
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<tr>
<td>59</td>
<td>Total number of fractions</td>
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<tr>
<td>60</td>
<td>Total dose</td>
<td>100 - 1600</td>
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<tr>
<td>63</td>
<td>Dose per fraction</td>
<td>10 - 250</td>
</tr>
<tr>
<td>64</td>
<td>Number of days</td>
<td>2 - 6</td>
</tr>
<tr>
<td>65</td>
<td>Total number of fractions</td>
<td>2 - 12</td>
</tr>
<tr>
<td>68</td>
<td>CNS irradiation dose</td>
<td>100 - 1800</td>
</tr>
<tr>
<td>70</td>
<td>Gonadal irradiation dose</td>
<td>100 - 500</td>
</tr>
<tr>
<td>72</td>
<td>Splenic irradiation dose</td>
<td>100 - 1500</td>
</tr>
<tr>
<td>74</td>
<td>Residual tumor dose</td>
<td>100 - 1600</td>
</tr>
<tr>
<td>77</td>
<td>Other site irradiation</td>
<td>100 - 1600</td>
</tr>
<tr>
<td>80a</td>
<td>ALG, ALS, ATG, ATS</td>
<td>&gt;0 - 15,000</td>
</tr>
<tr>
<td>80b</td>
<td>Busulfan</td>
<td>&gt;0 - 2000</td>
</tr>
<tr>
<td>80c</td>
<td>Methylprednisilone</td>
<td>&gt;0 - 10,000</td>
</tr>
<tr>
<td>80d</td>
<td>Prednisone</td>
<td>&gt;0 - 300</td>
</tr>
<tr>
<td>80e</td>
<td>Other Corticosteroid</td>
<td>&gt;0 - 10,000</td>
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<tr>
<td>80f</td>
<td>Cyclophosphamide</td>
<td>&gt;0 - 24,000</td>
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<tr>
<td>80g</td>
<td>Cytarabine (Ara-C)</td>
<td>&gt;0 - 90,000</td>
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<tr>
<td>80h</td>
<td>Etoposide</td>
<td>&gt;0 - 7500</td>
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<tr>
<td>80i</td>
<td>Melphalan</td>
<td>&gt;0 - 300</td>
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<tr>
<td>80j</td>
<td>Thiotepa</td>
<td>&gt;0 - 1250</td>
</tr>
<tr>
<td>80k</td>
<td>Nitrosourea</td>
<td>&gt;0 - 1200</td>
</tr>
<tr>
<td>80l</td>
<td>Monoclonal antibody</td>
<td>&gt;0 - 25,000</td>
</tr>
</tbody>
</table>

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### FORM 120, 520, 620 – Recipient Baseline and Transplant Data

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<th>Range</th>
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<tbody>
<tr>
<td>80m</td>
<td>Intrathecal methotrexate</td>
<td>&gt;0 - 25,000</td>
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<tr>
<td>80n</td>
<td>Intrathecal ARA-C</td>
<td></td>
</tr>
<tr>
<td>80o</td>
<td>Fludarabine</td>
<td></td>
</tr>
<tr>
<td>80p</td>
<td>Cladribine</td>
<td></td>
</tr>
<tr>
<td>80q</td>
<td>Other prep drugs</td>
<td>&gt;0 - 25,000</td>
</tr>
<tr>
<td>86</td>
<td>Nucleated cell count</td>
<td>5.0 - 50.0</td>
</tr>
<tr>
<td>87</td>
<td>Total volume of marrow</td>
<td>100.0 - 2000.0</td>
</tr>
<tr>
<td>93</td>
<td>Total volume of marrow infused</td>
<td>10.0 - 2000.0</td>
</tr>
<tr>
<td>94</td>
<td>Cell count of infused marrow</td>
<td>5.0 - 350.0</td>
</tr>
<tr>
<td>96</td>
<td>Total volume of cryopreserved marrow</td>
<td>1.0 - 500.0</td>
</tr>
<tr>
<td>97</td>
<td>Nucleated cell count of cryopreserved marrow</td>
<td>1.0 - 200.0</td>
</tr>
</tbody>
</table>

### FORM 120, 520, 620 Insert I – Acute Myelogenous Leukemia:

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Range</th>
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<tbody>
<tr>
<td>13</td>
<td>WBC</td>
<td>0.1 - 250.0</td>
</tr>
<tr>
<td>14</td>
<td>Blasts in blood</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>15</td>
<td>Blasts in bone marrow</td>
<td>30.0 - 99.9</td>
</tr>
<tr>
<td>19</td>
<td>Number of metaphases examined</td>
<td>1 - 100</td>
</tr>
<tr>
<td>31</td>
<td>WBC</td>
<td>1.0 - 50.0</td>
</tr>
<tr>
<td>32</td>
<td>Blasts in blood</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>33</td>
<td>Blasts in bone marrow</td>
<td>0 - 99.9</td>
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### FORM 120, 520, 620 Insert II – Acute Lymphoblastic Leukemia

<table>
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<td>4</td>
<td>WBC</td>
<td>0 - 500.0</td>
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<tr>
<td>5</td>
<td>Blasts in blood</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>6</td>
<td>Blasts in bone marrow</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>10</td>
<td>Number of metaphases examined</td>
<td>1 - 100</td>
</tr>
<tr>
<td>22</td>
<td>WBC</td>
<td>1.0 - 50.0</td>
</tr>
<tr>
<td>23</td>
<td>Blasts in blood</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>24</td>
<td>Blasts in bone marrow</td>
<td>0 - 99.9</td>
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### FORM 120, 520, 620 Insert III – Chronic Myelogenous Leukemia (CML)

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<td>2</td>
<td>Hemoglobin</td>
<td>5.0 - 18.0</td>
</tr>
<tr>
<td>3</td>
<td>Hematocrit</td>
<td>15.0 - 55.0</td>
</tr>
<tr>
<td>4</td>
<td>Platelets</td>
<td>20.0 - 1500.0</td>
</tr>
<tr>
<td>5</td>
<td>WBC</td>
<td>3.0 - 500.0</td>
</tr>
<tr>
<td>6</td>
<td>Eosinophils</td>
<td>0 - 75.0</td>
</tr>
<tr>
<td>7</td>
<td>Basophils</td>
<td>0 - 75.0</td>
</tr>
<tr>
<td>8</td>
<td>Blasts</td>
<td>0 - 99.9</td>
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<tr>
<td>22</td>
<td>Hemoglobin</td>
<td>5.0 - 18.0</td>
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<tr>
<td>23</td>
<td>Hematocrit</td>
<td>15.0 - 55.0</td>
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<tr>
<td>24</td>
<td>Platelets</td>
<td>10.0 - 1500.0</td>
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<tr>
<td>25</td>
<td>WBC</td>
<td>1.0 - 250.0</td>
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<tr>
<td>26</td>
<td>Eosinophils</td>
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<tr>
<td>27</td>
<td>Basophils</td>
<td>0 - 75.0</td>
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<tr>
<td>30</td>
<td>Blasts plus promyelocytes</td>
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### FORM 120, 520, 620 Insert IV – Other Leukemias

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<td>Hemoglobin</td>
<td>5.0 - 18.0</td>
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<tr>
<td>3</td>
<td>WBC</td>
<td>0.1 - 500.0</td>
</tr>
<tr>
<td>4</td>
<td>Lymphocytes</td>
<td>0 - 100.0</td>
</tr>
<tr>
<td>5</td>
<td>Platelets</td>
<td>10.0 - 1000.0</td>
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<tr>
<td>6</td>
<td>Blasts in blood</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>7</td>
<td>Blasts in bone marrow</td>
<td>0 - 99.9</td>
</tr>
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### FORM 120, 520, 620 Insert V – Myelodysplasia/Myeloproliferative Disorders

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<td>16</td>
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<tr>
<td>17</td>
<td>Platelets</td>
<td>10.0 - 1500.0</td>
</tr>
<tr>
<td>18</td>
<td>WBC</td>
<td>0.1 - 200.0</td>
</tr>
<tr>
<td>19</td>
<td>Neutrophils</td>
<td>0 - 99</td>
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<tr>
<td>20</td>
<td>Monocytes</td>
<td>0 - 99</td>
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<td>21</td>
<td>Blasts in blood</td>
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<td>25</td>
<td>Blasts in marrow</td>
<td>0 - 29</td>
</tr>
<tr>
<td>27</td>
<td>Number of metaphases</td>
<td>1 - 100</td>
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<tr>
<td>38</td>
<td>cm below left costal margin</td>
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<td>43</td>
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<tr>
<td>45</td>
<td>Neutrophils</td>
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### FORM 120, 520, 620 Insert V – Myelodysplasia/Myeloproliferative Disorders

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<td>Monocytes</td>
<td>0 - 99</td>
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<tr>
<td>47</td>
<td>Blasts in blood</td>
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</tr>
<tr>
<td>51</td>
<td>Blasts in marrow</td>
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### FORM 120, 520, 620 Insert VI – Multiple Myeloma

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<tr>
<td>4</td>
<td>Serum calcium</td>
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<tr>
<td>5</td>
<td>Serum M component concentration</td>
<td>0 - 8.0</td>
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<tr>
<td>6</td>
<td>24 hour urine light chain excretion</td>
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</tr>
<tr>
<td>7</td>
<td>Serum beta 2 microglobulin</td>
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### FORM 120, 520, 620 Insert VII – Other Malignancy

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### FORM 120, 520, 620 Insert VIII – Aplastic Anemia

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</tr>
<tr>
<td>4</td>
<td>Hematocrit</td>
<td>6.0 - 40.0</td>
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<tr>
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<td>RBC</td>
<td>0.5 - 4.0</td>
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<td>Uncorrected reticulocytes</td>
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<tr>
<td>7</td>
<td>WBC</td>
<td>0.1 - 10.0</td>
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<tr>
<td>8</td>
<td>Granulocytes</td>
<td>1.0 - 99.9</td>
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<tr>
<td>9</td>
<td>Platelets</td>
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<td>Platelets</td>
<td>10.0 - 100.0</td>
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<td>0.1 - 20.0</td>
</tr>
<tr>
<td>19</td>
<td>Granulocytes</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>20</td>
<td>Blasts</td>
<td>0 - 2.0</td>
</tr>
</tbody>
</table>

### FORM 120, 520, 620 Insert IX – Hodgkin And Non-Hodgkin Lymphoma

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Valid Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>LDH at diagnosis</td>
<td>30 – 4000 IU/L (µkat/L not validated)</td>
</tr>
<tr>
<td>12</td>
<td>Upper limit of normal for LDH</td>
<td>30 - 1250</td>
</tr>
<tr>
<td>174</td>
<td>Size of largest mass</td>
<td>(0 - 20) x (0 - 20)</td>
</tr>
<tr>
<td>Question</td>
<td>Description</td>
<td>Valid Range</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------------------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>4</td>
<td>WBC</td>
<td>0.01 – 20.00</td>
</tr>
<tr>
<td>5</td>
<td>Lymphocytes</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>6</td>
<td>T cells (CD3 or equivalent)</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>7</td>
<td>CD4+ cells</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>8</td>
<td>CD8+ cells</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>9</td>
<td>B cells (SIg+ or equivalent)</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>10</td>
<td>NK cells (CD16+ or equivalent)</td>
<td>0 - 99.9</td>
</tr>
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</table>

**FORM 120, 520, 620 Insert XI – Wiscott Aldrich Syndrome (WAS)**

<table>
<thead>
<tr>
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<th>Description</th>
<th>Valid Range</th>
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</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
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**FORM 130, 530, 630 – 100-Day Follow-Up Visit of Recipient**

<table>
<thead>
<tr>
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<th>Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>WBC</td>
<td>0.1 - 2.0</td>
</tr>
<tr>
<td>20</td>
<td>Neutrophils</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>23</td>
<td>WBC</td>
<td>0.5 - 11.0</td>
</tr>
<tr>
<td>24</td>
<td>Neutrophils</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>49</td>
<td>Karnofsky/Lansky score</td>
<td>10 - 100</td>
</tr>
<tr>
<td>50</td>
<td>Platelet count</td>
<td>5.0 - 500.0</td>
</tr>
<tr>
<td>51</td>
<td>Total serum bilirubin</td>
<td>0.2 - 20.0 mg/dL or 3.5 - 350.0 µmol/L</td>
</tr>
<tr>
<td>84</td>
<td>Total number of inpatient days</td>
<td>1 - 100</td>
</tr>
</tbody>
</table>

**FORM 130, 530, 630 Insert I – Severe Combined Immunodeficiency (SCID)**

<table>
<thead>
<tr>
<th>Question</th>
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<th>Valid Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>None</td>
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</tbody>
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**FORM 130, 530, 630 Insert II – Wiscott Aldrich Syndrome (WAS)**

<table>
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<tr>
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<th>Description</th>
<th>Valid Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
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**FORM 130, 530, 630 Insert III – Hodgkin And Non-Hodgkin Lymphoma**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Valid Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**FORM 130, 530, 630 Insert V – Leukodystrophies**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Valid Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Leukocyte galactocerebrosidase</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Leukocyte aryksulfatase A enzyme activity</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Mean fasting plasma VLCFA C26:0</td>
<td></td>
</tr>
</tbody>
</table>

**FORM 130, 530, 630 Insert VI – Mucopolysaccharidoses**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Valid Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Enzyme level</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Description</td>
<td>Valid Range</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>19</td>
<td>WBC</td>
<td>0.1 - 2</td>
</tr>
<tr>
<td>20</td>
<td>Neutrophils</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>23</td>
<td>WBC</td>
<td>0.5 - 11</td>
</tr>
<tr>
<td>24</td>
<td>Neutrophils</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>47</td>
<td>Karnofsky/Lansky score</td>
<td>10 - 100</td>
</tr>
<tr>
<td>48</td>
<td>Platelet count</td>
<td>5 - 500</td>
</tr>
<tr>
<td>49</td>
<td>Total serum bilirubin</td>
<td>0.2 - 20 mg/dL or 3.5 - 350 µmol/L</td>
</tr>
</tbody>
</table>

**FORM 150, 550, 650 Yearly Follow-Up for Greater Than Two Years Post-Transplant**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Valid Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
Appendix F

National Marrow Donor Program®
Search America Search Request

Date: __________________________________________________________

Transplant Center number: ________  ________  ________  ________

Name of transplant center contact: ____________________________________________

(Please print)

Transplant center address: ___________________________________________________

___________________________________________________________________________

___________________________________________________________________________

Fax number: ( _________ ) _____________________________________________________

Phone number: ( _________ ) ___________________________________________________

RECIPIENT INFORMATION
(If recipient is a minor, use parent address and Social Security Number)

Recipient name: ____________________________________________________________

(Please print)

Last known street address: _____________________________________________________

___________________________________________________________________________

City: ____________________________ State: _______________ Zip Code: _______________

Last known phone number: ( _________ ) __________________________________________

Social Security Number: ________________________________________________________

Fax or mail this form to:
National Marrow Donor Program
Research Department
Suite 500
3001 Broadway Street NE
Minneapolis, MN 55413
Fax: (612) 362-3497
Appendix G

National Marrow Donor Program®
Lost to Follow-Up Declaration

<table>
<thead>
<tr>
<th>Registry Use Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence Number:</td>
</tr>
<tr>
<td>Date Received:</td>
</tr>
</tbody>
</table>

A recipient may be declared Lost to Follow-Up on a visit-by-visit basis. A recipient may only be declared Lost to Follow-Up if the transplant center has been unsuccessful at reaching the recipient at the address and phone number on file at the transplant center and has requested a search for a current address or phone number through Trans Union.

1. Follow-up visit for which the recipient is lost to follow-up:
   1. o 130, 530, 630 – 100 days
   2. o 140, 540, 640 – Six months
   3. o 140, 540, 640 – Specify year: ____________________________
   4. o 150, 550, 650 – Specify year: ____________________________

2. I verify the following unsuccessful attempts to locate the recipient:
   1. o yes 2. o no Called home and/or work phone numbers – all phone numbers no longer current
   1. o yes 2. o no Sent letter – returned forwarding expired or non-deliverable for some reason
   1. o yes 2. o no International patient – have lost contact
   1. o yes 2. o no Treating physician has not seen patient or has not had any contact in the past year
   1. o yes 2. o no Search request through Search America

3. Signed: __________________________________________

   Person completing form

   Please print name: _______________________________________

   Phone: (__________) ________________________________

   Fax: (__________) ________________________________

   E-mail address: _______________________________________

NMDP Form Lost to Follow-Up v1 (1–1) January 2002
Copyright © 2001 National Marrow Donor Program. All rights reserved.
For internal use only: Document F00066 12/21/2001    Replaces: n/a

Fax or mail this form to:
The NMDP Clinical Research, Suite 500
3001 Broadway St. N.E., Minneapolis, MN 55413
Fax: 612/362-3497
Retain a copy at the transplant center.
Continuous Process Improvement (CPI) Indicators for NMDP Forms 120, 520, 620; 130, 530, 630; 140, 540, 640; and 150, 550, 650 (Phase II) and Procedures for Non-Compliance

The following Continuous Process Improvement (CPI) indicators have been established for NMDP Transplant Centers regarding data forms submission:

<table>
<thead>
<tr>
<th>Form</th>
<th>90% submitted within</th>
</tr>
</thead>
<tbody>
<tr>
<td>120, 520, 620 (baseline)</td>
<td>60 days</td>
</tr>
<tr>
<td>130, 530, 630 (100 day follow-up)</td>
<td>120 days</td>
</tr>
<tr>
<td>140, 540, 640 (6 month to 2 year follow-up)</td>
<td>90 days</td>
</tr>
<tr>
<td>150, 550, 650 (3 year and greater follow-up)</td>
<td>45 days</td>
</tr>
</tbody>
</table>

Transplant Centers will receive reports three times a year (January, May, September) listing the number of follow-up forms that were due in a given trimester and the number and percentage of each that were submitted (error-free) within the specified time intervals. Reports will be lagged by one trimester to allow 120 days from the due date for a center to submit the form. For example, the report in January will cover forms that came due in the previous May through August.

If a center has fewer than 10 total forms due within a reporting period, their evaluation will be based on the 10 most recent prior due forms. Centers with less than 10 total due forms will be considered in compliance if they have no more than one overdue form.

Compliance will be enforced according to the following schedule:

1. Both the Medical Director and the Transplant Coordinator of any center that has submitted less than 90% of total forms due during a reporting period will receive a letter from the NMDP Manager of Clinical Research informing them that their submission rates are below standards and not meeting CPI indicators. By the next report (4 months later) the center will be expected to:
   a. have completed at least 90% of forms that came due in the new reporting period.
   b. bring the cumulative rate for the two most recent periods (the new period and the period immediately prior) combined up to at least 90%.
2. If either a or b is not satisfied at the next report the center will receive a letter from the chair of the MPI Committee informing them that they are in violation of reporting standards and may be placed on probation. By the next report the center will be expected to:

   a. have completed at least 90% of forms that came due in the new reporting period.
   b. bring the cumulative rate for the three most recent periods (the new period and two immediately prior) combined up to at least 90%.

3. If either a or b is not satisfied at the next report the center will receive a second letter from the chair of the MPI Committee stating that they have been placed on probation for failure to report sufficient follow-up information. By the next report they will be expected to:

   a. have completed at least 90% of forms that came due in the new reporting period.
   b. bring the cumulative rate for the four most recent periods (the new period and three immediately prior) combined up to at least 90%.

4. If by the next report the stated conditions still have not been met, searches will be suspended for that Transplant Center. Search privileges would resume as soon as the conditions given above have been satisfied. The MPI Committee would recommend site visits and/or termination of NMDP participation at their discretion.

Each report will give numbers of each type of form (120, 520, 620; 130, 530, 630; 140, 540, 640; and 150, 550, 650) that became due within the given period of time as well as numbers and percentages of forms received at the NMDP. Totals will also be given for all forms combined. Results from the two previous periods will be updated and also displayed on the report. Thus, if a center is in danger of suspended searches because of missing forms from a year ago, they will still be able to see those on the current report. Totals will also be displayed for all forms that came due prior to two periods ago and all time through the end of the current period. Finally, a summary of total number of forms due but not yet received at the NMDP will be given for each type of form.
Appendix I

Summary
On-site Data Audit Plan of the National Marrow Donor Program

Audit Cycle

1. Each U.S. Transplant Center will be audited once within a four-year audit cycle. Transplant Centers will be assigned to one of the years in the four-year cycle.

2. To be eligible for an on-site audit, a Transplant Center must have transplanted a minimum of ten patients and be located in the U.S.

3. When a Transplant Center joins the NMDP network, the new Transplant Center’s first audit will occur in the year following the accrual of the center’s tenth patient.

Patient Selection and Eligibility Requirements

1. The number of patients audited at each transplant center will be between 10 and 25 patients. If a center has performed between 10 and 25 transplants, all patients will be audited. If a center has performed more than 25 transplants, 25 patients will be randomly selected for audit.

2. A patient is not eligible for audit until both a Form 120, 520, 620 and Form 130, 530, 630 have been submitted to the NMDP.

3. Patients will not be selected for audit more than once.

Forms and Data Fields

1. Forms 120, 520, 620; 130, 530, 630; 140, 540, 640; 150, 550, 650; 190, 590, 690; 580; 680; and corresponding inserts will be audited. See Attachment 1 for a complete listing of form versions included in the audit. Randomly selected fields on all forms for each patient will be audited.

2. Certain data fields, called critical fields, will be audited for every patient included in the audit. Critical fields have been identified as being essential to the accurate completion of outcome analyses. See Attachment 2 for a complete listing of critical fields.
Methodology

1. Monitors will compare the data submitted to the STAR® Database with data in the patient’s medical record chart.

2. Discrepancies will be categorized into one of three groups: no documentation, interpretation errors, and errors of omission.

Audit Analysis and Reports

1. Transplant centers will receive an audit report stating their center’s overall error rate, critical field error rate, random field error, and frequencies of error types (e.g., no documentation, interpretation errors, errors of omission). The report will also include a discussion of the results.

3. Cycle reports summarizing audit results for all transplant centers combined will be prepared for Research and Publications Committee, the Donor/Patient Safety Monitoring Committee and the Membership and Process Improvement Committee.
Attachment 1

Form Versions Included in the Audit

Form 120, 520, 620 v6, v7, v8  Recipient Baseline and Transplant Data

Form 120, 520, 620 – Inserts
Insert I v1, v2  Acute Myelogenous Leukemia
Insert II v1, v2  Acute Lymphoblastic Leukemia
Insert III v1, v2  Chronic Myelogenous Leukemia (CML)
Insert IV v1, v2  Other Leukemias
Insert V v1, v2  Myelodysplasia / Myeloproliferative Disorders
Insert VI v1, v2  Multiple Myeloma
Insert VII v1, v2  Other Malignancy
Insert VIII v1, v2  Aplastic Malignancy
Insert IX v1  Hodgkin and Non-Hodgkin Lymphoma
Insert X v1  Severe Combined Immunodeficiency (SCIDS)
Insert XI v1  Wiskott Aldrich’s Syndrome (WAS)
Insert XIII v1  Leukodystrophies
Insert XIV v1  Mucopolysaccharidoses and Other Storage Diseases
Insert XV v1  Chediak-Higashi Syndrome
Insert XVI v1  Hemophagocytic Lymphohistiocytosis
Insert XVII v1  X-Linked Lymphoproliferative Disease
Form 580 v2  Filgrastim Mobilized PBSC Protocol – Transplant Center PBSC
Product Analysis
Form 680 v1  Cord Blood Unit Supplement

Form 130, 530, 630 v7, v8, v9  100-Day Follow-Up Visit of Recipient

Form 130, 530, 630 – Inserts
Insert I v1  Severe Combined Immunodeficiency (SCIDS)
Insert II v1  Wiscott-Aldrich Syndrome (WAS)
Insert III v1  Post-Transplant Information for Hodgkin and Non-Hodgkin
Lymphoma
Insert V v1  Leukodystrophies 100-day Follow-Up Visit of Recipient
Insert VI v1  Mucopolysaccharidoses 100-day Follow-Up Visit of Recipient
Insert VIII v1  Chediak-Higashi Syndrome Post-Transplant Follow-Up Form
Insert IX v1  Hemophagocytic Lymphohistiocytosis Post-Transplant Follow-
Up Form
Insert X v1  X-Linked Lymphoproliferative Disease Post-Transplant Follow-
Up Form
Form 140, 540, 640 v4, v5, v6  Six Month to Two Year Follow-Up Visit of Recipient

Form 140, 540, 640 – Inserts
Insert I v1  Severe Combined Immunodeficiency (SCIDS)
Insert II v1  Wiscott-Aldrich Syndrome (WAS)
Insert III v1  Post-Transplant Information for Hodgkin and Non-Hodgkin Lymphoma
Insert V v1  Leukodystrophies Annual Follow-Up Visit of Recipient
Insert VI v1  Mucopolysaccharidoses Annual Follow-Up Visit of Recipient
Insert VIII v1  Chediak-Higashi Syndrome Post-Transplant Follow-Up Form
Insert IX v1  Hemophagocytic Lymphohistiocytosis Post-Transplant Follow-Up Form
Insert X v1  X-Linked Lymphoproliferative Disease Post-Transplant Follow-Up Form

Form 150, 550, 650 v1, v2, v3  Yearly Follow-Up for Greater Than Two Years Post-Transplant
Insert III v1  Post-Transplant Information for Hodgkin and Non-Hodgkin Lymphoma
Insert V v1  Leukodystrophies Annual Follow-Up Visit of Recipient
Insert VI v1  Mucopolysaccharidoses Annual Follow-Up Visit of Recipient

Form 190, 590, 690 v3, v4, v5  Recipient Death Information
## Current List of Critical Fields

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<tr>
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<td>120, 520, 620</td>
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<tr>
<td>Disease Stage</td>
<td>120, 520, 620 Insert</td>
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<tr>
<td>Diagnosis Date</td>
<td>120, 520, 620 Insert</td>
</tr>
<tr>
<td>Patient Birth Date</td>
<td>120, 520, 620</td>
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<tr>
<td>Patient CMV Status</td>
<td>120, 520, 620</td>
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<tr>
<td>Patient Race</td>
<td>120, 520, 620</td>
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<tr>
<td>Karnofsky Score at Transplant</td>
<td>120, 520, 620</td>
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<td>Infusion Date</td>
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<tr>
<td>Pre-Conditioning Drugs Indicator</td>
<td>120, 520, 620</td>
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<td>Cy, Bu, Ara-c, VP-16, Other Drugs</td>
<td>120, 520, 620</td>
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<td>Radiation Indicator</td>
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<tr>
<td>Manipulated for GVHD Indicator</td>
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<td>Contact Date</td>
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<td>Death Indicator</td>
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<td>Engraftment Date</td>
<td>130, 530, 630/140, 540, 640</td>
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<tr>
<td>Subsequent Decline Date</td>
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<td>Disease Status</td>
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<tr>
<td>Relapse Date</td>
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<tr>
<td>Second Infusion Indicator</td>
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<tr>
<td>Second Infusion Date</td>
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<tr>
<td>Acute GVHD Indicator</td>
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<tr>
<td>Date of Onset</td>
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<tr>
<td>Skin involvement</td>
<td>130, 530, 630/140, 540, 640</td>
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<td>Intestinal Tract</td>
<td>130, 530, 630/140, 540, 640</td>
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<tr>
<td>Liver</td>
<td>130, 530, 630/140, 540, 640</td>
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<tr>
<td>Chronic GVHD Indicator</td>
<td>130, 530, 630/140, 540, 640/150, 550, 650</td>
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<tr>
<td>Organ Involvement</td>
<td>130, 530, 630/140, 540, 640</td>
</tr>
<tr>
<td>Karnofsky Score</td>
<td>130, 530, 630/140, 540, 640/150, 550, 650</td>
</tr>
<tr>
<td>Date of Death</td>
<td>190, 590, 690</td>
</tr>
<tr>
<td>Cause of Death</td>
<td>190, 590, 690</td>
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</table>
### Helpful Numbers

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone/Fax/E-mail</th>
<th>Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marie Matlack</td>
<td>Phone: 612/627-5811 Fax: 612/362-3497 E-mail: <a href="mailto:mmatlack@nmdp.org">mmatlack@nmdp.org</a></td>
<td>Data requests, TransLink (questions about forms due report and CPI only)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kay Gardner</td>
<td>Phone: 612/362-3439 Fax: 612/362-3497 E-mail: <a href="mailto:kgardner@nmdp.org">kgardner@nmdp.org</a></td>
<td>Recipient baseline and follow-up forms, Phase II CPI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Christina Olson</td>
<td>Phone: 612/884-8443 Fax: 612/362-3497 E-mail: <a href="mailto:colson@nmdp.org">colson@nmdp.org</a></td>
<td>Recipient baseline and follow-up forms, Phase II CPI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sheryl Tasky</td>
<td>Phone: 612/884-8442 Fax: 612/362-3497 E-mail: <a href="mailto:stasky@nmdp.org">stasky@nmdp.org</a></td>
<td>Recipient baseline and follow-up forms, Phase II CPI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donna Smith</td>
<td>Phone: 612/617-8314 Fax: 612/362-3497 E-mail: <a href="mailto:dsmith@nmdp.org">dsmith@nmdp.org</a></td>
<td>Recipient baseline and follow-up forms, Phase II CPI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laurie Ladwig</td>
<td>Phone: 612/362-3454 Fax: 612/362-3497 E-mail: <a href="mailto:lladwig@nmdp.org">lladwig@nmdp.org</a></td>
<td>Recipient baseline and follow-up forms, Phase II CPI</td>
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<td>Judy Brusseau</td>
<td>Phone: 612/884-8420 Fax: 612/362-3497 E-mail: <a href="mailto:jbrussea@nmdp.org">jbrussea@nmdp.org</a></td>
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<td>Randy Krunkkala</td>
<td>Phone: 612/627-5868 Fax: 612/627-5895 E-mail: <a href="mailto:rkrunkka@nmdp.org">rkrunkka@nmdp.org</a></td>
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### Conversion Chart

#### Feet/Inches to Centimeters

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<th>ft./in.</th>
<th>inches</th>
<th>cm</th>
<th>ft./in.</th>
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<th>cm</th>
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<th>cm</th>
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<td>91.4</td>
<td>4 ft. 0 in.</td>
<td>(48)</td>
<td>121.9</td>
<td>5 ft. 0 in.</td>
<td>(60)</td>
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<td>6 ft. 0 in.</td>
<td>(72)</td>
<td>182.9</td>
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<td>(37)</td>
<td>93.9</td>
<td>4 ft. 1 in.</td>
<td>(49)</td>
<td>124.5</td>
<td>5 ft. 1 in.</td>
<td>(61)</td>
<td>154.9</td>
<td>6 ft. 1 in.</td>
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<tr>
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<td>(50)</td>
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<td>5 ft. 2 in.</td>
<td>(62)</td>
<td>157.5</td>
<td>6 ft. 2 in.</td>
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<td>4 ft. 3 in.</td>
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<td>5 ft. 3 in.</td>
<td>(63)</td>
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<td>6 ft. 3 in.</td>
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<td>7 ft. 0 in.</td>
<td>(83)</td>
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### Formula

1 inch = 2.54 centimeters (cm)

To convert inches to centimeters: $X$ inches x 2.54 = $X$ cm

Example: 29 inches x 2.54 = 73.7 cm
**Conversion Chart**

**Pounds to Kilograms**

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<td>104.1</td>
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</tbody>
</table>

**Formula**

1 pound = .4535 kilogram

To convert from pounds to kilograms: X pounds x .4535 = X kilograms

Example: 63 lbs. x .4535 = 28.6 kg
## Appendix M

### Drug List

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<thead>
<tr>
<th>ALPHABETIZED LISTING</th>
<th>CATEGORY</th>
<th>OTHER NAMES FOR THIS DRUG</th>
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<td>AML INDUCTION REGIMEN</td>
<td>cytarabine, daunorubicin</td>
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<td>ANTINEOPLASTIC</td>
<td>mercaptopurine</td>
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<td>6-MP</td>
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<td>mercaptopurine</td>
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<tr>
<td>6-Thioguanine</td>
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<td>BRAIN TUMORS REGIMEN (pediatrics)</td>
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<td>ANTIFUNGAL</td>
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### ALPHABETIZED LISTING

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<tr>
<td>10:00 p.m.</td>
<td>2200</td>
</tr>
<tr>
<td>11:00 p.m.</td>
<td>2300</td>
</tr>
<tr>
<td>12:00 midnight</td>
<td>0000</td>
</tr>
</tbody>
</table>
## Cytogenetic Abbreviations and Terminology

<table>
<thead>
<tr>
<th>Abbreviation/Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>p</td>
<td>short arm of a chromosome</td>
</tr>
<tr>
<td>q</td>
<td>long arm of a chromosome</td>
</tr>
<tr>
<td>p+</td>
<td>addition of chromosomal material to the short arm of a chromosome</td>
</tr>
<tr>
<td>q+</td>
<td>addition of chromosomal material to the long arm of a chromosome</td>
</tr>
<tr>
<td>p-</td>
<td>loss of chromosomal material to the short arm of a chromosome</td>
</tr>
<tr>
<td>q-</td>
<td>loss of chromosomal material to the long arm of a chromosome</td>
</tr>
<tr>
<td>t</td>
<td>translocation of chromosomes; e.g., t(1;19)</td>
</tr>
<tr>
<td>+</td>
<td>addition of an entire chromosome (trisomy); e.g., +21</td>
</tr>
<tr>
<td>-</td>
<td>deletion of an entire chromosome (monosomy); e.g., -7</td>
</tr>
<tr>
<td>Ph+</td>
<td>Philadelphia chromosome, arises from translocation t(9;22)</td>
</tr>
<tr>
<td>del</td>
<td>deletion of chromosomal material; e.g., del(7)(q21q34)</td>
</tr>
<tr>
<td>inv</td>
<td>inversion of chromosomal material; e.g., inv(1)(p36q21)</td>
</tr>
<tr>
<td>der</td>
<td>derivative</td>
</tr>
<tr>
<td>metaphase</td>
<td>cell phase at which chromosomes may be examined</td>
</tr>
<tr>
<td>karyotype</td>
<td>designation of results of chromosome analysis; karyotype may be defined at the cell level, cell line or clone level, or at the level of the individual</td>
</tr>
</tbody>
</table>

---

**Chromosome**

regions on the chromosome

---

**Figure:** Diagram of chromosome showing regions with numbers 12, 21, 22, 25, 24, 27, and 16. Directions indicate Short arm and Long arm.
How To Interpret Cytogenetic Nomenclature

\[ 47, XY, \text{del}(7)(q21q34), +8, t(8;9)(q13;q34)[6]/46, XY[3] \]

Key

1. Number of chromosomes detected.
2. Sex chromosomes.
3. Deletion of chromosomal material on the long arm of chromosome 7 between regions 21 and 34.
4. Trisomy 8; extra chromosome 8.
5. Translocation of chromosomal material on the long arm of chromosome 8 and the long arm of chromosome 9.
6. Number of cells (metaphases) examined with these abnormalities.
7. Separates information about differing karyotypes.
8. Number of chromosomes detected.
9. Sex chromosomes.
10. Number of cells examined with this normal karyotype.
Appendix P

Reporting Engraftment Following A Second Stem Cell Infusion
From the Original Stem Cell Donor

Follow the guidelines defined below for reporting engraftment from subsequent stem infusions on the Form 130, 530, 630 - 100 Day Follow-up Visit of Recipient.

A. Use these guidelines if the following events occurred within the first 100 days:

1. The recipient failed to engraft after the original stem cell infusion and
2. Received a subsequent stem cell infusion.

**Report sustained engraftment from the second infusion** by answering question 15 on form 130, 530, 630 as “yes, ANC ≥ 500/mm³ achieved and sustained for three consecutive lab values obtained on different days with no subsequent decline” and answering questions 16.

**Report non-engraftment after the second infusion** by answering question 15 on form 130, 530, 630 as either “no, ANC ≥ 500/mm³ was not achieved and there was no evidence of recurrent disease in the bone marrow” or “no, ANC ≥ 500/mm³ was not achieved and there was documented persistent disease in the bone marrow post transplant.”

B. Use these guidelines if the following events occurred within the first 100 days:

1. The recipient failed to engraft after the original stem cell infusion, and
2. Received a subsequent stem infusion and engrafted, and
3. Then experienced a subsequent decline in ANC.

Answer question 15 on form 130, 530, 630 as “yes, ANC ≥ 500/mm³ three consecutive days with subsequent decline in ANC to < 500/mm³ for greater than three days,” and answer questions 17-21 (and 22-24 if applicable).

C. Use these guidelines if the following events occurred within the first 100 days:

1. The recipient engrafted after the original stem cell infusion, and
2. Then experienced a subsequent decline in ANC, and
3. Received a subsequent infusion.

Answer question 15 on form 130, 530, 630 as “yes, ANC ≥ 500/mm³ three consecutive lab values obtained on different days with subsequent decline in ANC to < 500/mm³ for greater than three days,” and answer questions 17-21. If the recipient engrafted after the second infusion, this will be reported in questions 22-24.
D. If each of the following events occurred within the first 100 days:

1. The recipient engrafted after the original stem cell infusion, and
2. Then relapsed and received a subsequent stem cell infusion to treat the relapse.

Answer question 15 on Form 130, 530, 630 as “yes, ANC ≥ 500/mm³ for three consecutive lab values obtained on different days with subsequent decline in ANC to < 500/mm³ for greater than three days,” and answer questions 17-21. Answer questions 22-24 if the recipient engrafted after the second infusion. Question 18, “Date of decline in ANC to < 500/mm³ for greater than three days” should reflect the date of the first of three lab values where the ANC dropped to below 500 after the beginning of chemotherapy for the second infusion.

Follow the guidelines defined below for reporting engraftment from subsequent stem infusions on the Form 140, 540, 640 - Six Month To Two Year Follow-up Visit Of Recipient.

On the Form 140, 540, 640, follow the same guidelines for reporting engraftment from subsequent infusions that were defined for the Form 130, 530, 630. If an initial engraftment has not been reported on a previous follow-up form, and the recipient engrafts after the subsequent infusion, then answer question 15 on Form 140, 540, 640 as “yes” and complete questions 16. If an initial engraftment was reported on a previous report, and then the recipient received a subsequent stem cell infusion for either graft failure or relapse, answer question 16 on Form 140, 540, 640 as “no, recipient’s initial hematopoietic recovery was recorded on a previous report.” Report the subsequent decline in ANC (this includes a decline caused by administration of chemotherapy drugs in preparation for the second infusion) by answering question 17 as “yes” and answering questions 18-21. Engraftment from the subsequent infusion will be reported in questions 22-24.
Appendix Q

Body Surface Nomogram

This Body Surface Nomogram is an adaptation of the DuBois Formula. Locate the subject’s height on the scale at the left, and his or her weight on the scale at the right. Drawing a new line connecting the subject’s height and weight intersects the middle scale at the corresponding surface area.
Appendix R

Post-Transplant Follow-Up Disease-specific Inserts
(by insert)

<table>
<thead>
<tr>
<th>Insert number</th>
<th>Disease(s) form is completed for</th>
<th>Time frame completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insert I</td>
<td>Severe Combined Immunodeficiency (SCIDs)</td>
<td>100 day, 6 month, 1 year &amp; 2 year</td>
</tr>
<tr>
<td>Insert II</td>
<td>Wiscott-Aldrich Syndrome (WAS)</td>
<td>100 day, 6 month, 1 year &amp; 2 year</td>
</tr>
<tr>
<td>Insert III</td>
<td>Hodgkin and Non-Hodgkin Lymphoma</td>
<td>100 day, 6 month, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Insert V</td>
<td>Leukodystrophies (Globoid Cell, Metachromatic and Adrenoleukodystrophy)</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Insert VI</td>
<td>Mucopolysaccharidoses (Hurler, Hunter, Sanfilippo A-D, Morquio A-B, Maroteaux-Lamy, Sly Syndrome, Gaucher, Niemann-Pick, I-cell, Wolman, Fucosidosis, Neuronal ceroid-lipofuscinosis enzyme-NCL 1-2, Mannosidosis, Aspartyl glucosaminidase, Hypoxanthine-guanine phosphoribosyltransferase, Other storage disease)</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Insert VIII</td>
<td>Chediak-Higashi Syndrome</td>
<td>100 day, 6 month, 1 year and 2 year</td>
</tr>
<tr>
<td>Insert IX</td>
<td>Hemophagocytic lymphohistiocytosis</td>
<td>100 day, 6 month, 1 year and 2 year</td>
</tr>
<tr>
<td>Insert X</td>
<td>X-linked Lymphoproliferative Disease</td>
<td>100 day, 6 month, 1 year and 2 year</td>
</tr>
</tbody>
</table>
## Post-Transplant Follow-Up Disease-specific Inserts
(by disease)

<table>
<thead>
<tr>
<th>Disease form is completed for</th>
<th>Insert number</th>
<th>Time frame completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute lymphoblastic leukemia (ALL)</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute mast cell leukemia</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute myelogenous leukemia (AML)</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute undifferentiated leukemia</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Adrenoleukodystrophy</td>
<td>Insert V</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Amegakaryocytosis / congenital thrombocytopenia</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Aspartyl glucosaminidase</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Ataxia telangiectasia</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Bilineage leukemia</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Biphenotypic leukemia</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Breast cancer</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Cartilage – hair hypoplasia</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Central nervous system tumors</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Chediak-Higashi syndrome</td>
<td>Insert VIII</td>
<td>100 day, 6 month, 1 year and 2 year</td>
</tr>
<tr>
<td>Chronic granulomatous disease</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Chronic lymphocytic leukemia (CLL)</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Chronic myelogenous leukemia (CML)</td>
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</tr>
<tr>
<td>Combined immunodeficiency disease</td>
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<td>Not Applicable</td>
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<tr>
<td>Common variable immunodeficiency disease</td>
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<td>Not Applicable</td>
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<tr>
<td>Diamond-Blackfan anemia</td>
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</tr>
<tr>
<td>DiGeorge anamoly</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Ewing sarcoma</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Familial erythrophagocytic lymphohistiocytosis (FEL)</td>
<td>Insert IX</td>
<td>100 day, 6 month, 1 year and 2 year</td>
</tr>
<tr>
<td>Fanconi anemia</td>
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</tr>
<tr>
<td>Fucosidosis</td>
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<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Gaucher</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Glanzmann thrombasthenia</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Globoid cell</td>
<td>Insert V</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Hairy cell leukemia</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Hemophagocytic lymphohistiocytosis</td>
<td>Insert IX</td>
<td>100 day, 6 month, 1 year and 2 year</td>
</tr>
<tr>
<td>Hemophagocytosis</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Histiocytosis-X</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Hodgkin and Non-Hodgkin lymphoma</td>
<td>Insert III</td>
<td>100 day, 6 month, 1 year, 2 year and ≥ 2 year</td>
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<tr>
<td>Hunter</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
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<tr>
<td>Hurler</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Hybrid leukemia</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
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</table>
### Post-Transplant Follow-Up Disease-specific Inserts
(by disease)

<table>
<thead>
<tr>
<th>Disease form is completed for</th>
<th>Insert number</th>
<th>Time frame completed</th>
</tr>
</thead>
<tbody>
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<td>Hypoxanthine-guanine phosphoribosyltransferase</td>
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<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>I-cell</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Juvenile CML</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Kostmann neutropenia</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Leukocyte adhesion deficiency</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Leukodystrophies</td>
<td>Insert V</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Mannosidosis</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Maroteaux-Lamy</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Metachromatic</td>
<td>Insert V</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Morquio A-B</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
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<td>Mucolipidoses</td>
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<td>Mucopolysaccharidoses</td>
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<td>Multiple myeloma</td>
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</tr>
<tr>
<td>Myelodysplastic / myeloproliferative disorders (MDS)</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Neuroblastoma</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Neuronal ceroid-lipofuscinosis enzyme-NCL 1-2</td>
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<td>100 day, 1 year, 2 year and ≥ 2 year</td>
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<tr>
<td>Neutrophil actin deficiency</td>
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<td>Not Applicable</td>
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<td>Niemann-Pick</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
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<td>Osteopetrosis</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Other storage disease</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Plasma cell leukemia</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Prolymphocytic leukemia (PLL)</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Sanfilippo A-D</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>Severe aplastic anemia (SAA)</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Severe Combined Immunodeficiency (SCIDS)</td>
<td>Insert I</td>
<td>100 day, 6 month, 1 year and 2 year</td>
</tr>
<tr>
<td>Sickle cell anemia</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Sly syndrome</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
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<td>Small cell lung cancer</td>
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<td>Thalassemia major</td>
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<tr>
<td>Waldenstrom macroglobulinemia</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Wiscott Aldrich syndrome (WAS)</td>
<td>Insert II</td>
<td>100 day, 6 month, 1 year and 2 year</td>
</tr>
<tr>
<td>Wolman</td>
<td>Insert VI</td>
<td>100 day, 1 year, 2 year and ≥ 2 year</td>
</tr>
<tr>
<td>X-linked lymphoproliferative disease</td>
<td>Insert X</td>
<td>100 day, 6 month, 1 year and 2 year</td>
</tr>
</tbody>
</table>
Appendix S

Follow-up Forms Due After a Subsequent Stem Cell Infusion

Subsequent stem cell infusion following primary marrow transplant

Continue with follow-up based on first transplant if
  ➢ Cryopreserved marrow from original donor
  ➢ Marrow or mobilized PBSC from non-NMDP unrelated donor (Cooperative Registry donors)
  ➢ Non-MDP cord blood

New baseline form and follow-up starts over based on new infusion date if
  ➢ Fresh marrow from original unrelated donor
  ➢ Mobilized peripheral blood stem cells from original donor
  ➢ Marrow from second NMDP unrelated donor
  ➢ Mobilized peripheral blood stem cells from second NMDP unrelated donor
  ➢ NMDP cord blood

Form 150 due annually on anniversary of original marrow infusion if
  ➢ Marrow from related donor
  ➢ Peripheral blood from related donor
  ➢ Cord blood from related donor
  ➢ Autologous cryopreserved marrow
  ➢ Autologous cryopreserved peripheral blood
Follow-up Forms Due After a Subsequent Stem Cell Infusion

Subsequent stem cell infusion following primary mobilized PBSC transplant

Continue with follow-up based on first transplant if

- Cryopreserved mobilized peripheral blood stem cells from original donor
- Marrow or mobilized PBSC from non-NMDP unrelated donor (Cooperative Registry donors)
- Non-NMDP cord blood

New baseline form and follow-up starts over based on new infusion date if

- Fresh marrow from original donor
- Fresh mobilized peripheral blood stem cells from original donor
- Marrow from second NMDP unrelated donor
- Mobilized peripheral blood stem cells from second NMDP unrelated donor
- NMDP cord blood

Form 150 due annually on anniversary of original marrow infusion if

- Marrow from related donor
- Peripheral blood from related donor
- Cord blood from related donor
- Autologous cryopreserved marrow
- Autologous cryopreserved peripheral blood
Follow-up Forms Due After a Subsequent Stem Cell Infusion

Subsequent stem cell infusion following cord blood transplant

Continue with follow-up based on first transplant if
- Marrow or mobilized PBSC from non-NMDP unrelated donor (Cooperative Registry donors)
- Non-NMDP cord blood

New baseline form and follow-up starts over based on new infusion date if
- Fresh marrow from NMDP unrelated donor
- Fresh mobilized peripheral blood stem cells from NMDP unrelated donor
- Second NMDP cord blood

Form 150 due annually on anniversary of original marrow infusion if
- Marrow from related donor
- Peripheral blood from related donor
- Cord blood from related donor
- Autologous cryopreserved marrow
- Autologous cryopreserved peripheral blood