

<p style="text-align: center;">St. Louis Cord Blood Bank</p> <p style="text-align: center;"><small>SSM Cardinal Glennon Children's Medical Center St. Louis University Department of Pediatrics</small></p> <p style="text-align: center;"><i>The First Gift™</i></p>	<p>ADVERSE REACTIONS OF DONORS</p>
<p>Cellular Therapy Laboratory & St. Louis Cord Blood Bank 3662 Park Avenue, St. Louis MO 63110, 314-268-2787</p>	<p>CL.10.06</p>

PRINCIPLE:

The St. Louis Cord Blood Bank acts to ensure that any adverse event that possibly occurs as a result of participation in cord blood donation are recorded and reported to the St. Louis Cord Blood Bank. It is the responsibility of the St. Louis Cord Blood Bank to maintain a quality assurance program to track adverse events.

PURPOSE:

This policy describes the process of recording and reporting adverse events at collection sites to the St. Louis Cord Blood Bank (SLCBB).

POLICY:

Maternal or Infant Adverse Reaction:

An adverse event is defined as an unexpected outcome where the mother or infant involved is negatively impacted as a result of cord blood collection.

1. If there is a case where the mother or infant are adversely affected by the collection of cord blood, hospital staff are instructed to document the incident and send that documentation to SLCBB. Examples of potential maternal/infant adverse reactions could be:
 - a) increased risk of post-collection infection, or
 - b) an unexpected twin delivery.
2. SLCBB requests notification and written event report **within 24 hours**, including grading of severity and resolution of reaction(s). Hospital staff may send their own internal record of the event, or they may complete a Donor Adverse Reaction Event Form (CL.10.A.XX). See reference information below.
3. The St. Louis Cord Blood Bank will investigate the incident, track and evaluate trends. This may involve further communication with the hospital, physician/midwife and/or nurses.

Physician/Midwife or RN Incident:

Physician/midwives and nurses are encouraged to report problems they encounter with cord blood collection (ex. needle stick), again, using the CL.10A.XX form or their facility's record.

Collection Site Protocol:

SLCBB expects and encourages hospital staff to Please be sure to follow any internal institutional incident reporting protocol as well.

PROCEDURAL NOTES:

1. This issue is part of the hospital site visit checklist which is performed every 3 years. The inspector asks if any adverse reaction has occurred.
2. Additionally, each participating hospital will be asked on an annual basis if any adverse reaction was recorded in the previous year.
3. Each reported reaction will be investigated according to QM.04, Occurrence Report Policy

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MATERIALS:

None

RELATED POLICIES/PROCEDURES:

CL.02.XX Training and Authorization of the Cord Blood Collection Team
QM.04.XX Occurrence Reporting and Corrective Action Policy

RELATED FORMS:

CL.02A.XX Physician/Midwife Attestation
CL.02B.XX Initial RN Training
CL.10A.XX Donor Adverse Reaction Event Report

REFERENCES:

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

AABB Standards for Cellular Therapy Product Services, Current Standards

Standard for Surveillance of Complications Related to Blood Donation. Working Group on Donor Vigilance of the International Society of Blood Transfusion Working Party on Haemovigilance in collaboration with The International Haemovigilance Network The AABB Donor Haemovigilance Working Group. December 11, 2014

Send Occurrence Report Forms to the following address.

St. Louis Cord Blood Bank
SSM Cardinal Glennon Children's Medical Center
3662 Park Avenue
St. Louis, MO 63110
Tele. (314) 268-2787 or 888-453-2673
Fax (314) 268- 4197