 <p>St. Louis <b>Cord Blood Bank</b> SSM Health Cardinal Glennon Children's Hospital Saint Louis University Department of Pediatrics</p>	<p><b>MATERNAL CONSENT POLICY</b></p>
<p>3662 Park Avenue, St. Louis MO 63110, 314-268-2787</p>	<p><b>CL.05.09</b></p>

**PRINCIPLE:**


The St. Louis Cord Blood Bank is a non-profit, public cord blood bank that collects only donated umbilical cord blood. All participating mothers must make an informed decision regarding the donation of cord blood and sign the consent for participation.

**PURPOSE:**

To ensure all participating mothers sign an informed consent

**POLICY:**


1. Ideally, an interested mother will contact the St. Louis Cord Blood Bank (SLCBB) prior to admission to the hospital. Preliminary information about the program is frequently provided by the obstetricians'/midwives' office, clinic, Lamaze instruction, childcare classes or the community. Informational brochures are available in many medical offices, hospitals, prenatal and other classes.
2. If the donor mother expresses interest in making a donation, during the 2<sup>nd</sup> or 3<sup>rd</sup> trimester of pregnancy, SLCBB will send her a copy of the consent form (CL.05A.XX; see Policy Notes below) in an informational packet. She will be encouraged to review the information and be familiar with the terminology. This timing is planned so that the donor mother will have time to pose questions or concerns to SLCBB Nurses/Collections staff before she signs it.
  - a. Every effort is made to ensure that the information provided is accurate, objective, non-coercive and culturally appropriate. Marketing material shall always stress that this program is a donation program only.
  - b. Families wanting private storage must make arrangements with a private cord blood storage facility prior to delivery.
  - c. If either the mother of the baby or the father of the baby has objections to the cord blood donation, the consent should not be signed and the collection will not take place.
  - d. Besides witnessed consent (see below), SLCBB Nurses/Collections staff will confirm consent at the 2 week follow-up telephone call.
3. In situations where a family has a child who has a medical condition that might be treated with a stem cell transplant, and are currently pregnant with a child that is a full sibling to the sick child, directed donation may be an option where the cord blood is collected and stored specifically for personal use.
4. The donor mother may sign the consent form, witnessed, before arriving at the collection site for labor and delivery. However, if collection site staff are not sure the consent form has been signed, the following practice there will be undertaken as a redundant precaution.

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5. When the donor mother arrives at the collection site, an obstetrical nurse will present the consent form to the mother with request that she sign it prior to delivery and/or active labor (See Policy Notes below).
  - a. The observing nurse shall witness the mother signing the consent and sign the consent form as her witness.
  - b. The collection site staff should provide another copy of the consent form to the family at this time, for their reference.
  - c. The collection site staff should place the signed consent into the Cord Blood Collection Kit box. This way, the consent will be transported with the collected specimens to the St. Louis Cord Blood Bank, where it will remain in the donor's confidential file.
  - d. In the cases where the decision to donate is not made until the mother arrives at the hospital, the collection site staff should still ensure that the mother reads the consent, is offered the opportunity to ask questions, and signs the consent prior to delivery and/or active labor.
  
6. Upon receipt of the cord blood collection at the SLCBB, a SLCBB Nurses/Collections staff member must ensure consent has been obtained before approving the collection for processing and/or research purposes. If a signed consent was not received, a SLCBB nurse will speak with the donor mother and/or the hospital to confirm donor mother gave consent for donation prior to collection. The hospital will be instructed to fax the signed consent to the SLCBB ASAP and/or send the original with the following courier pick up.

**POLICY NOTES**

1. All forms are available in Spanish (CL.05A-SPA.XX). For any other language barrier, utilization of the language line coordinated by SSM Health Cardinal Glennon Children's Hospital is available to SLCBB Nurses or the donor mother.
  
2. St. Louis Cord Blood Bank has an arrangement with Saint Luke's Cancer Institute of Kansas City for the collection of cord blood donations in the Kansas City area. A consent form (CL.05A\_KC.XX) had been created to recognize the arrangement and has been used for Kansas City area collections. The Kansas City version of the forms are not being actively printed, however, they may still be in circulation and will be acceptable.
  
3. Active labor is defined as cervical dilation of 3-4 centimeters and regular contractions. Most women present to the hospital for induction or in early labor, allowing time for education to permit "informed" consent. The potential donor must be alert, comfortable and able to give informed consent. General or systemic anesthesia and sedation medications, such as IV Valium, Versed must not have been administered prior to consent process (EPIDURAL IS OK). To be considered valid, the education process must culminate in a signature. The purpose is to prevent the donor from entering this agreement "cold".

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4. In cases of surrogate mother, informed consent shall be obtained from both the surrogate and the genetic mother.
5. In cases when it is known prior to donation that the donor mother is placing her infant up for adoption, consent must be obtained from both the donor mother and one of the donor baby's legal parents or guardian. If it is discovered after donation that the baby has been placed up for adoption, and consent from one of the donor baby's legal parents or guardian is not able to be obtained, the unit will not be made available for patient use.

**MATERIALS:**

N/A

**RELATED FORMS:**

CL.05A.XX	Consent for Donation (English version)
CL.05A-SPA.XX	Consent for Donation (Spanish version)
CL.05A_KC.XX	Consent for Donation Saint Luke's Cancer Institute (Kansas City metro area)

**REFERENCES:**

FACT-NetCord Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release, Current Edition

HRSA Current Guidelines