Dear Collection Staff,

Thank you for taking some of your valuable time to read this information. Cord blood harvesting is an elective procedure that most expectant parents have thought about extensively. One family may want to collect because it gives them peace of mind. Some families want to collect because they have a child at home who is affected by a transplantable disease. Either way, it is very important to them. As healthcare providers, it is our duty to help families however and whenever we can.

There are a few important points to be aware of:

1. This may be the only opportunity to collect stem cells from this child. This family may have another child at home with a transplantable condition. This cord blood may be needed to facilitate a life-saving cord blood transplantation procedure.
2. The care of the mother and newborn should always come first. Thus, if there are any problems during or immediately after the delivery, the cord blood collection should be deferred.
3. Most insurance companies do not cover the fee charged to the family for processing and storing the cord blood.

Therefore, it is essential that all of the staff involved in cord blood collections be prepared to perform the procedure. If you have any questions about this information or need some last minute tips, please call the BMT Lab staff at (502) 629-7771 or by email at FamilyLink@nortonhealthcare.org. For immediate questions or assistance please contact us digital beeper at (502) 421-0800.

Sincerely,

Alexandra Cheerva, MD, MS
Blood & Marrow Transplantation
Medical Director
Family Link® Cord Blood Storage Program

Collection Procedure for the Clinician

Method: Closed collection, utilizing cannulation of the umbilical vein with a needle to harvest cord blood from the placenta after infant separation. Variation of method is determined by placenta location: In Utero or Ex Utero.

Policy: Advance approval by the attending Obstetrician (OB) /midwife and medical director of the Family Link Cord Blood Storage Program (FLCBSP) is required. The expectant mother must submit required enrollment documents to the FLCBSP (See BMTL-FL-700 Donor Eligibility/Enrollment). The cord blood collection service will notify the birthing facility’s labor and delivery department of the mother’s intent to harvest/store the cord blood. The harvesting supplies will be provided by the FLCBSP. All cord blood harvesting activities must meet AABB standards, FDA guidelines, and adhere to established KCH BMT Program Procedures. Netcord (FACT) standards are considered and followed if feasible.

Principle: Human umbilical cord blood is a rich source of hematopoietic precursors and is useful as a stem cell transplant product. Cord Blood is a transplant option in the absence of other acceptable donors. Harvest and storage from newborns provides a potential source of directed donor stem cells if the newborn or a matching family member should require a transplant. Since only a limited volume of cord blood may be obtained in a short time frame after normal delivery, care must be taken to maximize recovery of fetal blood from the umbilical veins and placenta. Both methods allow for high recovery of available cord blood stem cells and also retain high viability of the harvested cells.

Specimen: The cord blood unit of the infant donor and 6 tubes of mother’s peripheral blood are tracked and identified by a unique Donor/Kit# assigned by the FLCBSP. In the event of a multiple birth, each infant is assigned a unique Donor/Kit#. The birthing facility should designate twins as Infant A and Infant B.

Birthing Facility Equipment/Supplies:
1. Sterile work area, supplies
2. Personal Protective Equipment
3. Scissors
4. Cord clamp for umbilical cord
5. Sterile Betadine (optional)
6. Sterile Alcohol (optional)
7. Sterile Gauze
8. Instrument to close metal crimps for tubing seal
9. Additional Supplies for Ex Utero Option
Family Link® Cord Blood Storage Program

Work Table  Two stands differing in height 18’’ to 12’’
Absorbent Pads  Basin

**Kit Equipment:**
1. Telatemp Monitor

**Kit Reagents/Materials:**
1. Inner Styrofoam/outer cardboard box
2. 2 - Cord blood unit labels with patient identification, biohazard labels, and biohazard tie tags
3. 4 - 5 cc Red top gel tubes for maternal blood
4. 2 - 6 cc Purple top tube for maternal blood
5. 2 - Pall Medical cord blood donor bags with 25 ml CPD
6. Povidone Iodine preps
7. Sterile Alcohol pads
8. Metal crimps for tubing seal
9. Cord clamp for tubing seal
10. Zip-lock & biohazard bags
11. Packing tape
12. Room temperature gel pack
13. Family Instructions (BMTL-FL-400 Form 11)
14. Family Link Cord Blood Storage Program OB/Midwife Instructions (BMTL-FL-400 Form3)
15. Maternal Blood Draw Record (BMTL-FL-702 Form2)
16. Instruction for Transporting cord blood (BMTL-FL-400 Form12)
17. Data Collection Record (BMTL-FL-702 Form3)
18. Data Collection Record Multiple Birth (BMTL-FL-702 Form4)

**Quality Control:**
1. Aseptic collection techniques are maintained during the cord blood harvest. The cord blood is packaged in a sterile primary container that is sealed and handled in a manner to minimize the risk of cell loss and microbial contamination. (Refer to BMTL SOP#753-8102 Aseptic Technique and/or related birthing facility SOP.

**Procedure:**
1. **Harvesting/Processing Request:** Prospective cord blood donors are evaluated and eligibility is determined by the cord blood collection service medical director and/or designated nursing staff as permitted at each facility. If eligible, a Notification of Cord Blood Collection form (BMTL-FL-400 Form5) as well as a copy of the Cord Blood Collection Instructions (BMTL-FL-400 Form3) is submitted to the birthing facility and OB office prior to delivery.

2. **Delivery Room:** The collection staff should scrub and put on available attire as required prior to entry into the delivery room. The collection staff should review collection instructions.

(Refer to BMTL-FL-400 Form5) The harvesting physician should inform the staff present of any steps that might require their assistance. The nursing staff or tech usually obtain and set up supplies needed for the cord blood harvest.
Family Link® Cord Blood Storage Program

3. **Collection Method:** The In Utero collection (A. Option) is considered invasive and is performed by a physician or midwife while the Ex Utero collection (B. option) is noninvasive and permits other personnel to perform the collection. The In Utero method is usually preferred because uterine contractions are believed to increase the flow of cord blood and decrease the chance of clotting. Clamping the cord greater than 1 min after birth results in a decreased placental volume. Collection should begin as soon as the infant is separated from the placenta. Significant delays of mixing the cord blood in anticoagulant permit clotting to progress. Modifications to the collection method or cancellation by the attending OB physician may be necessary due to placenta or cord condition, complicated delivery, known sepsis/infection, mother’s and/or baby’s condition, etc.

**Note:** Use the In Utero collection option for C-section deliveries. Outside of cord blood collection bags are *not* sterile. Use extra precaution with aseptic technique for collection of cord blood.

**A. In Utero Collection Option:**

As soon as the baby is delivered and the umbilical cord is clamped and cut, the collection staff must be ready to perform and complete the cord blood harvest before the placenta is delivered. The mother should remain in the delivery position.

1) **Clean the Umbilical Cord:** Wipe the surface of the umbilical cord with a sterile alcohol pad/gauze to remove visible blood from the surface. Choose a venipuncture site as distal from the umbilical cord insertion as possible to maximize the volume of blood collected. Wipe the surface of the cord planned for phlebotomy for 15 seconds with a sterile povidone iodine prep or betadine soaked gauze. Scrub using a circular motion starting at the site and extending outward in an ever-widening area. Wipe the surface with another sterile povidone iodine prep or betadine soaked gauze in one direction from the planned phlebotomy site. Allow the povidone iodine to dry for complete decontamination.

   If desired to better visualize the vessel, wipe the surface in the opposite direction with a sterile alcohol pad/gauze. To prevent recontamination of the venipuncture site always go from a clean to “dirty” area rather than the other way around. Do not touch the phlebotomy site before venipuncture once it has been cleaned. On occasion, you may need to select/clean a second venipuncture site if drainage of placental blood is not adequate from the first site.

2) **Venipuncture:** Aseptically remove the CPD cord blood collection bag from its foil and plastic packaging. Be sure to close both white clamps located on the attached tubing. Immediately after cleaning the phlebotomy site, remove the cap from one of the donor needles of the collection bag, keeping the bag lower than the needle. Insert the needle, bevel down, into the selected umbilical vein site and thread the needle up the vein to assure adequate and secure insertion. Hold the needle in place during the collection.

3) **Drain the Placental Blood:** Keep the cord blood collection bag below the level of the In Utero placenta so that drainage can occur by gravity. Open the white clamp on the cord blood bag tubing being used, allowing blood to flow into the collection bag. Rotate the collection bag periodically to assure adequate mixing of blood and anticoagulant. Collect as much cord blood as possible up to 150 ml per bag. If the draining stops before an adequate specimen is collected, a second venipuncture should be attempted. In that case, close the white clamp and repeat steps A, B, and C using the second donor needle.

4) **Terminate Collection:** When blood is no longer draining into the collection bag, close the
white clamp on the tubing and carefully withdrawal the donor needle. Vent the tubing by removing the blue air vent cap (turning counter clockwise) and allowing the blood to drain below the spike port. (See illustration) Fold the vented tubing above the spike port and seal using the cord clamp and two metal crimps. The crimps should be pinched with an instrument to obtain an adequate seal.

5) **Remove Blood Collection Bag Needle and Excess Tubing**: Cut the tubing above both the cord clamp and the metal crimps. Discard both needles and excess tubing in a sharp’s container.

**B. Ex Utero (Delivered Placenta) Collection Option:**
Prior to delivery of the baby, a collection area is prepared near the birthing room. Two stands or counters are draped with sterile pads to allow for the placenta to be placed on the upper stand that is 12-18” above the lower stand. The collection bag will be placed on the lower stand to allow the cord blood to drain by gravity. The clamped placenta is delivered and placed in a sterile basin covered with a sterile pad and given to the collection staff. Option A steps 1), 2), 3), 4), and 5), above are then followed. If drainage slows, the placenta may be gently rocked to allow for increased drainage from peripheral to more central veins.

4. **Labeling of Cord Blood Unit**: Complete yellow highlighted areas on the unit/donor identification labels provided with the kit. The donor must be positively identified, either verbally using DOB, Social Security number and/or Patient name or by the patient’s facility armband. Attach completed labels and the “deliver to” and relevant “biohazard” tie tag to the cord blood bag. Place the labeled cord blood unit in the biohazard bag provided. All products, components, or aliquots must be labeled properly following FDA Guidelines, AABB standards, and FACT standards. Refer to Instructions for Cord Blood Collection (BMTL-FL-400 Form3), Labeling of Cord Blood Products (BMTL-FL-601), and BMTL SOP# 753-8259 Labeling of Products.

The collection staff records the following data on the CB Unit/Donor Id Labels:
- Maternal Donor/Patient identification verification, date/initials
- Collection date/time/time zone
- Expiration date/time
- Doctor/nurse collector’s initials

Already included on the label:
Product Type: HPC, CORD BLOOD
- Unique collection number (Donor/Kit #)
- Product type label, including additives (25 ml CPD)
- Expires 24 hrs from collection label (FLCBSP timeframe)
- For use by intended recipient only label
- Mother’s Social Security # and Mother’s name as patient identifiers (Date of birth is used if mother does not have a Social Security #)
- Name of Cord Blood Program, city, state, zip code, phone number, FDA registration
- Name of Birthing facility, city, state, phone number, zip code
- Biohazard label with infectious disease testing pending
- Tie tag with labels for “Deliver To”, “Biohazard #”, and “Medical Specimen”
- Relevant “biohazard” tie tag (if applicable)
5. **Completing the Data Collection Record:** Complete all sections of the Data Collection Record (BMTL-FL-702 Form3). Attach a copy of the hospital labor and delivery record. Place both in the pocket of the biohazard bag containing the cord blood unit. (Use BMTL-FL-702 Form 4 for multiple birth collections.)

6. **Maternal Specimens:** Following the Instructions on the Maternal Blood Draw Record (BMTL-FL-702 Form2), four 5cc red top gel tubes, and two 6cc purple top tubes of the mother’s peripheral blood is collected. The six tubes and the initialed Maternal Blood Draw Record are sent with the cord blood unit to the processing laboratory for further testing.

7. **Transporting Cord Blood Unit and Maternal Specimen:** The cord blood collection kit, the cord blood unit and maternal specimens should always be kept at room temperature, 20-24°C, at the birthing facility. The unit/specimens/paperwork are placed in zip lock bags and then inside the collection kit box. Room temperature stabilizing packs and a temperature monitor are already included in the kit. The family is instructed to notify the FLCBSP staff that the product has been collected and is en route to the processing facility. If after hours, the technologist on call should be digitally paged. (Refer to BMTL-FL-400 Form12)

   Processing Lab Phone#: (502) 629-7771
   Tech On Call Beeper#: (502) 421-0800

The kit is transported by the designated courier as soon as possible to the processing/BMT laboratory. If transporting to another facility for processing, a temperature-controlled vehicle must be used to maintain an ambient temperature, 15-25°C. The courier should complete required pickup/receiving logs. Routinely, the processing lab staff should begin processing within 24 hours of collection. If delayed past 24 hours, the processing lab will ensure that the cord blood product is refrigerated at, 1-6°C, which extends the expiration time of the unit to 48 hours from collection. (Refer to BMTL SOP# 753-8336 Long-term Storage of Non-cryopreserved Progenitor Cell Products)

8. **If Cord Blood cannot be harvested:** If for any reason the cord blood cannot be harvested, the processing lab must be notified. Arrangements will be made for proper disposal of the unused kit.

**Expected Results:** The submitted cord blood unit must contain unclotted cord blood and be labeled with unique tracking identification to be considered suitable for processing. See OB/Midwife Instructions for Cord Blood Collection (BMTL-FL-400 Form3) for cord blood collection guidelines. For transplant, greater than or equal to $1.0 \times 10^7$ nucleated cells/kg recipient body weight based on a pre-cryopreservation enumeration is preferred.

**Reporting Results:** The BMT Lab should notify/consult the FLCBSP medical director when expected results are not met. Approval from the medical director would be required to continue processing. The medical director and/or FLCBSP staff will inform the legal guardian of the extent to which the collection was successful or details of a failed or insufficient collection based on set criteria. Abnormal results for the prospective maternal donor shall be communicated to the appropriate physician/nursing staff for communication to the mother and/or her physician. Refer to Cord Blood Unit Evaluation Report (BMTL-FL-1000 Form1).
**Procedural Note:** A minimum volume is no longer required since clinically useful cellular levels have been met in cord blood products less than 30ml. Also, advances in cellular expansion and the use of multiple cord blood unit transplants may increase the usefulness of marginal and low cellular products. In these cases, the final determination of storage is made by the family after consultation with Family Link Medical Director and/or Clinical Staff.
OB/MIDWIFE INSTRUCTIONS FOR CORD BLOOD COLLECTION
- IN UTERO COLLECTION -

1. Aseptically remove CPD Cord Blood Collection Unit Bag from its foil and plastic packaging. **Close both white clamps** located on tubing. (see illustration #1).
2. Clamp and cut umbilical cord. Mother remains in delivery position.
3. At distal end of cord, sterilize puncture site (4” to 8”) first using providone iodine or betadine (allow to dry) (scrub 30 sec), then use alcohol.
4. Remove cap from one donor needle, keeping bag lower than needle.
5. Puncture cord with donor needle bevel down.
6. Open white clamp on tubing, allowing blood to flow into collection bag by gravity.
7. Rotate collection bag periodically to mix and prevent clotting.
8. Collect as much cord blood as possible from this site.
   Target range - 3 – 7 minutes collection time
   Fill bag (75 – 150 mls)
9. Close white clamp on tubing. **Use the second donor needle only if the blood flow ceases before the placenta appears empty, proceeding as in Step 3.**
10. Vent tubing by removing blue air vent cap (turning counter-clockwise).
11. Allow blood to drain below spike port.
12. Fold vented tubing above spike port and seal using Hollister Cord Clamp and two metal crimps. (see illustration #2)
13. Cut tubing above seals and discard needles in a sharps container.
   Attach Donor label, Biohazard label, and the ‘Deliver To’ Tie Tag to cord blood bag.
   Place bag in biohazard bag provided.
15. Complete all sections of the “Data Collection Record”. Attach a copy of the hospital labor and delivery record and place both in pocket of the biohazard bag containing cord blood bag. Return bag to box.

**EX UTERO COLLECTION OPTION:**
If unable to collect cord blood before the placental delivery.
1. Place placenta in a sterile basin, fetal side up.
2. Drape umbilical cord over the side to allow gravity flow.
3. Follow InUtero instructions, proceeding as in Step 3.

**CORD BLOOD COLLECTION GUIDELINES**
1. The volume of cord blood is greater than or equal to 30 ml, preferably between 75 ml and 150 ml.
2. Stored product meets clinically useful cellular levels.
3. No visible clots were present in the cord blood product.
4. Bacterial and Fungal culture from the cord blood product had no growth after 14 days.