FS No. 021-0723

Cord Blood Donation

BACKGROUND. In the past, umbilical cord blood was disposed of as medical waste at the time of birth. However, today the cord blood is often collected and donated for medical uses. Since the emergence of stem cell research in the late 1990s, many birth mothers have elected to donate (or bank) the blood obtained from their newborn babies' umbilical cords. Cord blood donation (or banking) is a rare opportunity to collect and save the stem cells from newborn babies' umbilical cord blood for potential medical uses and is a practice widely accepted in both the private and military sectors. Clinical trials using cord blood include experimental therapies to treat cerebral palsy, traumatic brain injury, and juvenile diabetes. Cord blood is also being researched for use in regenerative medicine, where stem cells may help induce healing or regenerate cells to repair tissues. When a Medical Treatment Facility (MTF) is notified by the birth mother of her desire to donate (or bank) the cord blood, the MTF should be prepared to honor this request.

RELEASE PROCEDURES. In the United States, the Food and Drug Administration (FDA) regulates cord blood under the category of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps). Title 21 Code of Federal Regulations (CFR) 1271, *Human Cells, Tissues, and Cellular and Tissue-Based Products*[1], under the FDA, regulates public and private cord blood banks. Private cord blood banks are used to store cord blood that is saved and intended for use by the birth mother's family. Donated cord blood becomes the property of the public cord blood bank and will be available for anyone that needs a stem cell implant. All cord blood banks are required to register with the FDA which sets standards for cord blood testing and provides inspections to ensure that proper practices are being upheld. The mention of any non-federal entity and/or its products is for informational purposes only, and is not to be construed or interpreted, in any manner, as federal endorsement of that non-federal entity or its products. Cord blood banks also receive additional accreditation; however, it is important to note that not all cord blood banks are accredited.

Some MTFs already participate in Cord Blood Programs[2,3] and have procedures in place that address the screening/testing of the birth mother and the collection, packaging, labeling, transportation, distribution, and shipping of the cord blood to the designated blood bank. For those MTFs that do not participate in Cord Blood Programs, the MTF shall establish a donor release policy and implement standard operating procedures for the collection, packaging, labeling, transportation, distribution, and shipping of the cord blood. At a minimum, the donor release policy shall ensure that only accredited cord blood banks are utilized. Use of accredited cord blood banks are required to ensure proper collection, packaging, transportation, and preservation of the cord blood. The two main accrediting agencies for cord blood banks are the American Association of Blood Banks (AABB) at www.aabb.org and the Foundation for the Accreditation of Cellular Therapy (FACT) at www.factwebsite.org.

The recommended timeline for coordinating and preparing for cord blood donation is:

- 24th week pregnancy: Birth plan developed
- 30th week pregnancy: Expectant mother contacts blood bank and begins screening and blood testing
- 34th week pregnancy: Blood bank approves donation and provides the expectant mother with cord blood collection kit
- Birth: MTF staff collects cord blood, packages it, and ships or transports it to the blood bank

PREPARATION. Coordination for the release of cord blood must be conducted in advance of the delivery and incorporated into patient counseling. Physicians should ensure that a birth plan has been developed by the expectant mother and agreed to by both parties during patient counseling (preferably 3 months in advance of delivery). The birth plan shall describe the expectant mother's desire to donate the cord blood and identify the cord blood bank designated to receive the donation.

Expectant mothers who wish to donate (or bank) cord blood must contact an accredited cord blood bank as soon as possible to request a cord blood donation kit and begin screening for cord blood donation. Arrangements with the cord blood bank must be completed by the 34th week of pregnancy. In general, the cord blood bank will

Defense Centers for Public Health–Aberdeen, Environmental Health Sciences Division
8252 Blackhawk Road, Aberdeen Proving Ground, MD 21010
410-436-3651 or DSN 584-3651

require the expectant mother to complete a donor screening form, which is a series of questions designed to capture information regarding the donor's medical history and relevant social behavior, including activities, behaviors, and descriptions considered to increase the donor's relevant communicable disease risk (e.g., HIV and hepatitis B and C). A sample of the expectant mother's blood is typically requested by the cord blood bank near the time of birth so the blood may be tested for infectious disease. The cord blood bank will also require the expectant mother to sign a consent form that explains what tests will be conducted on the cord blood. If there are no abnormalities identified during cord blood testing, the cord blood bank will approve the donation request and will provide the expectant mother with a cord blood collection kit. The expectant mother must provide the MTF physician with the cord blood collection kit in advance of delivery.

MANAGEMENT IN THE MTF. When a release of cord blood has been requested, the MTF shall follow instructions provided by the accredited cord blood bank and ensure the safe management of the cord blood until such time that it is shipped to the designated cord blood bank. Following birth, the cord blood should be deposited at the point of generation into the cord blood collection kit provided by the accredited cord blood bank. Cord blood will be managed as regulated medical waste (RMW) according to applicable RMW regulations if proper coordination and donation requirements are not met prior to delivery. Collection instructions differ with each cord blood bank; however, at a minimum, cord blood collection kits typically contain the following items:

1. Sterile cord blood collection bag
2. Cord tissue sample container
3. Blood draw vials for mother's blood screening
4. Biohazard specimen bag
5. Cord blood collection kit instruction sheet
6. Shipping instructions
7. Collection and delivery forms
8. Absorbent pad/material
9. If required, temperature control items such as gel packs, insulation, and temperature indicators

SHIPPING/TRANSPORTATION REQUIREMENTS. Follow shipping and transportation instructions provided by the accredited cord blood bank. Keep shipping box at room temperature. Do not refrigerate unless temperature control items are provided in the kit. The cord blood shall be packaged sufficiently to completely contain the cord blood. At a minimum, the packaging must consist of the following components:

1. A leak-proof primary receptacle
2. A leak-proof secondary receptacle
3. An outer packaging of adequate strength for its capacity, mass, and intended use, and with at least one surface having minimum dimensions of 100 mm x 100 mm
4. Absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary and secondary packaging so that during transport, any release or leak will not reach the outer packaging

All bags and other containers shall be tightly closed before release and/or transport from the MTF.

The outer container will be labeled as Exempt Human Specimen.

REFERENCES.

1. *Code of Federal Regulations,* "Human Cells, Tissues, and Cellular and Tissue-Based Products," Title 21, Part 1271.
2. "Participating Hospitals," National Marrow Donor Program, Be the Match. https://bethematch.org/donatecord/.
3. "USA Donation Hospitals," Parents Guide to Cordblood Donation Foundation. https://parentsguidecordblood.org/en/donationspot/