

CHAPTER 10

DATA COLLECTION

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10.1 DATA COLLECTION PROCEDURES

Data for the Cord Blood Transplantation (COBLT) Study will be submitted on forms supplied by the National Marrow Donor Program (NMDP), the International Bone Marrow Transplant Registry (IBMTR), and on supplementary forms supplied by the Medical Coordinating Center (MCC).

10.1.1 Training and Certification

COBLT requires training and certification of COBLT Clinic Coordinators in forms completion and submission. Clinic Coordinators who attend a data management training session at a COBLT Clinic Coordinators Meeting will be considered certified in forms completion and submission. Clinic Coordinators who have not attended a data management training session can be granted certification by the Data Coordinator at the MCC.

On completion of the training requirements, Clinic Coordinators will be assigned a certification number by the Data Coordinator. The certification number will be unique for each Clinic Coordinator and must be recorded on all study forms submitted to the MCC. COBLT does not require that certified personnel complete forms. However, COBLT does require that all forms be reviewed and submitted by a certified Clinic Coordinator.

10.1.2 Forms Completion

The COBLT Recipient ID and the COBLT Name Code, the first 3 letters of the patient's last name, will be used to identify individual patients participating in the COBLT Study. Patient names, social security numbers, and any other patient identifiers must be removed from all NMDP and IBMTR forms before submission to the MCC.

All reported data items should be legibly completed. Illegible data items cannot be entered into the master database and will be reported as missing values. If data for a required item are not available, a line must be drawn through the data box and "Not Tested" written in the margin beside the box. On questions that state "check all that apply," all appropriate data items should be marked, as the computer system will set any unmarked item to a negative response.

Corrections to COBLT data should be made on the form by placing a line through the incorrect number(s) or word(s), recording and circling the correct response, and dating and initialing the correction. All corrections should be done with an ink pen; correction fluid should never be used.

10.1.3 Forms Submission and Missing Forms

Supplementary forms and copies of NMDP and IBMTR forms should be mailed to the Data Coordinator at the MCC using COBLT mailing labels. A copy of every form submitted to the MCC

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should be retained at the clinic in a patient's COBLT file. Each mailing must include a completed Forms Mail Log (Section 10.4.1). The Forms Mail Log is used by the MCC to confirm receipt of forms and can assist in tracking forms that were sent by the Clinical Centers.

Only current versions of NMDP forms, IBMTR insert, and COBLT supplementary forms will be accepted by the MCC. Forms with old version numbers will be returned to the Clinic and a completed current version of the form requested. Clinic Coordinators will be supplied with new forms whenever the date printed on the form's lower left corner is changed. Clinic Coordinators should discard old forms when new forms are received.

Table 10.1.1 summarizes the timing of submission of the COBLT supplementary forms, the NMDP forms, and the IBMTR insert. Table 10.1.2 details the criteria for forms submission. Forms that are not received at the MCC within the submission criteria are considered delinquent. Delinquent forms will be identified by the MCC on a bi-monthly basis and a Missing Forms Report will be distributed to the Clinical Centers. A missing form will continue to be requested either until the data for the form are sent and integrated into the MCC's master database or until an exception is granted and entered into the Missing Forms Exception File. Exceptions should be requested by indicating on the Missing Forms Report that no data are available. The report should then be mailed or faxed to the Data Coordinator at the MCC.

10.1.4 Missing and Incorrectly Coded Data

Missing data, incorrectly coded data, questionable data, and inconsistent coding between data items on and within forms will be detected by the MCC database quality system during each database update. All probable errors and inconsistencies detected by the database quality system generate a query message. Query reports will be mailed to COBLT Clinical Centers within the first week of each month.

10.1.5 Ordering Forms

A packet consisting of the following forms will be mailed after each patient registration:

- ! 17 Acute GVHD Assessment Forms
- ! 6 Post-Transplant Infection Forms
- ! 3 Re-Admission Forms
- ! 3 Hematopoiesis Assessment Forms - Neutrophils
- ! 3 Hematopoiesis Assessment Forms - Red Cell
- ! 2 Toxicity Forms
- ! 1 Relapse Form
- ! 1 Infusion Form
- ! 10 Specimen Submission Forms

The COBLT Supplementary Forms Request (Section 10.4.2) should be used to order additional supplementary patient data forms and laboratory forms. Mailing labels can also be ordered using the Supplementary Forms Request. The order may be mailed or faxed to the COBLT Administrator at the MCC.

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10.1.6 Additional Reporting Requirements

COBLT clinics are required to provide information on all patients receiving cord blood, unrelated-donor marrow, and haplo-identical transplants at their centers, both on and off protocol. Clinic Coordinators should complete and fax to the MCC, on the first working day of each month, a Monthly Recruitment Report (Section 10.4.3). The report should reflect the previous month's activities.

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**Table 10.1.1
Forms Submission Schedule**

FORM	Prior to Transplant	Days Post-Transplant						Months Post-Transplant						
		1-28	29-42	43-99	100	120	150	6	9	12	18	24	36	48
Eligibility	X													
CBU Thawing and Infusion Form		X												
Acute GVHD Weekly Assessment		Submit weekly				X	X							
NMDP 120: Baseline + Insert		X												
IBMTR Cord Blood Transplant Insert		X												
Toxicity		X	X											
Hematopoiesis Assessment - Neutrophils			X ¹		X ¹									
Hematopoiesis Assessment - Red Cells					X			X ²		X ²				
NMDP 130: 100-Day Visit					X									
Specimen Submission Form - Immune Reconstitution ³		X	X	X				X	X ⁴	X	X ⁴	X	X	X
NMDP 140: Follow-Up Visit								X		X		X	X	
Post-Transplant Infection		Submit after each infectious episode or at follow-up visits if no infection has occurred												
Re-Admission		Submit for each hospitalization after the initial discharge												
Relapse		Submit at time of relapse												
Adverse Experience		Submit for each unexpected serious adverse experience												

1. Or at time of graft failure.
2. Due if Red Cell Engraftment not previously documented.
3. Only required for patients with malignant diseases.
4. Optional.

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**Table 10.1.2
Criteria for Forms Submission**

Supplementary Forms:

Form	Submission Criteria
CBU Thawing and Infusion	≤ 15 days after CBT
Acute GVHD	≤ 14 days after GVHD staging date
Post-Transplant Infection	≤ 14 days after infection starting date or ≤ 45 days after follow-up visit target date
Re-Admission	≤ 14 days after discharge date
Toxicity	≤ 14 days after end of assessment period
Relapse	≤ 7 days after date of relapse
Hematopoiesis Assessment-Neutrophils	≤ 7 days after end of assessment period
Hematopoiesis Assessment-Red Cell	≤ 7 days after end of assessment period
Adverse Experience	≤ 24 hours after adverse experience
Specimen Submission	≤ 14 days after visit target date

NMDP and IBMTR Forms:

Form	Submission Criteria
120: Baseline + Insert	≤ 28 days after registration
IBMTR Insert	≤ 28 days after registration
130: 100-Day	≤ 45 days after 100-day target date
140: Follow-up	≤ 45 days after visit target date
190: Death	≤ 7 days after death

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10.2 FORMS AND INSTRUCTIONS

10.2.1 Eligibility Form

This form is designed to ensure that patients registered onto the COBLT Study meet the eligibility criteria. The Eligibility Form should be faxed to the Data Coordinator at the Medical Coordinating Center (MCC) for eligibility confirmation prior to registration.

Note: All dates on this form must be earlier than the date the form is received at the MCC.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: If "Other" is used for any data item, then the corresponding "Specify" text must be filled in.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE ELIGIBILITY FORM.

1. Indicate the source of the cord blood unit (CBU) selected for transplant.
 - ! If the unit is from a COBLT Cord Blood Bank, record the COBLT Cord Blood Bank unit I.D. number and proceed to Question 5.
 - ! If the unit is from a source other than a COBLT Cord Blood Bank, continue with Question 2.
- 2a-c. Record CBU I.D. number, the post-processing/pre-cryopreservation total nucleated cell count, and the patient weight used when selecting the CBU for transplant.
3. Indicate whether or not a sample of the CBU has been sent to a COBLT HLA Typing Lab.
4. Record the CBU HLA Typing.

Note:

- *'Typing Method' and 'Antigens/alleles provided' MUST be completed.*
 - *If the recipient is known to be homozygous (from familial typing), 'Antigens/alleles provided' should be recorded as 'Two' and the comments should reflect that the patient is known to be homozygous for the locus.*
 - *If the recipient is presumed to be homozygous, 'Antigens/alleles provided' should be recorded as 'One' and the comments should reflect that the patient is presumed to be homozygous for the locus.*
5. Indicate if the confirmatory HLA-Typing Report – Recipient from the COBLT HLA Typing Lab has been received at the Transplant Center.
 6. Record the proposed starting date for conditioning therapy.

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7. Record the patient's date of birth
8. Indicate the patient's sex.
9. If the patient is female, indicate whether or not she is currently pregnant or breastfeeding.
10. Indicate whether or not the patient had a previous allogeneic stem cell transplant with cytoreductive preparative therapy.
11. If the answer to Question 10 is "Yes", indicate the date of allogeneic stem cell transplant.
12. Indicate whether or not the patient has had a previous autologous stem cell transplant.
13. If the answer to Question 12 is "Yes", indicate the date of autologous stem cell transplant.
14. Indicate whether the patient has a consenting, 5 of 6 or 6 of 6 HLA-matched related donor.
15. Record the date the patient signed the informed consent form to receive the cord blood transplant.
16. Indicate whether or not the primary disease includes active CNS leukemia involvement.
17. If the answer to Question 16 is "Yes", indicate whether or not the cerebrospinal fluid contains > 5 WBC/ μ L.
18. If the answer to Question 16 is "Yes", indicate whether or not malignant cells have been found as a result of cytopsin.
19. Record the functional status of the patient by indicating the current Karnofsky score for patients aged 16 or older or the current Lansky score for patients under 16 years of age.
20. Indicate whether or not the patient has an uncontrolled viral, bacterial, or fungal infection at the time of enrollment.
21. Indicate whether or not the patient is seropositive for HIV.
22. Indicate whether or not the patient has myelofibrosis.
23. If the answer to Question 22 is "Yes", record grade of myelofibrosis.
24. If the answer to Question 22 is "Yes", indicate whether or not the recipient has primary myelofibrosis.

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25. Indicate whether or not the patient has been diagnosed with dyskeratosis congenita.
26. Indicate whether or not the patient has symptomatic cardiac disease.
- 27a,b. If the answer to Question 26 is “Yes”, record the left ventricular ejection fraction at rest or record the shortening fraction at rest.
28. If the answer to Question 26 is “Yes” and left ventricular ejection fraction was measured, indicate whether or not it improves with exercise.
29. Indicate whether or not the patient has any pulmonary disease symptoms.
- 30a,b. If the answer to Question 29 is “Yes”, record DLCO, FEVI or FEC (Diffusion capacity) or record O₂ saturation on room air.
31. Record the most recent serum creatinine, SGOT, and total serum bilirubin values. Also indicate the serum creatinine upper limit of normal and lower limit of normal for your institution, and the SGOT upper limit of normal for your institution.
32. Indicate whether or not the serum creatinine value is greater than the institution’s ULN.
33. If the answer to Question 32 is “Yes”, record creatinine clearance value and LLN for your institution.
34. If the answer to Question 32 is “Yes”, record glomerular filtration rate (GFR) and LLN for your institution.
35. Record the patients primary disease.
36. If the patient has Acute Myelogenous Leukemia (AML) with translocation t(8;21) and inv (16), indicate whether or not the patient is in complete remission. Complete remission is defined as $\leq 5\%$ blasts in marrow.
37. If the answer to Question 36 is “Yes”, indicate whether or not the patient has failed first line induction therapy.
38. Indicate whether or not the patient is in first complete remission with translocation t(15;17). Complete remission is defined as $\leq 5\%$ blasts in marrow.
39. If the answer to Question 38 is “Yes”, indicate whether or not the patient has failed first-line induction therapy.
40. If the answer to Question 38 is “Yes”, indicate whether or not the patient has molecular evidence of persistent disease.

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- 41-43. Indicate whether or not the patient has Down Syndrome and is in first complete remission. Indicate whether or not the patient is in ≥ 3 medullary relapse. Indicate whether or not the patient has refractory disease (other than primary induction failure).
44. If the patient has Acute Lymphoblastic Leukemia (ALL), indicate whether or not the patient is in first complete remission. Complete remission is defined as ≤ 5 % blasts in marrow.
- 45-48. If the answer to Question 44 is “Yes”, indicate whether or not the patient has hypoploidy or pseudodiploidy with translocation t(9;22), 11q23, or t(8;14) or +MLL gene rearrangement. Record the white blood cell count in μL at presentation and indicate whether or not the patient achieved a complete remission after 4 weeks of induction therapy.
49. Indicate whether or not the patient has been diagnosed with B-ALL.
- 50-52. If the answer to Question 49 is “Yes”, indicate whether or not the patient has translocation t(8;14). Indicate whether or not the blasts have surface immunoglobulins. Indicate whether or not the patient is CD10+.
- 53-54. Indicate whether or not the patient is in ≥ 3 medullary relapse. Indicate whether or not the patient has refractory disease (other than primary induction failure).
55. If the patient has Chronic Myelogenous Leukemia (CML), record the date of diagnosis.
56. Record the phase of CML.
- 57-59. If the answer to Question 56 is “Chronic” phase, indicate whether or not the patient has an adequately matched unrelated bone marrow donor identified. Indicate whether or not the patient has been unresponsive to interferon. Indicate whether or not the patient is unable to tolerate interferon.
- 60-61. If the patient has Undifferentiated or Bi-Phenotypic Leukemia, indicate whether or not the patient is in ≥ 3 medullary relapse. Indicate whether or not the patient has refractory disease (other than primary induction failure).
- 62-69. If the patient has Juvenile Myelomonocytic Leukemia (JMML), indicate whether or not the Philadelphia chromosome is present. Record % marrow blasts and peripheral blood monocytes. Indicate whether or not there is spontaneous growth of peripheral blood and/or GM-CSF hypersensitivity. Indicate whether or not the patient has an increased hemoglobin F for his/her age. Indicate whether or not the patient has clonal abnormalities present and myeloid precursors present in the peripheral blood. Record the white blood cell count at diagnosis.
70. If the patient has Myelodysplastic Syndrome (MDS), indicate the patient’s disease using the disease definitions in COBLT Protocol, Section 2.2.1.

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- 71-74. If the patient has Hodgkins Disease, Non-Lymphoblastic Non-Hodgkins Lymphomas or Lymphoblastic Non-Hodgkins Lymphomas, indicate whether or not the patient is in first complete remission. Indicate whether or not the patient was a primary induction failure. Indicate whether or not tumors demonstrated chemosensitivity. Tumors have demonstrated chemosensitivity (defined as > 50 % reduction in mass size). Indicate whether or not the patient has a history of bone marrow involvement.
- 75-78. If the patient has Acquired Severe Aplastic Anemia, record the granulocyte, platelet and absolute reticulocyte count. Indicate whether or not the patient is unresponsive to medical therapy with anti-thymocyte globulin and/or cyclosporine.
- 79.a,b. If the patient has Hurler's Syndrome, Adrenoleukodystrophy, Maroteaux-Lamy Syndrome, Globoid Cell Leukodystrophy, Metachromatic Leukodystrophy, Fucosidosis, Mannosidosis or other Metabolic Disorder, and the patient is greater than 5 years of age, record the patient's IQ. If the patient is less than or equal to 5 years of age, indicate whether or not the patient's neurodevelopmental exam demonstrates potential for stabilization at a level of functioning where continuous life support would not be predicted to be required in the year following transplantation.
- 80-81. If the patient has Fanconi Anemia, indicate whether or not increased chromosomal fragility assays to mitomycin C and DEB have been documented. Indicate whether or not the patient has been diagnosed with severe pancytopenia, myelodysplastic syndrome with clonal chromosomal abnormalities and/or leukemic transformation.
82. If the patient has a combined immunodeficiency disorder, indicate whether or not the patient requires cytoreduction.
83. If the patient has Familial Erythrophagocytic Lymphohistiocytosis (FEL), indicate whether or not the cerebrospinal fluid is currently positive for disease as defined by abnormal brain MRI or neurologic symptoms or > 7/mm³ lymphocytes plus monocytes.
84. If the patient has Langerhans Cell Histiocytosis, Blackfan-Diamond, Kostmann's Congenital Agranulocytosis, indicate whether or not the disease is unresponsive to medical therapy.
85. Indicate the patient's COBLT strata.
86. Indicate the patient's planned conditioning regimen.
- ! If the patient's planned conditioning regimen are choices 1, 2, or 4, sign, date, and provide your 5-digit COBLT study I.D. on the form. Fax the form to 301-299-3991 to expedite the registration process, and notify search coordinator at the MCC of its submission.
- ! If the patient's planned conditioning regimen is Busulfan (Busulfex)/Melphalan, proceed to Question 87.

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87. Indicate whether or not the patient was diagnosed with infant acute leukemia when less than 2 years old.
88. If the answer to Question 87 is “Yes”, record date of diagnosis.
89. Indicate whether or not the patient has a malignant disease and is unable to tolerate TBI.
90. If the answer to Question 89 is “Yes”, record the reason the patient is unable to tolerate TBI.
- ! If the patient received prior dose-limiting radiation, record prior dose.
- ! If other reason, specify.
91. Indicate whether or not the patient has been diagnosed with leukemia or myelodysplastic syndrome due to prior therapy.

Note: Sign, date, and provide your 5-digit COBLT Study I.D. on the form. Fax the form to 301-251-1355 to expedite the registration process, and notify search coordinator at the MCC of its submission.

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10.2.2A CBU Thawing Form

This form is designed to obtain data on COBLT Cord Blood Units (CBU's) thawed for transplant or Transplant Center certification. The CBU Thawing Form should be completed at the time a CBU is thawed. All data items should be completed. Comments documenting unusual circumstances should be added at the end of the form.

Note: Thawing Procedures can be found in the Investigator's Brochure that accompanies every CBU used for transplant and in the COBLT MOP, Appendix B.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: Center Code is the center's NMDP ID.

Note: When recording data for CBU's thawed for Transplant Center certification, record 999 999 6 for the COBLT Recipient ID and CRT for COBLT Name Code.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE CBU THAWING FORM.

1. Record the date and starting time of the CBU thaw.
2. Record the total viable nucleated cell count of the CBU recorded on the Transplant Center Feedback Sheet or Thawing Certification CBU packing information.
3. Record the reagent and supply data.
 - Record the lot number of the cell wash/infusion bag set.
 - Record the lot number, expiration date and manufacturer for the Dextran 40.
 - Record the lot number, expiration date and manufacturer for the stock albumin.
4. Record the weight of washed and resuspended cells in the Transplant Bag from tared scale. The bag should be weighed after re-suspending the cells and prior to removal of the QC sample. This value should be recorded in grams and rounded to one decimal place.
5. Record the cell count and viability of washed and resuspended CBU in Transplant Bag.
 - Record the volume for infusion. This value should be recorded in milliliters and reported to one decimal place.
 - Record the cell viability. This value should be reported as a percentage.
 - Record the automated nucleated cell count. This value should be recorded $\times 10^6$ /mL and rounded to one decimal place.
 - Calculate the viable cell recovery to determine if recovery of additional cells is necessary (see thawing procedures for details).

Note: Total viable nucleated cells in the resuspended CBU is calculated by multiplying the volume for infusion, the cell viability, and the automated nucleated cell count. The calculated value should be $\times 10^8$. The total viable nucleated cells in the pre-freeze CBU is the value recorded for Question 2.

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6. Indicate whether or not cells from the waste-bag supernatant were recovered and infused. If the answer to Question 6 is “Yes”, complete Question 7. If the answer to Question 6 is “No”, skip to Question 9.
 7. Indicate whether or not the recovered cells were added to the Transplant Bag for infusion.
 8. If the answer to Question 7 is “Yes”, complete Question 8 with the final volume infused, cell viability, and cell count from the Transplant Bag. If the answer to Question 7 is “No”, complete Question 8 with the volume infused, cell viability, and cell count from the second bag.
 9. Calculate the final infused viable cell recovery.
 - Record the total viable nucleated cell count. This value should be recorded $\times 10^8$ and rounded to two decimal places.
- Note: If only 1 transplant bag is used for infusion, total viable nucleated cell count is calculated by multiplying the final volume for infusion, the final cell viability, and the final automated nucleated cell count. If 2 bags are used for infusion, add the total viable nucleated cell count for bag 2 (calculated for Question 8) to the total viable nucleated cell count for the first transplant bag (calculated for Question 5).*
- Record the viable cell recovery. This value should be recorded as a percentage and rounded to one decimal place.
- Note: Viable cell recovery is calculated by dividing the FINAL total viable nucleated cell count recorded for Question 9 by the total viable nucleated cells in the pre-freeze CBU recorded for Question 2.*
10. Record the recipient’s actual body weight on the day of infusion.
 11. Indicate if there were performance issues with the cryo bag or cell wash/infusion bag set. If Question 11 is “Yes”, specify the problem. If “No”, continue with Question 12.
 12. Record your 5 digit Study ID(s). These Study ID’s are issued by the Medical Coordinating Center.
 13. Indicate the results of the sterility assay. Record as ‘Pending’ at the time of thaw. When sterility assay results are available, update the form and fax to the MCC. If Question 13 is “Yes”, specify the type of bacteria. If the type of bacteria is unknown, write ‘Unknown’.

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10.2.2B CBU Infusion Form

This form is designed to obtain data on the infusion of the COBLT Cord Blood Unit (CBU). All data items should be completed. Comments documenting unusual circumstances should be added at the end of the form. The CBU Infusion Form should be faxed to the Data Coordinator at the Medical Coordinating Center (MCC) within 48 hours of transplant.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: Center Code is the center's NMDP ID.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE CBU INFUSION FORM.

- 1-2. Record the date, starting, and finishing time of the CBU infusion.
3. Indicate if any pre-infusion medications were administered within 2 hours of infusion
4. If the answer to Question 3 is "Yes", record the medication administered.
5. Indicate if emergency medications were administered during or within 2 hours of infusion.
6. If the answer to Question 5 is "Yes", record the emergency medications administered.
7. Record the highest grade of complication/toxicity the patient experienced within 24 hours of the infusion.

Note: A toxicity grade should be indicated for each category listed.

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10.2.3 Acute GVHD Weekly Assessment

This form is designed to obtain information on acute GVHD within the first 100 days post-transplant. The first Acute GVHD Weekly Assessment Form should be completed between day 4 and day 10 post-CBT. Assessments should be made every 7 days from the previous assessment date up to day 100 post-CBT and at day 120 and day 150 post-CBT. All data items should be completed. Comments documenting unusual circumstances may be added at the end of the form.

- Note:*
- *The COBLT Name Code is the first 3 letters of the patient's last name.*
 - *The COBLT Recipient ID is assigned by the MCC at the time a preliminary search form is submitted.*
 - *For Assessments 1 - 14, number should be recorded as the week number post transplant. The 120 day visit should be recorded as Assessment Number 15 and the 150 day as Assessment Number 16.*
 - *Center code should be completed using your center's 3-digit NMDP code.*
 - *If "Other" is used for any data item, then the corresponding "Specify" text must be filled in.*

Note: *The Rule of Nines is included on the back of the form to assist in estimating the percentage of body surface involved.*

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE ACUTE GVHD WEEKLY ASSESSMENT FORM.

1. Record the date on which the GVHD staging levels were determined.
2. Record the type of immunosuppressant received during the assessment period. If no immunosuppressant was received, record 'Not Given' during the assessment period.
3. Record the lowest immunosuppressant trough level determined during the assessment period and record the date this level was determined. If an immunosuppressant is given but the trough level is below detectable levels (e.g. < 25 or < 50, depending on assay used), record 25 and include comments.

Note: ***Assessment period** is defined as a 1-week period which encompasses the date of staging.*

4. Indicate the highest level of organ abnormalities for skin, intestinal tract, liver, and upper GI during the assessment period. Note that this should reflect all symptoms, not just symptoms attributed to GVHD.
5. Indicate for skin, intestinal tract (upper or lower), and liver the etiologies that contributed to the symptoms within the assessment period or within the subsequent 7-

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day period. For day 120 post-CBT, the assessment period covers the previous 20 days and subsequent 7-day period. For day 150 post-CBT, the assessment period covers the previous 30 days and subsequent 7-day period.

6. Indicate the biopsy results pertaining to GVHD for skin, intestinal tract (upper or lower), and liver. If a biopsy was not taken, record 'Not Done.'
7. Indicate whether or not primary or secondary treatment for GVHD was initiated. If treatment was initiated, indicate the type of treatment in the comments section of the form.

- Note:*
- *The answer should be marked as “No” if only topical treatment was given.*
 - *The answer should be marked as “No” if only cyclosporine or tacrolimus dose adjustments were made.*
 - *The answer should be marked as “Yes” if steroid doses are increased.*
 - *The answer should be marked as “Yes” for any new systemic treatment.*

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10.2.4 Toxicity Form

This form is designed to obtain information on regimen-related toxicities experienced by COBLT patients by Days 28 and 42 post-CBT. Toxicities should be graded using the scale on the back of the form.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: The COBLT Recipient ID is assigned by the MCC at the time a preliminary search form is submitted.

Note: Center code should be completed using your center's 3-digit NMDP code.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE TOXICITY FORM.

1. Record the date of evaluation. The evaluation date must be 28 days and 42 days or more post-CBT.
2. Indicate the highest grade of toxicity diagnosed by the day of evaluation. Use the grading scale on the back of the form to determine the grade.
3. Indicate the highest level of allergic reaction the patient experienced within the report period.
4. Indicate the highest level of persistent nausea and vomiting the patient experienced within the report period. If it is assessment period #1 (Day 28), sign and submit the form; otherwise, continue with Question #6.
5. Record the immunosuppression assay method.
6. Indicate if the patient was treated for hyperacute GVHD ("cytokine storm").
7. Indicate when the symptoms of the hyperacute GVHD first appeared.
8. Record the patient's maximum fever experienced during the reaction.
9. Indicate whether or not erythroderma was present.
10. Record the total dose of Solumedrol given during this period.
11. Record any other treatment given for the treatment of the hyperacute GVHD.

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10.2.5 Hematopoiesis Assessment - Neutrophils

This form is designed to collect data on engraftment and graft failure for all COBLT patients surviving at least 28 days post-CBT. The form should be completed at the following times:

Day 42 post-CBT: All patients surviving to at least day 14 post-CBT.
Day 100 post-CBT: All patients not experiencing secondary graft failure. Complete at day 100 or at time of death if patient dies between day 42 and day 100.
Secondary graft failure: All patients experiencing secondary graft failure.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: The COBLT Recipient ID is assigned by the MCC at the time a preliminary search form is submitted.

Note: Center code should be completed using your center's 3-digit NMDP code.

Note: If "Other" is used for any data item, then the corresponding "Specify" text must be filled in.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE HEMATOPOIESIS ASSESSMENT FORM-NEUTROPHILS.

1. Indicate whether or not the patient engrafted as evidenced by an ANC $\geq 500/\text{mm}^3$ on 3 consecutive days.
2. If the answer to Question 1 is "Yes", record the ANC values and the dates the values were obtained.
3. Indicate whether or not the patient had severe neutropenia (ANC $< 500/\text{mm}^3$) without subsequent improvement occurring either spontaneously or after growth factor therapy. Improvement is defined as ANC $\geq 500/\text{mm}^3$ consistently.
4. If the answer to Question 3 is "Yes", then record percent of marrow cellularity. Check box if marrow cellularity is not quantifiable, but less than 25%.
5. If the answer to Question 3 is "Yes", then record the date the marrow sample was obtained.
6. Record the results of any chimerism assays performed on the marrow or blood. If an assay was performed, record the assay date, the primary method used, and the assay results.
7. Indicate whether or not the patient received stem cell reinfusion (marrow or peripheral blood) due to inadequate hematopoietic function.
8. If the answer to Question 7 is "Yes", then record the date of stem cell infusion. Record the first date if the patient received more than one.

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10.2.6 Hematopoiesis Assessment - Red Cells

This form is designed to collect data on red cell engraftment for all COBLT patients surviving at least 28 days post-CBT. The form should be completed at the following times:

- Day 100 post-CBT: All patients surviving to at least day 14 post-CBT.
6 Month post-CBT: All patients who have not achieved RBC engraftment by day 100 post-CBT.
12 Month post-CBT: All patients who have not achieved RBC engraftment by 6 months post-CBT.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: The COBLT Recipient ID is assigned by the MCC at the time a preliminary search form is submitted.

Note: Center code should be completed using your center's 3-digit NMDP code.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE HEMATOPOIESIS ASSESSMENT FORM-RED CELLS.

1. Indicate whether or not the patient engrafted as evidenced by an absolute reticulocyte count $\geq 30,000/\text{mm}^3$ for 2 consecutive measurements. If this data was previously reported, check the appropriate box.
2. If the answer to Question 1 is "Yes", record the absolute reticulocyte count values and the dates the values were obtained.
3. Record the date of the most recent red cell transfusion, if known.
4. Record the date cyclosporine ended.

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10.2.7 Specimen Submission Form - Immune Reconstitution

This form is designed to document collection and shipment of Immune Reconstitution samples for COBLT patients with **malignant** diseases. The immune reconstitution studies and submission of the Specimen Submission form are **not** required for patients with non-malignant diseases. Immune Reconstitution studies will be performed at 1 month post-CBT to 3 years post-CBT. A schedule of Immune Evaluation samples can be found in Table 9.1.3.1.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: The COBLT Recipient ID is assigned by the MCC at the time a preliminary search form is submitted.

Note: Center code should be completed using your center's 3-digit NMDP code.

Note: A copy of the Specimen Submission Form should be sent to the MCC at the time of shipment.

Note: Samples should be sent to:

*Robertson Parkman, M.D.
Children's Hospital, Los Angeles
4650 Sunset Boulevard, Mail Stop #62
Los Angeles, CA 90027*

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE SPECIMEN SUBMISSION FORM.

1. Record the date that the blood sample was drawn.
2. Record the date that the sample was shipped to the laboratory for processing.
3. Record the date of the most recent tetanus immunization.
4. If this is the first assessment, provide infectious disease testing results.

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10.2.8 Post-Transplant Infection Form

This form is designed to obtain information on all infections occurring after recipient registration . A Post-Transplant Infection Form should be completed for each infection and submitted to the Medical Coordinating Center (MCC) within 14 days of the reported infection being resolved. If the patient has not had an infection between 2 COBLT follow-up visits (e.g., between the 6-month and the 1-year visit), complete Questions 1 and 2, sign, and submit the form to the MCC within 45 days of the visit target date. Comments documenting unusual circumstances may be added at the end of the form.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: The COBLT Recipient ID is assigned by the MCC at the time a preliminary search form is submitted.

Note: Center code should be completed using your center's 3-digit NMDP code.

Note: If "Other" is used for any data item, then the corresponding "Specify" text must be filled in.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE POST-TRANSPLANT INFECTION FORM.

1. Record the starting date of the infection, or, if no infection has occurred between 2 COBLT follow-up visits, record the date of the visit confirming the infection-free period.
2. Indicate whether or not the form documents an infection episode.
3. Report all clinically important infections present at the start of the infection episode. Use the codes listed on page 2 of the form to record the site(s) of infection, the organism(s) causing the infection, and the infection severity scale.
4. Indicate whether or not the only diagnosis for this infection episode was "Fever of Undetermined Origin."
5. Indicate whether or not the infection was treated in addition to ongoing prophylaxis.

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10.2.9 Re-Admission Form

This form is designed to obtain information on COBLT patients re-hospitalized following their initial hospital discharge. A Re-Admission Form should be submitted to the Medical Coordinating Center (MCC) within 14 days of the discharge date recorded on the form. All data items should be completed. Comments documenting unusual circumstances may be added at the end of the form.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: The COBLT Recipient ID is assigned by the MCC at the time a preliminary search form is submitted.

Note: Center code should be completed using your center's 3-digit NMDP code.

Note: If "Other" is checked as the primary or secondary cause, then the corresponding "Specify" text must be filled in.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE RE-ADMISSION FORM.

1. Record the date of discharge for this hospitalization period. If the patient dies in the hospital, the date of discharge is the date of death.
2. Indicate the patient's status at discharge.
3. Indicate the primary reason for re-admission. Only one primary reason can be recorded. Indicate for the remaining reasons whether they were contributing or non-contributing reasons for hospitalization.
4. Record the number of days the patient was on a ventilator for this hospitalization period. Record 0 if the patient had no days on a ventilator.

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10.2.10 Relapse Form

This form is designed to obtain data on the recurrence of disease in COBLT patients after cord blood transplantation. The form should be submitted as soon as all the information required to document relapse is complete. Relapse is defined and described in the COBLT Protocol, Section, 2.1.8. All data items should be completed. Comments documenting unusual circumstances should be added at the end of the form.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: Center Code is the center's NMDP ID.

Note: If "Other" is used for any data item, then the corresponding "Specify" text must be completed.

Note: Answer Question 51 for all patients.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE RELAPSE FORM.

1. Indicate the patient's primary diagnosis.

Note: Answer Questions 2-14 if the primary diagnosis is CML.

2. Indicate if immature hematopoietic cells have been documented in the peripheral blood.

3. If the answer to Question 2 is "Yes", record the date first documented.

4. Indicate if myeloid hyperplasia in the bone marrow has been documented in the absence of infection of growth factor.

5. If the answer to Question 4 is "Yes", record the date first documented.

6. Indicate if host cells have reappeared.

7. If the answer to Question 6 is "Yes", record the method(s) used. Check either "Yes" or "No" as appropriate for each method.

8. Indicate if the 9;22 translocation has reappeared.

9. If the answer to Question 8 is "Yes", record the date of cytogenetic analysis.

10. Record the number of metaphases analyzed.

11. Record the number of metaphases exhibiting the 9;22 translocation.

12. Indicate molecular (BCR/ABL) examinations of blood or bone marrow post-transplant.

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13. Record the date of second cytogenetic analysis.
14. Record the number of metaphases exhibiting the 9;22 translocation.

Note: Answer Questions 15-27 if the primary diagnosis is AML, ALL, Undifferentiated Leukemia, Bi-phenotypic Leukemia, Hodgkins Disease, Non-Lymphoblastic Non-Hodgkins Lymphoma, Lymphoblastic Non-Hodgkins Lymphoma, or Lymphoblastic Lymphoma.

15. Indicate if the leukemic blasts were documented in the marrow or peripheral blood. Record the % of Leukemic Blasts and the date the blasts were first observed. If % blasts are $\leq 25\%$, repeat test.
16. Indicate if host cells have reappeared.
17. Indicate if cytogenetic abnormalities have reappeared.
18. If the answer to Question 17 is “Yes”, record the method(s) used. Check either “Yes” or “No” as appropriate for each method.
19. Record the date the disease was first detected.
20. Indicate if the disease was detected at an extramedullary site. If the answer is “Yes”, continue with Questions 21-27.
21. Record the date the disease was first detected.
22. Indicate if the disease was confirmed by pathology.
23. Indicate if a new extramedullary mass had been documented.
24. Indicate if the previous masses have demonstrated an increase in size.
25. Indicate if the blasts were present in the cerebrospinal fluid.
26. If the answer to Question 25 is “Yes”, record the % of the white blood cell count in the cerebrospinal fluid.
27. Record the date the WBC was recorded.

Note: Answer Questions 28-41 if the primary diagnosis is Non-Lymphoblastic Non-Hodgkin’s Lymphoma, Lymphoblastic Non-Hodgkins Lymphoma, or Hodgkin’s Disease.

28. Indicate if there has been a progression more than 25% in the product of the 2 largest diameters of any measurable lesion. If the answer is “Yes”, answer Questions 29-36.

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29. Record the method(s) used. Check either “Yes” or “No” as appropriate for each method.
30. Record the diameter of lesion 1 pre-transplant.
31. Record the diameter of lesion 2 pre-transplant.
32. Record the date of the measurements.
33. Record the method(s) used to determine the diameter of the lesion. Check either “Yes” or “No” as appropriate for each method.
34. Record the current diameter of lesion 1.
35. Record the current diameter of lesion 2.
36. Record the date of the measurement.
37. Indicate if new definitive lesions have appeared.
38. If the answer to Question 37 is “Yes”, Indicate if the lesions have been confirmed by biopsy. If the answer is “Yes”, record the date of the biopsy.
39. Indicate if bone marrow specimens have been obtained.
40. If the answer to Question 39 is “Yes”, record the method used.
41. Indicate if there has been an appearance of lymphoma, if the answer is “Yes”, indicate the date of the appearance.

Note: Answer Questions 42-46 if the primary diagnosis is JMML.

42. Indicate if host cells have reappeared.
43. If the answer to Question 42 is “Yes”, record the method(s) used. Check either “Yes” or “No” as appropriate for each method.
44. Indicate if there are any clinical and laboratory features present which are consistent with the patient’s original disease.
45. Indicate if there has been a reappearance of an abnormal cytogenetic marker which was present at diagnosis.
46. Indicate if the patient has a GM-CSF hypersensitivity or spontaneous growth of CFU-GM in peripheral blood.

Note: Answer Questions 47-49 if the primary diagnosis is MDS.

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47. Indicate if any MDS-associated morphologic abnormalities have reappeared.
48. If the answer to Question 47 is “Yes”, record the dates of 2 consecutive marrow specimens and % cells of host origin.
49. Indicate if there has been a reappearance of an abnormal cytogenetic marker which was present at diagnosis.

Note: Answer Questions 50 and 51 if the primary diagnosis is FEL or LCH.

50. Indicate if erythrophagocytosis has been documented by biopsy or is infiltrative disease consistent with FEL or LCH.
51. Indicate if host hematopoiesis has reappeared.

Note: Answer Question 52 for all patients.

52. Indicate whether or not specific therapies were initiated for relapse reversal. If a therapy was initiated, record the first date of initiation.

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10.2.11 Adverse Experience Form

This form is designed to report a COBLT patient unexpected adverse experience. An adverse experience is defined as some unplanned, unwanted event which may or may not be related to the use of protocol therapy. Expected adverse experiences (i.e., those listed in the informed consent, product inserts, or study materials) need not be reported to the Medical Coordinating Center (MCC). Unexpected serious adverse experiences (i.e., adverse experiences NOT listed in the COBLT Protocol or the Informed Consent) must be reported to the MCC as indicated in the COBLT MOP Chapter 3, Section 3.2.

Note: The COBLT Name Code is the first 3 letters of the patient's last name.

Note: The COBLT Recipient ID is assigned by the MCC at the time a preliminary search form is submitted.

Note: Center code should be completed using your center's 3-digit NMDP code.

Note: Summarize the adverse experience on the form, attach a narrative description of the event, and include a description of the patient status. If an IRB notification has been prepared, that notice may serve as the narrative description.

Note: If "Other" is used for any data item, then the corresponding "Specify" text must be filled in.

Note: Principal Investigator must review adverse experience form and narrative description before submission to the MCC.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE ADVERSE EXPERIENCE FORM.

1. Document the adverse experience.
2. Indicate whether or not this is an unexpected serious adverse experience.
3. Indicate the severity of the adverse experience.
4. Indicate the suspected relationship to the study therapy using the definitions below:
 - Definite: Clear-cut temporal association with a positive rechallenge test or laboratory confirmation
 - Probable: Clear-cut temporal association not reasonably explained by the subject's known clinical state
 - Possible: Less clear temporal association; other etiologies are also possible
 - Remote: Less clear temporal association; other etiologies are probable

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None: No temporal association; related to other etiologies such as concomitant medications/conditions or subject's known clinical state

5. Indicate the effect of the adverse experience on study therapy.
6. Indicate whether or not treatment for the adverse effect was required.
7. Indicate the status of the adverse experience.
8. Record the date of resolution of the adverse experience, if known.
9. Indicate whether or not the adverse experience has been reported to your Institutional Review Board.

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10.3 NMDP/IBMTR FORMS AND INSTRUCTIONS

10.3.1A Form 120: Recipient Baseline and Transplant Data

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10.3.1B Form 120 Insert I – Acute Myelogenous Leukemia

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10.3.1C Form 120 Insert II – Acute Lymphoblastic Leukemia

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10.3.1D Form 120 Insert III – Chronic Myelogenous Leukemia (CML)

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10.3.1E Form 120 Insert IV – Other Leukemias

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10.3.1F Form 120 Insert V – Myelodysplasia/Myeloproliferative Disorders

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10.3.1G Form 120 Insert VI – Multiple Myeloma

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10.3.1H Form 120 Insert VII – Other Malignancy

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10.3.1I Form 120 Insert VIII – Aplastic Anemia

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10.3.1J Form 120 Insert IX – Hodgkin and Non-Hodgkin Lymphoma

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10.3.1K Form 120 Insert X – Severe Combined Immunodeficiency (SCID)

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10.3.1L Form 120 Insert XI – Wiskott Aldrich Syndrome (WAS)

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10.3.1M Form 120 Insert XIII – Leukodystrophies

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10.3.1N Form 120 Insert XIV – Mucopolysaccharidoses and Other Storage Diseases

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10.3.2 IBMTR Cord Blood Transplant Insert

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10.3.3A Form 130: 100-Day Follow-Up Visit of Recipient

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10.3.3B Form 130 Post Transplant Follow-up Form Insert I – Severe Combined Immunodeficiency (SCIDS)

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10.3.3C Form 130 Post Transplant Follow-up Form Insert II – Wiscott Aldrich Syndrome (WAS)

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10.3.3D Form 130 Post Transplant Follow-up Form Insert III – Information for Hodgkin and Non-Hodgkin Lymphoma

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10.3.4A Form 140: 6-Month to 2-Year Follow-Up Visit of Recipient

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10.3.4B Form 140 Post Transplant Follow-up Form Insert I – Severe Combined Immunodeficiency (SCIDS)

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10.3.4C Form 140 Post Transplant Follow-up Form Insert II – Wiscott Aldrich Syndrome (WAS)

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10.3.4D Form 140 Post Transplant Follow-up Form Insert III – Information for Hodgkin and Non-Hodgkin Lymphoma

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10.3.5 Form 150: Yearly Follow-Up for Greater Than Two Years Post-Transplant

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10.3.6 Form 160: Leukemia and MDS Yearly Follow-up for Relapse Post-Stem Cell Transplant

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10.3.7 Form 190: Recipient Death Information

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10.4 DATA MANAGEMENT AND REPORTING

10.4.1 Forms Mail Log

The Forms Mail Log is designed to confirm receipt of all COBLT forms at the Medical Coordinating Center (MCC) and to assist in tracking forms sent to the MCC by the COBLT Clinical Centers. A completed Forms Mail Log must accompany each batch of forms mailed to the MCC. Clinic Coordinators should keep copies of logs submitted to the MCC.

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10.4.2 Supplementary Forms Request

The Supplementary Forms Request should be used to order additional supplementary patient data forms, and mailing labels. The order may be mailed or faxed to the COBLT Administrator at the Medical Coordinating Center (MCC).

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10.4.3 Monthly Recruitment Report

The Monthly Recruitment Report is designed to provide information on all patients receiving cord blood, unrelated-donor marrow, or haplo-identical transplants at a COBLT Center. The report should reflect the previous month's activities.

Note: Fax a completed report to the Medical Coordinating Center (MCC) at 301-251-1355 on the first working day of each month.

Note: Center code should be completed using your center's 3-digit NMDP code.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE MONTHLY RECRUITMENT REPORT.

1. Record the report month and year. *The report should reflect the previous month's activities.*
2. Indicate whether or not any clinically eligible patients who were NOT enrolled on the COBLT Study Protocol received a cord blood transplant during the report month.

If the answer to Question 2 is "Yes", then record the number of patients who received a cord blood transplant and the source of the cord blood unit (CBU) for the following categories:

- The number of non-enrolled clinically eligible patients who received a cord blood transplant after an unsuccessful search of the COBLT registry or unsuccessful search of COBLT approved non-COBLT cord blood banks (CBBs) for a suitable cord blood unit (CBU).

Note: An unsuccessful search is defined as a search performed at the COBLT registry which results in a CBU that does not meet the COBLT HLA matching criteria (see Protocol 2.2.1, #12).

- The number of non-enrolled clinically eligible patients who received a cord blood transplant because a unit with a better HLA match was available from a non-COBLT approved bank.
- The number of non-enrolled clinically eligible patients who received a cord blood transplant because a unit with a higher cell count was available from a non-COBLT approved bank.
- The number of non-enrolled clinically eligible patients who received a cord blood transplant for any other reason not mentioned above. Specify reason(s).
- The number of non-enrolled clinically eligible patients who received a cord blood transplant for whom no search was made at the COBLT registry or COBLT approved registries for a suitable CBU. Specify the reason(s) why the search was not initiated.

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3. Indicate total number of patients NOT meeting the COBLT Protocol eligibility criteria, regardless of COBLT CBU availability, received a cord blood transplant during the report month. Document CBU source and reason(s) for ineligibility.

4. Record the number of haplo-identical transplants performed during the report month.

Note: A haplo-identical transplant is defined as a related donor with a 4/6 or 3/6 HLA match.

5. Record the number of unrelated donor marrow transplants performed during the report month.

6. Record the number of unrelated peripheral blood stem cell transplants performed during the report month.

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10.4.4 COBLT Bag Order Form

The COBLT Bag Order Form should be used to order COBLT collection bag sets and transfer/freezing bag sets for cord blood banks (CBBs) and COBLT cell wash/infusion bag sets for transplant centers. Orders should be faxed to the COBLT Administrator at the Medical Coordinating Center (MCC) no more than once per month. The MCC submits bag orders to Pall Medical, the bag manufacturer, within 48 hours of receipt of the COBLT Bag Order Form.