

CORD BLOOD TRANSPLANTATION STUDY MOP

CHAPTER 8

SEARCH PROCEDURES

CHAPTER 8

COBLT CORD BLOOD BANK SEARCH PROCEDURES

Sections 8.1 through 8.6 describe the search process for cord blood units stored at the two COBLT Cord Blood Banks, Duke University and UCLA. Section 8.7 addresses requirements for using cord blood units from non-COBLT Cord Blood Banks.

Searching for a suitably matched Cord Blood Unit (CBU) stored in a participating Cord Blood Bank (CBB) is performed by using the COBLT online search system at each Transplant Center. The COBLT online search system provides a tool that enhances the ability of each transplant center to perform, update, and monitor searches at the search coordinators' convenience. It also simplifies the coordination between the Medical Coordinating Center (MCC) and the participating transplant centers.

Recipient HLA-A, HLA-B, and HLA-DRB1 typing data are compared to typing data of the CBUs in the donor registry. HLA allele designations are defined according to the WHO Nomenclature Committee for Factors of the HLA System, with the original list from December 1996. Valid designations and mappings to allele level and serological level HLA types can be found on the system by selecting "HLA Mappings"(Exhibit 8.0). The COBLT Histocompatibility Subcommittee updates this list regularly and makes decisions on the serologic equivalents.

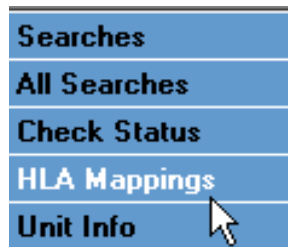


Exhibit 8.0

The COBLT study has three levels of searching and reserving COBLT CBUs - Preliminary Search, Formal Search, and CBU Reservation. Each level is described below and illustrated in Figure 8.2.

8.1 PRELIMINARY SEARCH

A preliminary search is performed to identify CBUs with a suitable cell dose and HLA type for a recipient. A preliminary search is initiated online by the transplant center. To initiate a search, select "Add/Update" (Exhibit 8.1.1). Preliminary searches performed online are available immediately for review. The first dialogue box of the add/update page is illustrated in Exhibit 8.1.2.



Exhibit 8.1.1

CORD BLOOD TRANSPLANTATION STUDY MOP

To Add a New Recipient or Update Recipient Data, Please Enter

COBLT Name Code:	<input type="text"/>	
Center :	<input type="text" value="Test Center"/>	
Date of Birth:	<input type="text" value="MM/DD/YYYY"/>	
Date Request Submitted:	<input type="text" value="03/26/2001"/> MM/DD/YYYY	<input type="button" value="Add/Update"/>

Exhibit 8.1.2

Recipient HLA typing for a preliminary search may be performed by serology or by DNA technology for Class I (HLA-A and HLA-B), and by DNA technology for HLA-DRB1. Serology may be submitted for HLA-DR, however this is not recommended. HLA typing may be updated at any time during the search process by updating recipient data online. The search algorithm will use the most recent HLA data available for each search performed to calculate a COBLT score and an “approximate” NMDP matching grade at each locus (HLA-A, -B, and -DRB1). Table 8.1.1 displays the score definitions.

**Table 8.1.1
Search Report Score and Typing Grade**

Number of Potential Antigen Matches by Level of Resolution					
COBLT Score	High Resolution DNA Typed	Low-Intermediate DNA Typed	Serologic Private/split	Serologic Broad	Mis-Match
2	2				
2	1	1			
2		2			
2	1		1		
2		1	1		
2			2		
2	1			1	
2		1		1	
2			1	1	
2				2	
1	1				1
1		1			1
1			1		1

CORD BLOOD TRANSPLANTATION STUDY MOP

The COBLT scoring algorithm assigns a “2” when there are 2 potential matches between a donor and recipient at one locus (e.g., 02XX, 31XX - 02XX, 31XX). A COBLT Score of 1 is assigned when there is one potential match and one mismatch between a donor and recipient at one locus (e.g., 40XX, 44XX - 39XX, 44XX).

8.1.1 COBLT Search Report

Following the submission of a preliminary search form, a search report may be viewed online or by viewing the Adobe.pdf (Exhibit 8.1.1.1). The recipient is uniquely identified by the seven digit COBLT ID assigned at the time the preliminary search is initiated.

Reports include recipient information and a list of potentially matched CBUs. The report lists up to 25 CBUs which satisfy the COBLT HLA matching requirements and have a minimum of 1.0×10^7 nucleated cells/per kilogram of recipient weight. On the report, COBLT CBUs are ordered first by HLA match, and within each HLA match category, by increasing nucleated cell counts. The search report provides the COBLT score, the COBLT Cord Blood Bank code, the unique CBU identification number, HLA typing, whether or not confirmatory HLA typing has been performed, donor ethnicity, ABO type, nucleated cell count, CFU-GM, and CD 34+ count for each listed CBU. In addition, the level of resolution is indicated underneath the COBLT score. The resolution is defined as a low resolution match (L), mismatch (X), or high resolution match (H). An example of the level of resolution would be LXLLHH.

Reports for new searches are automatically repeated every 7 days for a maximum of six months or until a request to discontinue the search is requested online. Searches can be extended beyond six months by notifying the MCC online. Cancellation of a search may also be initiated online. When a search is canceled a reason for cancellation must be indicated.

Date:	01/07/03	From:	The COBLT Coordinating Center
Center:	Test Center	Fax:	301-251-1161
Search Performed:	01/07/03	Phone:	301-251-1355

Cord Blood Matching Results

Recipient Name:		Recipient ID:	1023357	Name Code:	AAA
Gender:	n	HLA A:	0101		DNA
DOB:	01/01/00		24XX		
Weight:	10.0	HLA B:	08XX		DNA
Ethnicity:	Unknown Unknown		40XX		
Blood Type:	n/a	HLA DRB1:	1301		DNA
Rh:	n/a		1101		

COBLT Score	CBU ID	NCC/kg (x10 ⁷)	Confirmed	Gender ABO Rh	Ethnicity	CFU-GM (x10 ⁵) CD34 (x10 ³)
122	W15930003223100R	9.8	N	M	Eur/W.Russia Eur/W.Russia	6.3
LXLLHH				O -		1.9
HLA A:	01XX 31XX					
HLA B:	08XX 40XX					
HLA DRB1:	11011 13011					

Exhibit 8.1.1.1

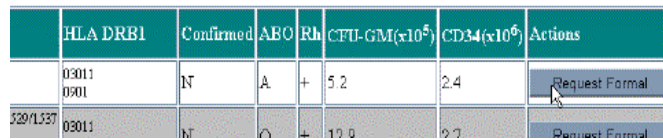
CORD BLOOD TRANSPLANTATION STUDY MOP

8.1.2 Selecting a COBLT CBU for a Formal Search

Within the best HLA match group (5/6 and 6/6 versus 4/6), the unit providing the highest cell dose should be selected. This criteria may be modified if within a 4/6 or 3/6 match group a CBU is available with a much greater cell dose than any CBU within the 5/6 or 4/6 HLA match group, respectively. Additional secondary selection criteria are determined by each transplant center following institutional guidelines.

8.2 FORMAL SEARCH

A formal search is initiated by requesting a formal search online (Exhibit 8.2.1). The formal search process enables a transplant center to place up to three units on request per recipient and to initiate confirmatory HLA typing for the recipient and CBU(s). The confirmatory HLA typing process for recipients is illustrated in Figure 8.2.



	HLA DRB1	Confirmed	ABO	Rh	CFU-GM($\times 10^6$)	CD34($\times 10^6$)	Actions
	03011 0901	N	A	+	5.2	2.4	Request Formal
329/1337	03011	N	A	+	10.0	2.7	Request Formal

Exhibit 8.2.1

Recipients who are HLA typed by molecular DNA methods are not required to obtain confirmatory typing by COBLT HLA Laboratory prior to registration. The transplant center's HLA typing must be at high resolution level for HLA DRB1 and at least at low resolution for HLA-A and HLA-B.

COBLT CBUs on request continue to appear on COBLT transplant center search reports but a request status is indicated beside the CBU number. CBUs are placed on request for a maximum of 60 days.

COBLT CBUs may be requested by multiple transplant centers at any given time. If the MCC receives a request to reserve a unit which is on request by more than one transplant center, then the MCC will notify the other transplant centers of the reservation. The notified transplant centers will have up to three business days to notify the MCC of continued interest in that unit. If more than one transplant center continues to express interest in a particular unit, the issue will be referred to the Cord Blood Allocation Review Subcommittee with any affected members recusing themselves from the Subcommittee discussion and recommendation.

Upon receipt of a completed Formal Search online, the MCC will send a Confirmatory Typing Request for COBLT CBU(s) to the appropriate HLA reference laboratory(ies) to activate the confirmatory typing process (Figure 8.3 and 8.4).

Confirmatory typing for a recipient may also be initiated online. After confirmatory typing for a unit has been requested another option appears that allows the user to request confirmatory typing for the recipient. Upon receipt of a recipient confirmatory typing request, the MCC will send a Confirmatory Typing Request for the recipient to the appropriate HLA reference laboratory(ies) to activate the confirmatory typing process. (Exhibit 8.2.2).

CORD BLOOD TRANSPLANTATION STUDY MOP

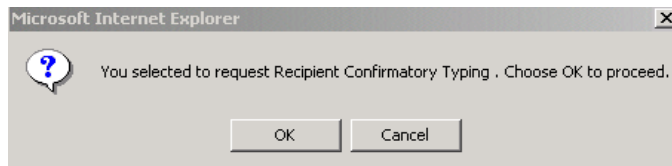


Exhibit 8.2.2

The Recipient Sample Shipping Notification (Figure 8.5A) should accompany the recipient sample when it is sent to the HLA laboratory. A copy should also be faxed to the MCC. It is recommended that recipient confirmatory HLA typing be completed before a patient can be registered. The recipient sample must be labeled with COBLT Recipient ID and name code.

Confirmatory typing data for both the recipient and the CBU(s) are transmitted to the MCC by the HLA reference laboratories for incorporation into the COBLT search databases. Confirmatory HLA typing for CBU(s) will be automatically updated. Confirmatory HLA typing for the recipient must be reviewed by the transplant center before the database is updated.

The MCC will compare recipient typing results provided by the transplant center to typing results provided by the HLA typing laboratory. In the event of typing discrepancies, a Typing Results-Recipient is generated (Figure 8.6). The transplant center must review the HLA typing data and enter the final HLA typing online. Discrepancies in the HLA typing between the transplant center and the reference laboratory must be resolved by indicating the consensus HLA typing on the Typing Results-Recipient (Figure 8.6) and submitting the updated report to the MCC.

8.3 COBLT CBU RESERVATION

At this time, the transplant center has the option of reserving a CBU for a recipient or continuing the formal search process (see Figure 8.1). One COBLT CBU per recipient can be reserved for a maximum of four months with the possibility of an extension. Transplant centers requesting a reservation extension should contact the Search Coordinator at the MCC. All requests for extensions will be tracked by the MCC. Reserved units will not appear on other search reports. Reservation of a unit is initiated online (Exhibit 8.3.1 and 8.3.2).

Reservations:

#	Donor ID	Date Requested	Expiration Date	Actions	Additional Information												
1	W15820067402000	04/12/2001	08/12/2001	Cancel	<table border="1"> <thead> <tr> <th>NCCx10⁷/Kg</th> <th>HLA A</th> <th>HLA B</th> <th>HLA DRB1</th> </tr> </thead> <tbody> <tr> <td>7.97</td> <td>0202C</td> <td>1832C</td> <td>0701</td> </tr> <tr> <td></td> <td>2522C</td> <td>3322C</td> <td>1401</td> </tr> </tbody> </table>	NCCx10 ⁷ /Kg	HLA A	HLA B	HLA DRB1	7.97	0202C	1832C	0701		2522C	3322C	1401
NCCx10 ⁷ /Kg	HLA A	HLA B	HLA DRB1														
7.97	0202C	1832C	0701														
	2522C	3322C	1401														

Exhibit 8.3.1

Formal Search Requests:

#	Donor ID	Date Requested	Expiration Date	Actions	Additional Information												
1	W158299063149001	04/12/2001	06/12/2001	Reserve Cancel Formal Search	<table border="1"> <thead> <tr> <th>NCCx10⁷/Kg</th> <th>HLA A</th> <th>HLA B</th> <th>HLA DRB1</th> </tr> </thead> <tbody> <tr> <td>4.86</td> <td>02XX</td> <td>1312</td> <td>0301</td> </tr> <tr> <td></td> <td>6801</td> <td>44XX</td> <td>0901</td> </tr> </tbody> </table>	NCCx10 ⁷ /Kg	HLA A	HLA B	HLA DRB1	4.86	02XX	1312	0301		6801	44XX	0901
NCCx10 ⁷ /Kg	HLA A	HLA B	HLA DRB1														
4.86	02XX	1312	0301														
	6801	44XX	0901														

Exhibit 8.3.2

CORD BLOOD TRANSPLANTATION STUDY MOP

After the CBU Reservation has been requested online, the Transplant Center Feedback Sheet will be produced and sent to the transplant center. The sheet contains updated CBU information and Maternal Sample infection disease test results. Notification of interest by a transplant center will also be sent to the appropriate CBB.

8.4 REQUEST FOR SHIPMENT OF A RESERVED COBLT UNIT

At the time a patient is registered on the COBLT Protocol, the MCC will produce a Confirmation of Registration / CBU Release Request (Figure 8.7). This sheet will provide the COBLT Recipient ID, the requested CBU ID, date registered, and the proposed start of conditioning date. Upon receipt, the transplant center will complete the middle portion of the Confirmation of Registration / CBU Release Request and provide the proposed shipment date, contact information, and a shipping address. Once the sheet has been completed and signed by the transplant center PI it is faxed to the CBB.

The Confirmation of Registration / COBLT CBU Release Request will serve as the written request for shipment of the reserved CBU. Note that shipments will be routinely scheduled for weekdays (i.e., Monday to Thursday shipment for Tuesday through Friday receipt), however, all efforts should be made to ship Tuesday and Wednesday. This will help to ensure optimal staffing for receipt and storage of the CBU.

The CBU will typically be requested 2-3 weeks prior to transplant (1-2 weeks prior to initiating conditioning). Note that once a CBU is shipped, it will not be returned to the bank inventory if the intended recipient does not proceed to transplant. Thus, the storage time of the unit should be minimized at the transplant center to reduce the chances of discarding CBUs.

The CBB will notify the MCC when a shipment request has been received by completing the final portion of the Confirmation of Registration / CBU Release Request. The MCC will prepare and send the Investigators Brochure (Appendix B) including the Transplant Center Feedback Sheet to the CBB. The CBB will include the Investigators Brochure with the CBU shipment. At the time of shipment, the CBB completes the CBU Disposition Form and the unit is removed from the search registry.

8.5 CONFIRMATION OF RECEIPT OF CORD BLOOD UNIT

Accompanying all shipped CBUs is a Transplant Center Feedback Sheet. The lower portion of this report is completed at the time of receipt of the CBU to document the adequacy of the condition of the shipping container and the CBU upon receipt at the transplant center. After completion of the lower portion, the report is sent by facsimile to the originating CBB.

After thawing of the CBU which is performed shortly before the transplant, the post-thaw total nucleated cell count and cell viability are recorded on the report. The report is sent to both the originating CBB and the MCC by facsimile on the day of transplant.

CORD BLOOD TRANSPLANTATION STUDY MOP

8.6 MULTIPLE SEARCHES FOR A RECIPIENT AND TRANSFERRING SEARCHES

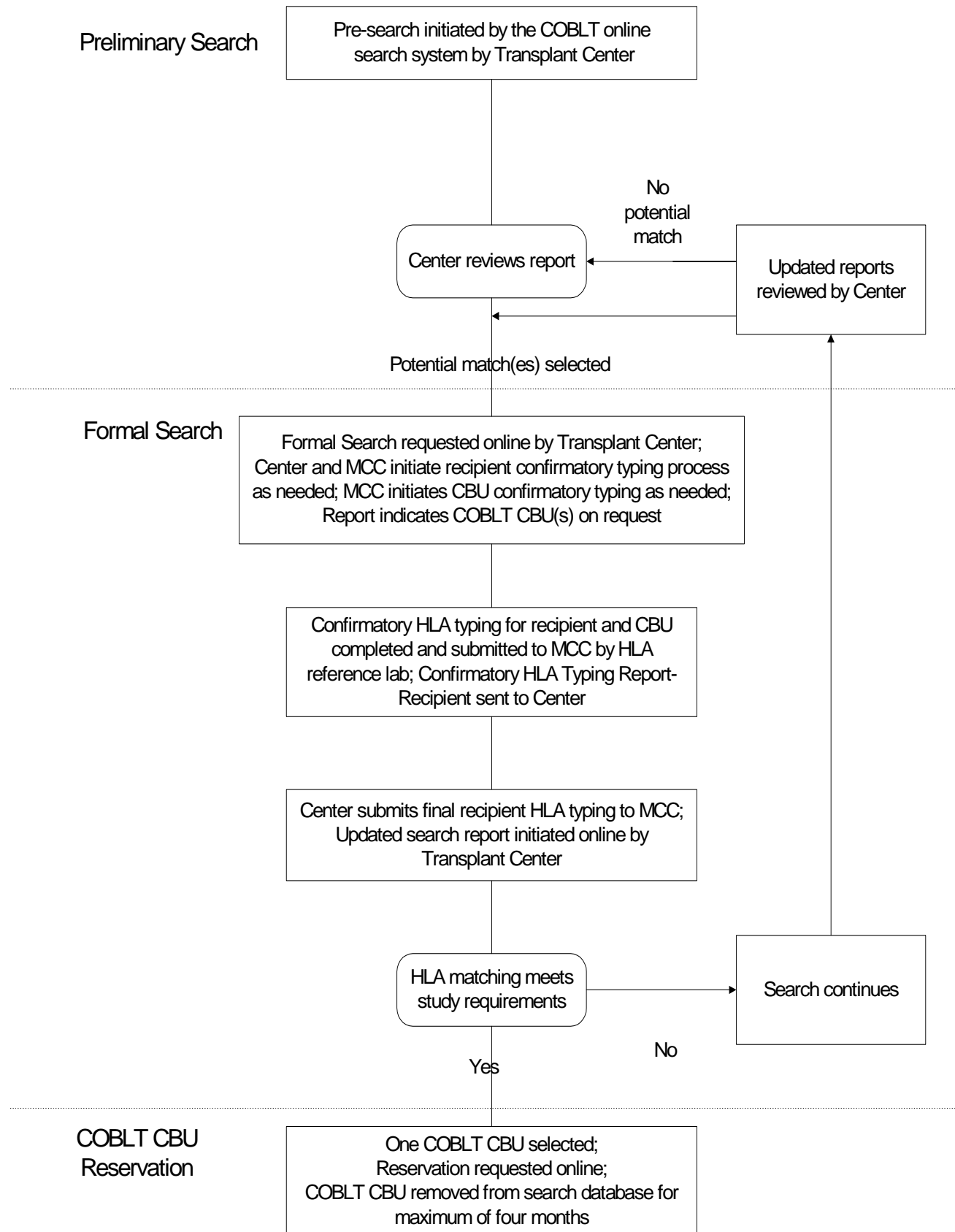
More than one center may perform a preliminary search for the same recipient. During the search process, the MCC attempts to identify multiple recipient searches from different centers for the same recipient. This information will be stored and tracked by the MCC.

Patients searched at one center can be transferred to a second center after completion of the Search Transfer Form. This form should be completed by the original searching center and submitted to the Search Coordinator at the MCC.

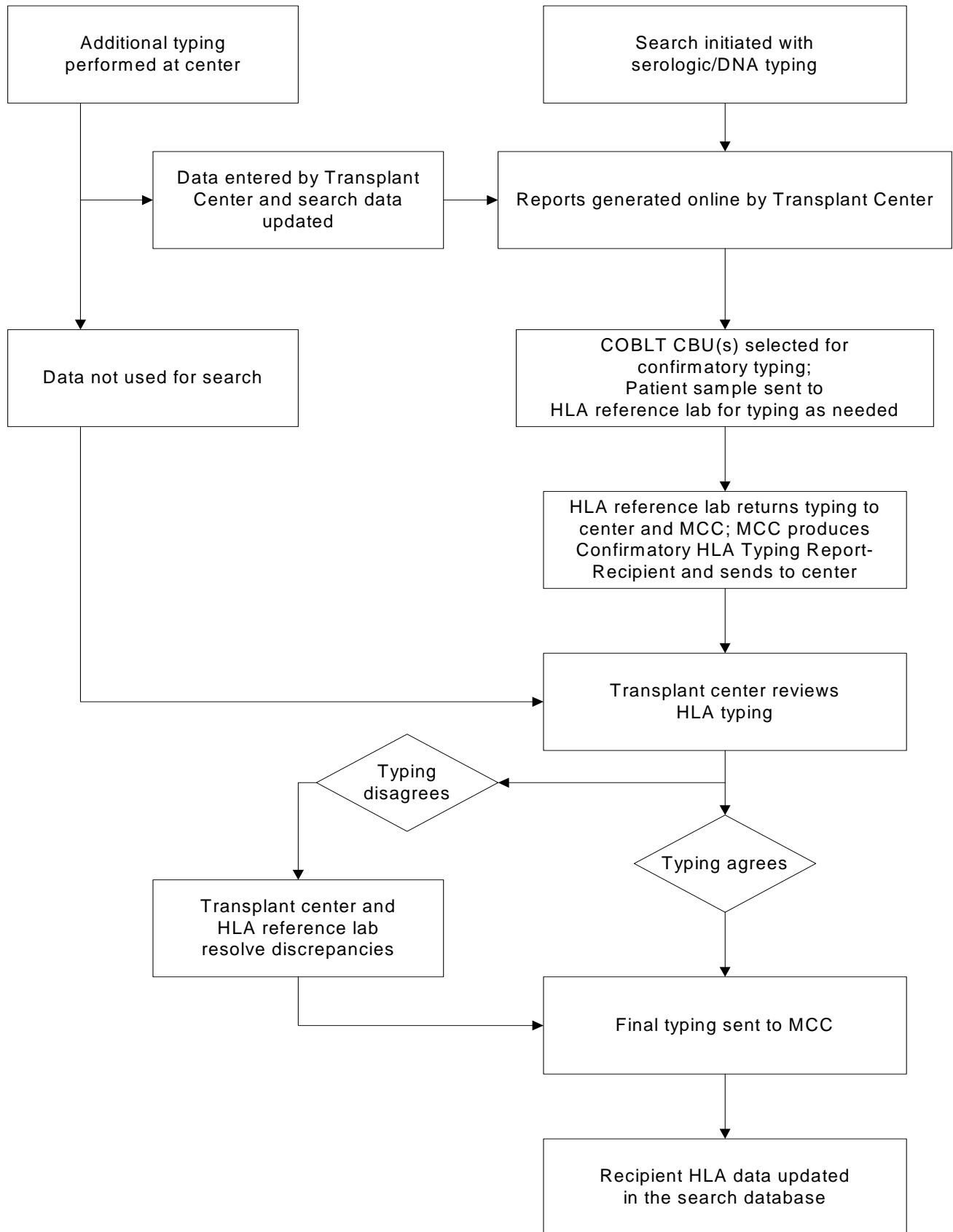
8.7 CORD BLOOD UNITS FROM NON-COBLT BANKS

A patient may still be transplanted with a non-COBLT cord blood unit and participate in the COBLT study. However, non-COBLT units must come from the New York Blood Center, NMDP-approved banks, or U.S. banks meeting NetCord-FAHCT standards. In addition, the transplant center must follow the COBLT protocol, which specifies conditioning regimens, GvHD prophylaxis, and standard operating procedures for handling units. It is recommended that all units from non-COBLT cord blood banks be confirmatory typed. Samples must be obtained from the wash during the thawing process for retrospective allele level DNA-based typing by the COBLT HLA laboratories. The Non-COBLT Cord Blood Unit Sample Shipping Notification (Figure 8.5B) should accompany the cord blood unit sample when it is sent to the COBLT HLA laboratory.

**Figure 8.1
COBLT CBU Searching and Reserving**



**Figure 8.2
Confirmatory HLA Typing Process by COBLT Laboratory**



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Figure 8.3

CONFIRMATORY TYPING REPORT - RECIPIENT	
To:	From: MCC, COBLT Study
Fax:	Fax: 301-251-1355
<p>This is a request from the Medical Coordinating Center to initiate confirmatory typing for recipient, _____. A sample from this recipient will be sent by _____. If you have any questions, please call the MCC at 301-251-1161.</p>	
Date:	
<input type="checkbox"/> Check here and fax back to the MCC to confirm receipt or Email confirmation to COBLTDM@emmes.com	
<hr/> <i>(To be completed by the HLA reference laboratory.)</i>	
CONFIRMATORY TYPING RESULTS	
Recipient:	Namecode:
HLA-A:	_____
HLA-B:	_____
HLA-DRB1:	_____
Optional HLAs:	
HLA-C:	_____
HLA-DQB1:	_____
HLA-DRB2:	_____
HLA-DRB3:	_____
HLA-DRB4:	_____
HLA-DRB5:	_____
<input type="checkbox"/> Check here if additional information has been attached.	
_____	_____
Signature	Date
Fax this completed HLA typing report for the above recipient to the MCC.	
To: MCC, COBLT Study	Fax: 301-251-1355

CORD BLOOD TRANSPLANTATION STUDY MOP

Figure 8.4

CONFIRMATORY TYPING REPORT - COBLT CORD BLOOD UNIT	
To:	From: MCC, COBLT Study
Fax:	Fax: 301-251-1355
This is a request from the Medical Coordinating Center to initiate confirmatory typing for CBU	
Please contact the MCC at 301-251-1161 if you have any questions.	
Date:	
<input type="checkbox"/> Check here and fax back to the MCC to confirm receipt or Email confirmation to COBLTDM@emmes.com	
<i>(To be completed by the HLA reference laboratory)</i>	
CONFIRMATORY TYPING RESULTS	
HLA-A:	_____
HLA-B:	_____
HLA-DRB1:	_____
Optional HLAs:	
HLA-C:	_____
HLA-DQB1:	_____
HLA-DRB2:	_____
HLA-DRB3:	_____
HLA-DRB4:	_____
HLA-DRB5:	_____
<input type="checkbox"/> Check here if additional information has been attached.	
_____	_____
Signature	Date
Send HLA typing results for the above unit to the MCC in electronic form for inclusion into the HLA typing database, <u>and</u> fax this completed report to the MCC.	
To: MCC, COBLT Study	Fax: 301-251-1355

CORD BLOOD TRANSPLANTATION STUDY MOP

Figure 8.5A



RECIPIENT SAMPLE SHIPPING NOTIFICATION

COBLT Recipient ID:

COBLT Name Code:

Center Code:

Recipient sample shipped on: / /

**This completed sheet must accompany the sample at the time of shipment to the HLA Reference Laboratory and the COBLT Recipient ID number MUST be recorded on the label of the recipient sample.*

(Optional) Hospital ID:

Please select one: Confirmatory Typing Sample Retrospective HLA Typing Sample

Specify type of buffer: _____

(Optional) Date results due: _____

Name of person shipping sample: _____ Phone #: _____

Signature of shipper Date

**Fax this completed sheet to the MCC at the time the recipient sample is shipped.*

To: COBLT MCC From: _____
Fax: 301-251-1355 Fax: _____

Recipient Confirmatory Typing and Retrospective HLA Typing - Specimen Shipping Instructions

What to send:

- ▶ For patients with normal WBC, 7 mL peripheral blood (yellow top-ACD or purple top-EDTA). Note that in smaller patients, 2mL of peripheral blood is usually sufficient if acquisition of 7 mL is problematic.
- ▶ For patients with low WBC, 20 mL peripheral blood (yellow top-ACD or purple top-EDTA) or a minimum of 5 mL peripheral blood PLUS 2 buccal swabs.
- ▶ For heterozygous HLA, 4 buccal swabs should be obtained. Additional sample may be required if homozygosity must be confirmed.
- ▶ Study-approved buccal swab kits must be used to collect samples. Kits can be obtained from the COBLT Medical Coordinating Center. All buccal swab samples should be sent to Dr. Baxter-Lowe's lab.
- ▶ For blood samples, send the samples in two tubes if possible.
- ▶ For alternative specimens, contact the Medical Coordinating Center at 301-251-1161.

How to send:

- ▶ Samples may be stored at room temperature up to a week prior to shipping
- ▶ Ship next day delivery, Monday thru Thursday for delivery at the labs Tuesday - Friday
- ▶ Label outside of container with: SHIP AT ROOM TEMPERATURE - DO NOT REFRIGERATE - HUMAN BLOOD SPECIMENS

Where to send:

Transplant Center	COBLT HLA Laboratory
Children's Hospital of L.A. Children's Hospital of Orange County City of Hope Duke University Fred Hutchinson CRC Hackensack University North Texas Hospital for Children UCLA UCSF	Dr. LeeAnn Baxter-Lowe UCSF Immunogenetic and Transplant Laboratory 45 Castro Street Main Hospital Level B San Francisco, CA 94114 Phone: 415-476-3883, 415-476-3886 FAX: 415-476-0379
Dana Farber Cancer Institute Indiana University University of Minnesota Cardinal Glennon Case Western Reserve University All other centers not listed	Dr. Marcelo Fernandez-Vina Navy Medical Research Institute GU-BMR Nicholson Research Building A, 4 th Floor 5516 Nicholson Lane Kensington, MD 20895 Phone: 301-998-8904 FAX: 301-998-8946

CORD BLOOD TRANSPLANTATION STUDY MOP

Figure 8.5B



NON-COBLT CORD BLOOD UNIT SAMPLE SHIPPING NOTIFICATION

COBLT Transplant Center Information:

Center Name: _____ Contact Person: _____

Phone: _____ Fax: _____

COBLT Recipient ID:

CBU ID:

Source of CBU Sample: New York Blood Center
 NMDP-approved CBB. Specify: _____
 Transplant Center - Post-thaw sample
 Other, Specify: _____

Transplant Center should fax this form to the Non-COBLT cord blood bank to complete shipping information. If this is a post-thaw sample, the transplant center should complete the entire form and send with the CBU sample to the COBLT HLA reference laboratory. A copy of the completed form should also be faxed to the MCC.

Shipping Information:
 Cord Blood Bank should complete the shipping information below and include a copy of this form when shipping the CBU sample to the COBLT HLA reference laboratory. A copy of this completed form should also be faxed to the COBLT Transplant Center contact person noted above.

Note: The CBU identification number must be recorded on the CBU sample label prior to shipping.

Date CBU sample shipped: / /

Specify type of buffer: _____

Shipped by: _____ Institution: _____

Phone: _____ FAX: _____

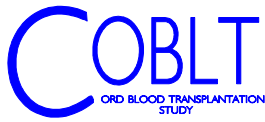
Where to send CBU sample:

Transplant Center	COBLT HLA Laboratory
Children's Hospital of L.A. Children's Hospital of Orange County City of Hope Duke University Fred Hutchinson CRC Hackensack University North Texas Hospital for Children UCLA	Dr. LeeAnn Baxter-Lowe UCSF Immunogenetic and Transplant Laboratory 45 Castro Street Main Hospital Level B San Francisco, CA 94114 Phone: 415-476-3883, 415-476-3886 FAX: 415-476-0379
Dana Farber Cancer Institute Indiana University University of Minnesota Cardinal Glennon Case Western Reserve University All other centers not listed	Dr. Marcelo Fernandez-Vina Navy Medical Research Institute GU-BMR Nicholson Research Building A, 4 th Floor 5516 Nicholson Lane Kensington, MD 20895 Phone: 301-998-8904 FAX: 301-998-8946

Note: Upon completion of the Shipping Information, the Transplant Center should fax this form to the MCC (301-251-1355) and the COBLT HLA Reference Laboratory.

V02, 04/03

Figure 8.6



DISCREPANT TYPING RESULTS - RECIPIENT

The following are the most recent HLA typing results provided by the Transplant Center and the HLA reference laboratory.

Recipient: _____

Namecode: _____

Transplant Center typing results:

HLA-A: _____

HLA-B: _____

HLA-DRB1: _____

HLA reference laboratory typing results:

HLA-A: _____

HLA-B: _____

HLA-DRB1: _____

Please check the appropriate box and follow the instructions:

- Typing provided by the HLA reference laboratory should be used as the final typing for the above recipient.** Complete this sheet and the Search Update Form with the final typing and fax both to the MCC.

- There is a discrepancy between the typing reported by the Transplant Center and the HLA Reference Laboratory.** Contact the HLA Reference Laboratory. Once final typing has been determined, complete this sheet and the Search Update Form with the final typing and fax both to the MCC. Fax this sheet to the HLA Reference Laboratory with instructions to sign and date sheet and fax to the MCC.

Final typing results:

HLA-A: _____

HLA-B: _____

HLA-DRB1: _____

Signature (Transplant Center)

Date

Signature (HLA Reference Lab)

Date

CORD BLOOD TRANSPLANTATION STUDY MOP

Figure 8.7

COBLT - CORD BLOOD TRANSPLANTATION STUDY CONFIRMATION OF REGISTRATION / CBU RELEASE REQUEST		
1 page		
TO: _____	FAX: _____	
FROM: The COBLT Medical Coordinating Center Phone 301-251-1161 Fax 301-251-1355		
DATE: _____		
COBLT Recipient ID: _____	Requested CBU ID: _____	
Date Registered: _____	Proposed start of conditioning: _____	

To be completed by the Transplant Center and faxed to the COBLT Cord Blood Bank		
TO: _____	Fax: _____	
FROM: _____	Fax: _____	
DATE: _____		
Proposed CBU shipment date: _____ Proposed transplant date: _____		
Name of Person Receiving Unit: _____		
Hospital: _____		
Address: _____		
City, State, Zip Code: _____		
Telephone Number: _____		
Fax number: _____		
_____ Signature	_____ Certification #	_____ Date

To be completed by the Cord Blood Bank and faxed to the COBLT MCC		
TO: COBLT MCC	FROM: _____	
Fax: 301-251-1355	FAX: _____	
This request has been received at Cord Blood Bank # _____. The above CBU will be shipped on _____. Please send an Investigators Brochure to the CBB.		
_____ Signature	_____ Certification #	_____ Date

CORD BLOOD TRANSPLANTATION STUDY MOP

8.8 SEARCH FORMS

8.8.1 Preliminary Search Form

This form is designed to identify CBUs with a suitable cell dose and HLA type for a recipient. Recipient HLA typing for a preliminary search may be performed by serology for Class I (HLA-A and HLA-B) and Class II (DRB1) alleles. However, for DRB1, DNA typing is highly recommended. Preliminary searches are performed and an initial search report is generated within one business day from receipt of the form.

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

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

Note: Following a preliminary search, a search report is generated at the MCC and transmitted to the transplant center. The recipient is uniquely identified by the COBLT Recipient ID assigned at the time of the preliminary search.

Note: A preliminary search is active for 6 months or until a request to discontinue the search is received at the Medical Coordinating Center (MCC). Searches can be discontinued or extended beyond six months by submitting a search update form.

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE PRELIMINARY SEARCH FORM.

1. Record the recipient's date of birth and gender.
2. Record the recipient's blood type ABO and Rh. This data is not required to initiate a preliminary search. The form should be updated and sent to the MCC when ABO and Rh are known.
3. Record the recipient's most recent weight (kg) rounded to the nearest decimal. Search reports cannot be generated without recipient weight.
4. Indicate the recipient's Primary Disease.
5. Indicate the ethnicity of the recipient's mother and father.
6. Indicate the recipient's HLA typing. Search reports cannot be generated without HLA typing results.

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.*

OPTIONAL: Record recipient's first name, middle initial, and last name.

7. Report transplant center data by indicating first initial, last name, and e-mail address.

CORD BLOOD TRANSPLANTATION STUDY MOP

8.8.2 Formal Search Form

This form is designed to place up to 3 COBLT units on hold per recipient. Submission of this form also activates requests for confirmatory HLA typing for the recipient and CBU(s). COBLT CBUs are placed on hold for a maximum of 60 days.

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

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE FORMAL SEARCH FORM.

1. Indicate up to 3 COBLT CBU ID number(s) to be placed on hold per recipient.
2. Indicate if recipient confirmatory typing should be initiated.
- 3a. Record date recipient sample sent to the COBLT contract laboratory. The recipient sample must be labeled with COBLT Recipient ID and name code.
- 3b. Indicate to which COBLT contract laboratory the sample was sent.

Note: If the information for Questions 3a and 3b is not provided at the time the form is initially submitted, update this information and fax to the MCC when the sample is shipped.

4. Report fax confirmation of formal search status by indicating first initial, last name, and fax number.

CORD BLOOD TRANSPLANTATION STUDY MOP

8.8.3 CBU Reservation Form

This form is designed to reserve a COBLT CBU. One CBU per recipient can be reserved for a maximum of 4 months.

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

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

1. Indicate the COBLT CBU ID number to be reserved for a recipient.
2. Report fax confirmation of COBLT CBU reservation by indicating the first initial, last name, and fax number.

CORD BLOOD TRANSPLANTATION STUDY MOP

8.8.4 Search Update Form

This form is designed to report the status of a COBLT search. This form can be submitted at any time during the course of the search.

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

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE SEARCH UPDATE FORM.

1. Indicate the planned course of action for the search.

If the answer to Question 1 is “Continue COBLT search following 6-month automatic search period”, update HLA’s in Question 3, if necessary, and sign and fax form.

If the answer to Question 1 is “Cancel COBLT search”, continue with Question 2.

If the answer to Question 1 is “Update recipient HLA typing”, continue with Question 3.

2. Provide one primary reason for search cancellation. Only one primary reason can be recorded. Indicate for the remaining reasons whether they were contributing or non-contributing reasons for search cancellation.
3. Provide the updated recipient HLA typing data.

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.*

CORD BLOOD TRANSPLANTATION STUDY MOP

8.8.5 Search Transfer Form

This form is designed to transfer control of search activity from one transplant center to a second center. After submission of this form, future search reports will only be sent to the “new” transplant center.

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

THE FOLLOWING NUMBERS REFER TO THE QUESTION NUMBERS ON THE SEARCH TRANSFER FORM.

Note: The top portion of this form should be completed by Search Coordinator initiating transfer.

1. Record date of transfer.
2. Record center code at new center.

Note: The bottom portion of this form should be completed by Search Coordinator at the final center.

3. Indicate COBLT ID to be used for future searches. The COBLT ID should either be the Recipient ID indicated at the top of the form or the Recipient ID which has been used by the “new” center’s preliminary searches.
4. Report fax confirmation of transfer by indicating the first initial, last name, and fax number.