

Collection of Cord Blood in South Australian Public Health Services

for the Purposes of
Private Cord Blood Banking

Clinical Directive

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Collection of Cord Blood for the Purposes of Private Cord Blood Banking 2018 Clinical Directive

1. Policy Statement

The Collection of Cord Blood for the Purposes of Private Cord Blood Banking 2018 Clinical Directive will guide SA Health employees on their limited role in the collection of autologous cord blood for the purposes of private cord blood banking.

It upholds the SA Health Strategic Plan 2017 - 2020 themes of Lead, Partner and Deliver through the use of evidence, translating research into practice and involving consumers in its development, and ensuring safe and effective support for those women making arrangements for private cord blood collection.

2. Roles and Responsibility

2.1 Executive Officer

The Executive Officer of the hospital providing birthing services must provide a procedure supporting the pregnant woman who has made arrangements for private cord blood collection to be collected immediately after birth of her baby.

2.2 Hospital Managers

Hospital managers will ensure that SA Health employees, who, in their employment are not involved in any of the processes including securing informed consent or the collection, labelling or storage of cord blood for the purposes of private cord blood banking.

2.3 SA Health Employees

SA Health employees must be aware that they are not permitted to be involved in any of the processes associated with the collection of cord blood including obtaining informed consent and the collection, labelling or storage of cord blood for the purposes of private cord blood banking whilst on duty in the employment of SA Health.

A SA Health employee can undertake cord blood collection during the periods that they are not undertaking work related to their employment within SA Health. The SA Health employee choosing to undertake contract employment with a private cord blood bank must wear appropriate identification and must not be identifiable as an SA Health employee while undertaking duties for the private cord blood bank. The employee must also seek written permission at Executive level for this secondary employment as per the South Australian Department of Health and Ageing HR Manual Policy¹.

3. Background

Umbilical cord blood is the blood left behind in the placenta and umbilical cord after the birth of a baby. It is rich in blood-forming stem cells, and over the past decade it has been used as an alternate source of stem cells for use in allogeneic (non-autologous) stem cell transplants to treat a range of malignant and non-malignant conditions affecting children and adults².

Research throughout the world continues to explore the potential uses of cord blood³.

Undertaking the procedure required for cord blood collection for the purposes of private cord blood banking may represent a conflicting priority for SA Health staff assisting with a birth and, as such has the potential to interfere with some birth practices and on occasions, the safety of a newborn baby and/or the mother.

It is acknowledged that all blood collection, including cord blood for the purposes of private cord blood banking, has litigious implications associated with labelling and delivery to the designated storage facility.

4. Policy Requirements

4.1 Principles

The collection of cord blood should not interfere with the safety of the woman and her baby during birth and the postnatal period.

Women seeking cord blood bank services must be made aware that these services cannot be provided by SA Health employees whilst in the employment of SA Health and that cord blood collection and storage arrangements must be undertaken by a private provider of this service. Women seeking this service should be provided with the policy for *Collection of Cord Blood in South Australian Public Health Services for the Purposes of Private Cord Blood Banking and patient information brochure*.

Informed consent for the collection of cord blood for the purposes of private cord blood banking must be obtained by the private cord blood collector during the woman's antenatal period. A copy of this consent along with the identity and credentials of the cord blood collector should be provided in the antenatal period to the designated SA Health hospital where the woman plans to give birth.

4.2 Standard Requirements

4.2.1 The woman seeking private cord blood bank services

Public and private patients in South Australian public hospital sites seeking cord blood bank services must make their own arrangements with a private cord blood bank representative during the antenatal period. This includes providing informed consent for, and the collection, storage and transfer of, their baby's cord blood for the purposes of private cord blood banking.

The woman seeking private cord blood bank services must sign a release form permitting a private cord blood bank representative to undertake the collection of cord blood for the purposes of private cord blood banking.

This form:

- > provided by the private cord blood bank, confirms that the woman understands that the cord blood collection service is not provided by SA Health employees or agents.
- > should stipulate that the private cord blood bank will have sole responsibility for the collection, transport and storage of cord blood for private cord blood banking.

The woman seeking privately operated cord blood bank services is responsible for ensuring that the private cord blood banking service is notified when she commences labour.

4.2.2 SA Health employees

SA Health employees are not permitted to be involved in any of the processes associated with the collection of cord blood including obtaining informed consent and the collection, labelling or storage of cord blood for the purposes of private cord blood banking whilst on duty in the employment of SA Health.

SA Health employees are not permitted to participate in the promotion of privately operated (autologous) cord blood banking services because the value of autologous cord blood as a therapeutic agent is yet to be determined.

SA Health and its employees are responsible for ensuring:

- > a signed copy of the consent form provided by the private cord blood company, approving the collection of the cord blood for the purposes of private cord blood banking, is available in the woman's medical record prior to the commencement of labour.
- > information provided to the SA Health hospital by the company regarding the identity of the private cord blood bank collector and their accreditation status with SA Health and evidence of a Child Related Employment Screening Assessment from the Department for Communities and Social Inclusion (and additional Department for Communities and Social Inclusion employment assessments as required by local hospital policy) is available at the hospital, ie sample 'Private Cord Blood Bank Collectors Verification Form for Access to Public Maternity Units' as per Appendix 1.
- > the private cord blood bank representative is available at a convenient location, in close proximity to the birth unit/operating room, to collect the cord blood for the purposes of private cord blood banking.
- > the collection of cord blood for the purposes of private cord blood banking does not interfere with any procedure involved in the treatment of mother or baby.
- > the private cord blood bank representative only proceeds with the ex-utero cord blood collection at the instruction of the medical practitioner/midwife involved with the birth.
- > the placenta identified for the purposes of private cord blood banking is placed in a rigid walled, leak-proof plastic container for storage and has attached < patient label of the mother > to the outside of the container and is part of a cross check process involving the private cord blood bank representative to ensure the correct placenta is provided for the cord blood collection.
- > SA Health hospitals are not used for the storage of cord blood for privately operated blood banks.

4.2.3 Private Cord Blood Bank

All private cord blood bank representatives who collect a baby's cord blood for the purposes of private cord blood banking must have appropriate private insurance and a satisfactory Child Related Employment Screening Assessment from the Department for Communities and Social Inclusion, (additional Department for Communities and Social Inclusion employment assessments may be required at some hospitals; private cord blood bank representatives should check local hospital requirements) for these activities.

The Department of Health and Ageing will not indemnify people undertaking these activities in a private capacity.

A private cord blood bank company can recruit SA Health employees to undertake cord blood collection when the employee is not on duty as part of their employment contract with SA Health. The SA Health employee choosing to undertake contract employment with the private cord blood bank must wear appropriate identification and must not wear the uniform of the SA Health employing organisation when they are performing duties for the private cord blood bank, and must have permission from SA Health to undertake secondary employment.

The private cord blood bank representative can be one of the following:

- > A designated collector employed or contracted to provide collection services by the private cord blood bank and who does not hold a concurrent position of employment with SA Health; or
- > An SA Health employee who is not on duty in their SA Health role at the time of service provision, and who is employed/contracted by the company to undertake the collection.
- > A visiting medical specialist acting in their private capacity for obstetric services.

Private cord blood banks will be required to:

- > Submit information on each potential private cord blood bank collector's professional background; Department for Communities and Social Inclusion Child Related Employment screening, (and additional Department for Communities and Social Inclusion employment assessments as required by local hospital policy); photographic identification; verifying the named person as a private cord blood bank - cord blood collector, using sample 'Private Cord Blood Bank Collectors Verification Form for Access to Public Maternity Units' as per Appendix 1.
- > Provide a copy of the woman's informed consent for cord blood collection for private cord blood banking for inclusion in the woman's medical record at the hospital.
- > Ensure collection staff wear personal identification at all times whilst on a public hospital site for the purposes of provision of cord blood bank collection services. This identification cannot be that of SA Health.
- > Ensure collectors act in accordance with hospital occupational health and safety policies.

Private cord blood banks are not permitted to refer to SA Health hospitals in their promotional material.

4.2.4 Documentation

In accordance with the SA Department of Health Medical Records Documentation and Data Capture Standards August 2000, contemporaneous documentation must be maintained with regards to the collection of cord blood for the purposes of private cord blood banking; this is to be filed in the patient's medical record.

5. Implementation and Monitoring

The Executive Officer of the SA Health hospital will report incidents of where cord blood has been collected for the purposes of private cord blood banking, in accordance with their Local health Network reporting requirements.

6. National Safety and Quality Health Service Standards

							
National Standard 1 Clinical Governance	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare-Associated Infection	National Standard 4 Medication Safety	National Standard 5 Comprehensive Care	National Standard 6 Communicating for Safety	National Standard 7 Blood Management	National Standard 8 Recognising & Responding to Acute Deterioration
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

7. Definitions

Allogeneic (non-autologous) – pertaining to genetically matched but not the individual's own cells

Autologous – an individual's own cells/blood which are collected for future use

Cord blood – blood taken during the post natal period from the umbilical cord

Executive Officer – includes General Managers in metropolitan public hospitals and Executive Officers/Directors of Nursing in country public hospitals

Informed consent – is a legal procedure to ensure that a patient knows all of the risks and costs involved in a procedure. The elements of informed consent include informing the patient of the nature of the procedure and the potential risks and benefits.

Malignant – used to describe cancer cells that have the capacity to invade tissue.

SA Health - is not the name of a Government Department or a legal entity. It is the "badge" adopted across the South Australian public health services portfolio to collectively refer to the Department of Health and Ageing (an administrative unit established under the Administrative Arrangements Act and all "Hospitals" incorporated under the Health Care Act, 2008). SA Health employees include employees of/working at the Department of Health and Ageing and the Hospitals.

Stem cells - relatively undifferentiated cells of the same family type that retain the ability to divide and form specialised cells, taking the place of cells that die or are lost

8. References

1. SA Health (Health Care Act) Human Resources Manual; www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet
2. Butler, M & Menitove, J 2011, 'Umbilical cord blood banking:an update', J Assist Reprod Genet, 28:669-676.
3. Waller-Wise, R, 2011, 'Umbilical Cord Blood: Information for Childbirth Educators', Journal of Perinatal Education, Vol20,1, Pg 54-60

9. Associated Directives / Guidelines & Resources

1. ACT Health Policy Collection of Cord Blood for the Purposes of Private Cord Blood Banking CHHS17/249, 26/10/2017: www.health.act.gov.au/sites
2. American College of Obstetricians and Gynaecologists, 2008, 'Umbilical Cord Blood Banking', *Obstetrics & Gynaecology*, vol 111, no 2, pp. 475-477.
3. NSW Government, Fact Sheet; *Cord Blood Collection*; Women's & Newborn Health: Westmead Hospital; WSP 469 Private cord blood banking V1 16/05/2016, accessed April 2018, www.wslhd.health.nsw.gov.au
4. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, College Statement, 2016(current), *Umbilical Cord Blood Banking C-Obs 18*, accessed April 2018, www.ranzcog.edu.au/publications/statements/C-obs18.pdf

10. Appendices

Appendix 1: Private Cord Blood Bank Collectors Verification Form for Access to Public Maternity Units

11. Acknowledgements

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12. Document Ownership & History

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Approval Date	Version	Who approved New/Revised Version	Reason for Change
10/5/2018	V4	SA Health Safety & Quality Strategic Governance Committee	Formally reviewed in line with year scheduled timeline for review.
24/4/2015	V3	SA Health Safety & Quality Strategic Governance Committee	Formally reviewed in line with year scheduled timeline for review.
30/6/2013	V2	SA Health Safety & Quality Strategic Governance Committee	Formally reviewed in line with year scheduled timeline for review.
30/9/2010	V1	SA Health Safety & Quality Strategic Governance Committee	Original approved version.

APPENDIX 1

Private Cord Blood Bank Collectors Verification Form for Access to Public Maternity Units

During the antenatal period, please forward the completed form to the SA Health maternity unit where there is a plan to collect cord blood for the purposes of private cord blood banking.

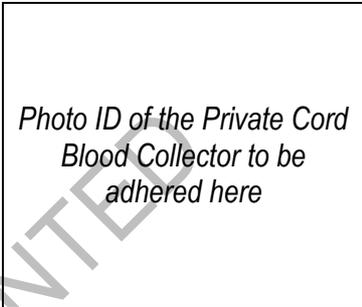
Name of the Private Cord Blood Bank Company :

Name of Private Cord Blood Bank Collector:.....

Signature of Private Cord Blood Bank Collector:.....

Address of Private Cord Blood Bank Collector:.....

.....



The private cord blood bank company needs to verify the following criteria for the above named person

	Name of the Private Cord Blood Bank Company representative verifying details	Signature of the Private Cord Blood Bank Company representative verifying details	Date signed by the Private Cord Blood Bank Company representative verifying details
The above named private cord blood bank collector:			
<ul style="list-style-type: none"> has a valid Department for Communities and Social Inclusion Child Related Employment Screening assessment . (date of the Child Related Employment Screening Assessment)..... NB CHSA hospitals - has additional Department for Communities and Social Inclusion employment assessments as required by the local hospital policy) 			
<ul style="list-style-type: none"> is aware that this verification is valid for three years commencing from the date of the Child Related Employment Screening Assessment. 			
<ul style="list-style-type: none"> has undertaken the appropriate education and has achieved competency to safely perform cord blood collection. 			
<ul style="list-style-type: none"> has undertaken the appropriate OHS&W education to safely perform cord blood collection 			
<ul style="list-style-type: none"> has undertaken the appropriate Infection Control education to safely perform cord blood collection. 			
<ul style="list-style-type: none"> is a SA Health employee (tick box) YES <input type="checkbox"/> NO <input type="checkbox"/> 			
<ul style="list-style-type: none"> has read and indicates they understand the SA Health Policy and associated patient information brochure: <i>Collection of Cord Blood in SA Public Health Services for the Purposes of Private Cord Blood Banking</i> 			
<ul style="list-style-type: none"> indicates they are aware that a SA Health employee is not permitted to be involved in any of the processes including securing informed consent or the collection, labelling or storage of cord blood for the purposes of private cord blood banking while rostered on duty in their employment within SA Health 			

The completed form must be provided; during the women's antenatal period; to the Birthing Suite/Unit at the SA Health maternity unit where there is a plan to collect cord blood for the purposes of private cord blood banking.