

**CAROLINAS CORD
BLOOD BANK**

DOCUMENT NUMBER: CCBB-LAB-005 FRM1
DOCUMENT TITLE: CBU Disposition FRM1
DOCUMENT NOTES: Document required for the BLA.

Document Information

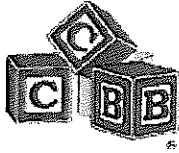
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Control Information

Author: KAEST002	Owner: KAEST002
Previous Number: CCBB-LAB-005 FRM1 Rev 2 ⁺ Change Number: CCBB-CCR-1458	



**Carolinas Cord Blood Bank
CCBB-LAB-005 FRM1
CBU Disposition Form**

BAR CODE LABEL

1. Date of disposition:
 / /

mm dd yyyy

2. Time point of unit disposition:

<p>a. <input type="checkbox"/> After barcode assigned; no collection (refer to section 3)</p> <p>b. <input type="checkbox"/> During or after collection; excluded at collection site (refer to section 4)</p> <p>c. <input type="checkbox"/> After receipt but prior to processing at the processing laboratory (see section 5)</p>	<p>d. <input type="checkbox"/> During processing/cryopreservation (see section 6)</p> <p>e. <input type="checkbox"/> After cryopreservation but prior to quarantine release (see section 7)</p> <p>f. <input type="checkbox"/> After quarantine release (see section 8)</p>
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3. After barcode assigned; no collection. Reason for exclusion at the collection site:

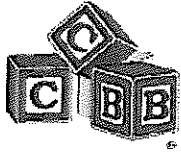
<p>a. <input type="checkbox"/> Staff not notified of delivery</p> <p>b. <input type="checkbox"/> Staff not available for collection</p> <p>c. <input type="checkbox"/> Medical history exclusion</p> <p>d. <input type="checkbox"/> Delivery complications</p> <p>e. <input type="checkbox"/> Baby born with congenital malformations</p> <p>f. <input type="checkbox"/> Cord clamp not applied/applied incorrectly</p> <p>g. <input type="checkbox"/> Documented chorioamnionitis (malodorous placenta, significant maternal fever)</p> <p>h. <input type="checkbox"/> Torn, clotted or no blood in cord or placenta</p>	<p>i. <input type="checkbox"/> Labeling error (missing, incorrect or improperly placed)</p> <p>j. <input type="checkbox"/> Two vessel cord</p> <p>k. <input type="checkbox"/> Mother withdrew consent</p> <p>l. <input type="checkbox"/> MD: No collection performed</p> <p>m. <input type="checkbox"/> Kit: No collection performed</p> <p>n. <input type="checkbox"/> Staff not available for shipping or receipt at lab</p> <p>o. <input type="checkbox"/> Consented donor ineligible</p> <p>p. <input type="checkbox"/> Barcode Unused, reason: _____</p> <p>q. <input type="checkbox"/> Other, specify: _____</p>
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Study ID: _____

4. During or after collection; excluded at the collection site. Reason for exclusion:

<p>a. <input type="checkbox"/> Low volume: _____ mL</p> <p>b. <input type="checkbox"/> Labeling error (missing, incorrect or improperly placed)</p> <p>c. <input type="checkbox"/> Baby born with congenital malformations</p> <p>d. <input type="checkbox"/> Training unit not submitted to the laboratory</p> <p>e. <input type="checkbox"/> Mother withdrew consent</p> <p>f. <input type="checkbox"/> Expired maternal samples (unable to redraw)</p> <p>g. <input type="checkbox"/> Missing documentation</p> <p>h. <input type="checkbox"/> Medical History exclusion</p>	<p>i. <input type="checkbox"/> Loss of integrity of collection bag (leaking, torn)</p> <p>j. <input type="checkbox"/> No (or incomplete) maternal samples drawn</p> <p>k. <input type="checkbox"/> Expired CBU</p> <p>l. <input type="checkbox"/> No collector training</p> <p>m. <input type="checkbox"/> Improper storage</p> <p>n. <input type="checkbox"/> Staff not available for shipping or lab receipt</p> <p>o. <input type="checkbox"/> Consented donor ineligible</p> <p>p. <input type="checkbox"/> Other; specify: _____</p>
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Study ID: _____



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5. After receipt but prior to processing at the processing laboratory. Reason for exclusion:

<p>a. <input type="checkbox"/> Low volume; specify volume: _____ mL</p> <p>b. <input type="checkbox"/> Labeling error (missing, incorrect or improperly placed)</p> <p>c. <input type="checkbox"/> Loss of integrity of collection bag (leaking, torn)</p> <p>d. <input type="checkbox"/> No (or incomplete) maternal samples drawn</p> <p>e. <input type="checkbox"/> Expired CBU</p> <p>f. <input type="checkbox"/> Missing documentation</p>	<p>g. <input type="checkbox"/> Expired maternal samples (unable to redraw)</p> <p>h. <input type="checkbox"/> No collector training</p> <p>i. <input type="checkbox"/> Mother withdrew consent</p> <p>j. <input type="checkbox"/> No CBU received</p> <p>k. <input type="checkbox"/> Unacceptable transport temperature</p> <p>l. <input type="checkbox"/> Other; specify _____</p>
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Study ID: _____

6. During processing/cryopreservation. Reason for exclusion:

<p>a. <input type="checkbox"/> Insufficient pre-processing TNCC: _____x10⁸</p> <p>b. <input type="checkbox"/> Insufficient post-processing TNCC: _____x10⁸</p> <p>c. <input type="checkbox"/> Low post-processing viability: _____%</p> <p>d. <input type="checkbox"/> Processing complication; specify: _____</p> <p>e. <input type="checkbox"/> Start of freeze >48 hours from collection of cord blood</p> <p>f. <input type="checkbox"/> Problem with heat sealing bag or segments</p> <p>g. <input type="checkbox"/> Maternal history exclusion realized after initiation of processing</p> <p>h. <input type="checkbox"/> Training unit, for sterility only</p>	<p>i. <input type="checkbox"/> Cryopreservation complication; specify: _____</p> <p>j. <input type="checkbox"/> NRBC >50%</p> <p>k. <input type="checkbox"/> Mother withdrew consent after initiation of processing</p> <p>l. <input type="checkbox"/> Other subsequent medical information; specify: _____</p> <p>m. <input type="checkbox"/> Maternal samples not received or acceptable for testing</p> <p>n. <input type="checkbox"/> Unacceptable transport temperature</p> <p>o. <input type="checkbox"/> Unable to obtain/incomplete maternal history</p> <p>p. <input type="checkbox"/> Other; specify: _____</p>
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Study ID: _____



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BAR CODE LABEL

7. After cryopreservation but prior to quarantine release. Reason for exclusion:

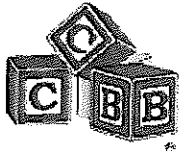
<p>a. <input type="checkbox"/> Failed sterility testing; specify organism ID: _____</p> <p>b. <input type="checkbox"/> Positive maternal donor screening test; specify test: _____</p> <p>c. <input type="checkbox"/> Maternal infectious disease testing not performed/incomplete</p> <p>d. <input type="checkbox"/> CFU zero</p> <p>e. <input type="checkbox"/> Positive CMV PCR on cord blood</p> <p>f. <input type="checkbox"/> Positive hemoglobinopathy screen</p> <p>g. <input type="checkbox"/> Subsequent medical information; specify: _____</p> <p>h. <input type="checkbox"/> Quarantine storage problems; specify: _____</p> <p>i. <input type="checkbox"/> Freezing curve out of specification -20 to -40° C _____ min.</p>	<p>j. <input type="checkbox"/> Mother withdrew consent</p> <p>k. <input type="checkbox"/> No collector training</p> <p>l. <input type="checkbox"/> Labeling or documentation issue</p> <p>m. <input type="checkbox"/> Unacceptable transport temperature</p> <p>n. <input type="checkbox"/> Low Potency: Viable CD34 < 1.00 x 10⁶</p> <p>o. <input type="checkbox"/> Unable to obtain/incomplete maternal history</p> <p>p. <input type="checkbox"/> MSC Cord Tissue Project</p> <p>q. <input type="checkbox"/> Zika Risk</p> <p>r. <input type="checkbox"/> Other; specify: _____</p>
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Study ID: _____

8. After quarantine release. Reason for disposition and/or exclusion:

<p>a. <input type="checkbox"/> Subsequent medical information; specify: _____</p> <p>b. <input type="checkbox"/> Mother withdrew consent</p> <p>c. <input type="checkbox"/> Manufacturing supply recall</p> <p>d. <input type="checkbox"/> Storage equipment failure</p> <p>e. <input type="checkbox"/> Assigned for transplant</p> <p>f. <input type="checkbox"/> Low segment potency: Viability of CD45+ < 40%</p> <p>g. <input type="checkbox"/> Low segment potency: ALDH^{br} as a % of Viable CD45+ < 0.1%</p> <p>h. <input type="checkbox"/> Low segment potency: CFU zero</p> <p>i. <input type="checkbox"/> Other; specify: _____</p>	<p>j. <input type="checkbox"/> Mother requests transfer to directed donor status. (Select Reason Below)</p> <p>i. <input type="checkbox"/> Baby donor diagnosed with malignancy</p> <p>ii. <input type="checkbox"/> Baby donor diagnosed with genetic disease</p> <p>iii. <input type="checkbox"/> Sibling diagnosed with malignancy</p> <p>iv. <input type="checkbox"/> Sibling diagnosed with genetic disease</p> <p>v. <input type="checkbox"/> Baby donor diagnosed with Hydrocephalus</p> <p>vi. <input type="checkbox"/> Baby donor/sibling diagnosed with Cerebral Palsy</p> <p>vii. <input type="checkbox"/> Baby donor diagnosed with HIE</p> <p>viii. <input type="checkbox"/> Baby donor/sibling diagnosed with Autism</p> <p>ix. <input type="checkbox"/> Other; specify: _____</p>
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Study ID: _____



**Carolinan Cord Blood Bank
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BAR CODE LABEL

9. Allocation of the cord blood unit :	Date: / / <i>mm dd yyyy</i>
a. <input type="checkbox"/> <u>No Collection</u> - label set discarded Discarded by Study ID: _____	
b. <input type="checkbox"/> <u>Fresh Unit</u>	
i. <input type="checkbox"/> Discarded as Biohazardous Waste Discarded by Study ID: _____	
ii. <input type="checkbox"/> Released for Research Released by Study ID: _____ Date Released: _____ PI: _____ IRB#: _____	
iii. <input type="checkbox"/> Released for Commercial Use (Verify "opt in" is documented on consent) Released by Study ID: _____ Release date (mm/dd/yyyy): _____ Released to: _____	
iv. <input type="checkbox"/> Released for QC or Staff Training Released by Study ID: _____ Release date (mm/dd/yyyy): _____ If applicable, validation/protocol #: _____	
v. <input type="checkbox"/> Reassigned to Direct Donation Released by Study ID: _____ <input type="checkbox"/> Shipped to Non-Duke Transplant Center <input type="checkbox"/> Shipped to Private Bank <input type="checkbox"/> Shipped to Duke Transplant Center <input type="checkbox"/> Other: _____ Date unit transferred (mm/dd/yyyy): _____ Transferred by; Study ID: _____	
c. <input type="checkbox"/> <u>Cryopreserved Unit</u>	
i. <input type="checkbox"/> Discarded as Biohazardous Waste Discarded by Study ID: _____	
ii. <input type="checkbox"/> Hold for Further Testing; Reason: _____ Designated by Study ID: _____ Once released from Hold, delete CBU Disposition record in EMMES. Retain original record. Release from Hold Study ID: _____	
iii. <input type="checkbox"/> Designated for Research Released by Study ID: _____ PI: _____ IRB#: _____	
iv. <input type="checkbox"/> Released for QC or Staff Training Released by Study ID: _____ Date Released (mm/dd/yyyy): _____ If applicable, validation/protocol #: _____	
v. <input type="checkbox"/> Designated for Commercial Use (Verify "opt in" documented on consent) Released by Study ID: _____ Release date (mm/dd/yyyy): _____ Released to: _____	
vi. <input type="checkbox"/> Released/Shipped to TC #: _____ Released by Study ID: _____ NMDP Recipient ID: _____ - _____ - _____ NMDP CBU ID: _____ - _____ - _____ Licensed: <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes", expiration date/time: _____ @ _____	

Signature Manifest**Document Number:** CCBB-LAB-005 FRM1**Revision:** 25**Title:** CBU Disposition FRM1

All dates and times are in Eastern Time.

CCBB-LAB-005 FRM1 CBU Disposition**Author**

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