STEM CELL LABORATORY (STCL)

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Autologous and Directed CBU Donations

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STCL-COLL-007
AUTOLOGOUS AND DIRECTED CBU DONATIONS

1 PURPOSE

1.1 To describe the indications for and procedures required for autologous and directed donor, related allogeneic cord blood donation and banking.

2 INTRODUCTION

2.1 In selected clinical situations, it is appropriate to donate and store cord blood for the baby from whom it came (*autologous donation*) or a first or second degree relative of this baby (*directed donation*). In these circumstances, specific arrangements must be made for cord blood collection and storage by obtaining approval from the medical director.

2.2 The Stem Cell Laboratory (STCL) at Duke provides this service for families in need. Examples of eligibility for the service are defined as follows.

2.2.1 Autologous Donation:

2.2.1.1 In Utero Stroke

2.2.1.2 Congenital Immunodeficiency Disorder amenable to gene therapy

2.2.1.3 Congenital Marrow Failure Disorder amenable to gene therapy

2.2.1.4 Congenital hemoglobinopathy amenable to gene therapy

2.2.1.5 Hypoxic Ischemia Encephalopathy (HIE)

2.2.1.6 Hydrocephalus

2.2.1.7 Inborn error of metabolism amenable to gene therapy

2.2.1.8 First degree relative with type 1 diabetes mellitus

2.2.2 Allogeneic Donation:

2.2.2.1 Full Sibling with cancer

2.2.2.2 Full Sibling with hemoglobinopathy

2.2.2.3 Full Sibling with congenital immunodeficiency disorder

2.2.2.4 Full Sibling with congenital or acquired marrow failure syndrome

2.2.2.5 Full Sibling with inborn error of metabolism

2.2.2.6 First degree relative with type 1 diabetes mellitus

2.2.3 In most cases, the cord blood donation will be occurring at a remote site and not at an established cord blood collection site.

2.2.3.1 In this case, a kit will be mailed to the collecting MD or Nurse Midwife delivering the baby or to the family to take to this individual. After collection, the cord blood is returned to the STCL via Federal Express or other courier overnight mail service.

2.2.3.2 Insurance information will be requested from the family for use in the Duke billing process. A *Billing and Claims Process Letter* will be provided to the family to detail the billing process and their financial obligations.

2.2.4 In some cases, the cord blood may be collected at a designated cord blood collection facility. In these cases, trained collection staff will perform the collection using SOPs for that facility.

3 SCOPE AND RESPONSIBILITIES

3.1 Transplant Coordinators, nurse coordinators, financial analyst, cord blood collection specialists, and STCL staff interact with these families, arrange for shipment of kit, collection of cord blood unit, completion of all applicable paperwork (*i.e. contract, medical history, etc.*). Arrangements are also made to ship the unit to Duke to be processed, cryopreserved, and stored.

3.2 The Medical Director must determine and approve eligibility before the CBU is collected. The Medical Director and QSU must sign *STCL-COLL-007 FRM 3 Auto/Directed CBU Product Summary Report* to determine eligibility of the donor (*and the product*).

4 DEFINITIONS/ACRONYMS

4.1	STCL	Stem Cell Laboratory
4.2	CBU	Cord Blood Unit
4.3	CCBB	Carolinas Cord Blood Bank
4.4	EDTA	Ethylene diamine tetra Acetic Acid
4.5	SOP	Standard Operating Procedure
4.6	ISBT	International Society Blood Transfusion
4.7	MD	Medical Doctor
4.8	QSU	Quality Systems Unit

5 MATERIALS

5.1 Cord blood collection kit with labels

5.2 Tubes for maternal samples

5.3 Shipping materials

5.4 Contract

5.5 Medical history form(s) along with all other applicable documents included

5.6 Chloraprep swab

6 EQUIPMENT

6.1 Temperature data logger (*when applicable for mail-ins*)

7 SAFETY

7.1 Wear all appropriate personal protective equipment when handling any potentially hazardous blood or body fluids to include, but not limited to, gloves, lab coats, etc.

8 PROCEDURE

8.1 Remote Collection

8.1.1 Medical Director or Collection Team Coordinator notifies laboratory of possible auto/directed donation.

8.1.2 Obtain name, mailing address, and phone number of family.

8.1.3 Obtain estimated delivery date of the baby.

8.1.4 Obtain approval from Medical Director to prepare collection kit for shipment.

8.1.5 Send collection kit to mother approximately four to six (4-6) weeks prior to expected due date (if possible).

8.1.6 Assign an ISBT barcode and create a paper lab file.

8.1.7 Obtain a label (See *STCL-COLL-007 FRM4 Auto/Directed CBU Collection Bag Label*) and affix ISBT barcode onto the label. Tape to the outside of the foil pouch containing the collection kit or staple to *CCBB-COL-007 FRM2 Volunteer Cord Blood Donor Information (VCBDIF) Delivery Information Form.*

8.1.8 Assemble collection kit per *STCL-COLL-007 JA6 Assembly of Collection Kits for Autologous-Directed Donations*.

8.1.9 Maternal Testing

8.1.9.1 Infectious disease testing is performed on maternal blood for the following:

8.1.9.1.1 HBsAG

8.1.9.1.2 Anti-HCV

8.1.9.1.3 HIV 1/2 Plus O

8.1.9.1.4 Anti-HBc

8.1.9.1.5 HTLV-I/II

8.1.9.1.6 Syphilis (Treponema palidum)

8.1.9.1.7 HIV Nat

8.1.9.1.8 HBV Nat

8.1.9.1.9 HCV Nat

8.1.9.1.10 WNV NAT

8.1.9.1.11 Chagas

8.1.9.1.12 CMV

8.1.9.2 Upon receipt of maternal samples into the laboratory, complete the *CCBB-COL-025 FRM2 IDT Requisition Form* by:

8.1.9.2.1 Record the date and time that the maternal samples were drawn at the top of the IDT Requisition Form.

8.1.9.2.2 Place one ISBT maternal sample barcode in the field indicated in the IDT Requisition Form.

8.1.9.2.3 Ensure that form *CCBB-COL-007 FRM3 VCBDIF Phlebotomist's Verification Form* was signed by the cord blood collector signifying that mother did not receive fluid resuscitation or a transfusion prior to obtaining maternal samples.

8.1.9.3 Give one 6 ml red-top (serum-clot) tube, one 6 ml lavender-top (EDTA) tube, and one PPT white-top (NAT) tube , along with completed *CCBB-COL-025 FRM2 IDT Requisition Form,* to the CCBB Laboratory administrative staff so samples can be processed and shipped to ViroMed or alternate testing lab.

8.1.9.4 Ensure that the contract (STCL-COLL-007 JA1 *Agreement for Directed Donation and Storage of Umbilical Cord Blood*) has been signed prior to ID testing (*whenever possibl*e). Since the maternal samples expire quickly upon receipt, follow-up with the family (*if signature needed*) may be required after samples have been sent for testing.

8.1.9.5 Retain the remaining tubes for processing per SOP *STCL-COLL-007 JA10 Auto/Directed Maternal Blood Sample Processing*.

8.1.9.6 IF maternal samples are greater than 72 hours old upon receipt, prepare an instruction letter and send a new set of tubes, along with return Federal Express shipping materials, to the mother so blood specimens can be recollected within 30 days of delivery and returned to the STCL immediately.

8.2 Autologous/Directed CBUs collected at CCBB collection sites.

8.2.1 Collect CBU and maternal samples as per SOP.

8.2.2 Ensure that contract (*STCL-COLL-007 JA1 Agreement for Directed Donation and Storage of Umbilical Cord Blood)* has been signed prior to ID testing (*if possible*).

8.2.3 Arrange for transport of the CBU to the STCL as quickly as possible.

8.2.4 Notify the STCL staff of delivery.

8.3 Receipt of CBU

8.3.1 Inspect the packaging to ensure that there is no evidence of leakage on the outside of the container.

8.3.2 Carefully open the box and review the paperwork enclosed to ensure that it is accurate and complete.

8.3.3 Inspect collection bag(s) and/or tubes for proper labeling, contamination, container damage or leaking. If one of these issues is noted, notify the Laboratory Manager/Medical Director for further instructions.

8.3.4 Complete *STCL-COLL-007 FRM2 Auto-Directed CBU Receipt Form*.

8.3.5 STCL staff will process, test and cryopreserve cord blood per SOPs *STCL-PROC-042 UCB Processing Using the Automated Sepax 2 S-100 Cell Processing System with UCB-HES Protocol or STCL-PROC-044 CBU Processing via Manual Method and STCL-PROC-045 Cryopreservation and Storage of CBU*. The data logger is downloaded (*when applicable for mail-ins*) to make sure the temperature remained within acceptable limits during shipment. If temperature is found to be out of acceptable limits, initiate *STCL-QA-007 FRM1 Non-Conforming Products* form.

8.3.6 STCL staff will fill out form *CCBB-LAB-005 FRM1 CBU Disposition* to reassign for auto/direct donation and enter information on the form into the CCBB's EMMES database to prevent listing of related CBUs into a public registry.

8.4 Once all of the CBU test results have been received:

8.4.1 Complete the HPC-C Product Information and Maternal ID Test Results sections of *STCL-COLL-007 FRM3 Auto/Directed CBU Product Summary Report* and place in CBU file.

8.4.2 Send the CBU file to Medical Director for review.

8.5 The Medical Director will review the documents listed below to determine and document donor eligibility.

8.5.1 *STCL-COLL-007 FRM3 Auto/Directed CBU Product Summary Report*

8.5.1.1 The donor is ineligible and CBU can only be released under urgent medical need if results of infectious disease testing include one or more of the following:

Test	Test Result
HBsAg	Reactive
HBV NAT	Reactive
HIV-I/II plus O Antibody and/or NAT	Reactive
Anti-HCV Antibody and/or NAT	Reactive
HBc Antibody	Reactive
HTLV-I/II Antibody	Reactive
West Nile NAT test	Reactive
Treponema palidum (Syphilis)	Reactive
Chagas-Trypanosoma cruzi Antibody	Reactive

8.5.1.2 All confirmed positive test results are reported to the North Carolina Health Department as required by law per procedure *CCBB-ADMIN-009 Notifying Donors of Positive Infectious Test Results* by CCBB.

8.5.1.3 CMV Immune Screen positive units will be tested for CMV NAT. CMV NAT positive units may be used in consultation with the Medical Director of the transplant center if deemed appropriate.

8.5.2 CCBB-COL-005 FRM1 Family Medical History Questionnaire

8.5.3 CCBB-COL-005 FRM2 Maternal Risk Questionnaire

8.5.4 When an infant donor and/or mother donor eligibility has not been completed in accordance with all donor screening and testing required, the CBU may be released under urgent medical need as an incomplete donor eligibility. The eligibility determination must be reported to the clinical program when completed.

NOTE: *HPC-C from an ineligible donor is not prohibited from use if intended for:

- Autologous Use [21 CFR 1271.90(a)(1)]
- Allogeneic use in a first-degree or second-degree blood relative [21 CFR 1271.65 (b)(i)]
- There is documented urgent medical need [21 CFR 1271.60 (d)]

8.6 STCL will generate *STCL-COLL-007 JA4 Letter for CBU Results*. The letter, detailing the test results for the CBU, will be mailed to the family after the Medical Director has reviewed and signed it.

8.7 The Medical Director and QSU will perform a quality review of CBU file and sign *STCL-COLL-007 FRM3 Auto/Directed CBU Product Summary Report* for quality release.

8.8 All CBUs, as reflected in the *STCL-COLL-007* JA1 *Agreement for Directed Donation and Storage of Umbilical Cord Blood ,* will be maintained and stored in a frozen state for a minimum of 10 years from date of receipt, unless directed otherwise by the Medical Director or designee.

8.9 Requirements for Cord Blood Units Stored for Clinical Administration for Auto/Directed donors:

8.9.1 Fresh post-processing sample

8.9.1.1 Total nucleated cell recovery should be $\geq$60%

8.9.1.2 Total viability should be $\geq$ 70%

8.9.1.3 Viability of CD34 cells should be $\geq$ 85%

8.9.1.4 Microbial Screen should be **negative** for aerobic and anaerobic bacteria and fungi – OR – identify and provide results of antibiotic sensitivities if positive.

8.9.1.5 Donor screening and testing should be deemed **acceptable** as defined by Applicable Law and NetCord-FACT Standards

8.9.2 Post-Thaw Attached Segment or Representative Sample Prior to Release

8.9.2.1 Viability of CD34 cells should be $\geq$ 70%

8.9.2.2 Viability of CD45 cells should be $\geq$ 40%

8.9.2.3 CFU (*or other validated potency assay*) – Growth (*or positive result for potency*)

8.9.3 Results that do not meet these criteria listed above will be reviewed by the medical director (or designee) prior to distribution of the CBU.

8.10 Release to Transplant Center

8.10.1 CBUs requested for AUTOLOGOUS use should be confirmed to ensure that the CB infant donor/recipient is the same individual. Some of the criteria that can be used to confirm the infant donor /recipient may include: infant's DOB, infant's sex, infant's mother's name, unique donation identification #, etc

8.10.2 STCL laboratory staff completes *STCL-FORM-056 Cellular Therapy Infusion Request Form* in preparation for an infusion in the autologous setting. The Medical Director will sign off on this document.

8.10.3 When an Auto/Directed CBU is requested for transplant in the allogeneic setting, confirmatory HLA typing must be performed on the recipient and on an attached segment (*if available*) or a sample vial from the unit before the unit can be approved for release.

8.10.4 An Auto/Directed CBU that has been released to another transplant center can be returned to the Stem Cell Laboratory's inventory as long

as the transplant center can provide documentation of appropriate storage and transport temperatures of ≤ -150º C.

8.11 Maintain linkage with family for updates and questions.

8.12 There is no known expiration date for directed/related donor and autologous cord blood. Units will be maintained beyond the contracted 10 years as long as the family indicates an interest in future usage or until such time that information about expiration of cryopreserved products is available.

8.13 Maintain laboratory records indefinitely in designated area.

9 RELATED DOCUMENTS/FORMS

9.1 STCL-COLL-007 JA1 Agreement for Directed Donation and Storage of Umbilical Cord Blood

9.2 STCL-COLL-007 JA2 Patient Instructions and Information Regarding Directed Donation and Storage of UCB

9.3 STCL-COLL-007 JA3 Collection of Autologous-Directed CBU

9.4 STCL-COLL-007 JA4 Letter for CBU Results

9.5 STCL-COLL-007 JA5 Letter to collecting MD

9.6 STCL-COLL-007 JA6 Assembly of Collection Kits for Autologous-Directed Donations

9.7 STCL-COLL-007 JA7 Packing and Shipping Diagram

9.8 STCL-COLL-007 JA8 Blue Box Instruction Checklists

9.9 STCL-COLL-007 JA9 Managing Data Loggers for CBU Shipments

9.10 STCL-COLL-007 JA10 Auto/Directed Maternal Blood Sample Processing

9.11 STCL-COLL-007 FRM1 Collection and Processing Order form

9.12 STCL-COLL-007 FRM2 Auto-Directed CBU Receipt Form

9.13 STCL-COLL-007 FRM3 Auto/Directed CBU Product Summary Report

9.14 STCL-COLL-007 FRM4 Auto/Directed CBU Collection Bag Label

9.15 STCL-COLL-007 FRM5 Auto-Directed HPC, Cord Blood Infusion Request Form

9.16 STCL-FORM-056 Cellular Therapy Infusion Request Form

9.17 STCL-PROC-042 UCB Processing Using the Automated Sepax 2 S-100 Cell Processing System with UCB-HES Protocol

9.18 STCL-PROC-044 CBU Processing via Manual Method

9.19 STCL-PROC-045 Cryopreservation and Storage of CBU

9.20 STCL-QA-007 Non-Conforming Products – Receipt, Processing, Distribution, and Disposition.

9.21 STCL-QA-007 FRM1 Non-Conforming Products

9.22 CCBB-COL-005 FRM1 Family Medical History Questionnaire

9.23 CCBB-COL-005 FRM2 Maternal Risk Questionnaire

9.24 CCBB-COL-007 FRM1 Volunteer Cord Blood Donor Identification FormCCBB-COL-007 FRM2 Volunteer Cord Blood Donor Identification Form Delivery Information Form

9.25 CCBB-COL-007 FRM3 Volunteer Cord Blood Donor Identification Form

9.26 CCBB-COL-025 FRM1 Maternal Sample Form

9.27 CCBB-COL-025 FRM2 IDT Requisition Form

9.28 CCBB-ADMIN-009 Notifying Donors of Positive Infectious Test Results.

9.29 CCBB-LAB-005 FRM1 CBU Disposition

10 REFERENCES

10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.

10.2 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and Netcord. International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release Current edition.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
11	Barbara Waters-Pick	• Changed references to CCBB-COL-016 FRM2 throughout the document to CCBB-COL-007 FRM2 as CCBB-COL-016 FRM2 is being archived • Removed CCBB-COL-016 FRM2 in the document since that form is being archived by the CCBB Program

Signature Manifest

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STCL-COLL-007 Autologous and Directed CBU Donations

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