# Policy for the Collection of Cord Blood

in South Australian Public Health Services

for the Purposes of Private Cord Blood Banking August 2010



### Disclaimer

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Although the clinical material offered in this policy provides a minimum standard it does not replace or remove clinical judgement or the professional care and duty necessary for each specific patient case. Where care deviates from that indicated in the policy contemporaneous documentation with explanation should be provided.

This policy does not address all the elements of clinical practice and assumes that the individual clinicians are responsible to:

- > Discuss care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes the use of interpreter services where necessary
- > Advise consumers of their choice and ensure informed consent is obtained
- > Provide care within scope of practice, meet all legislative requirements and maintain standards of professional conduct

Document all care in accordance with mandatory and local requirements

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# 1. Glossary Of Terms

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

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

<u>Informed consent</u> – 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

<u>SA Health</u> – 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 (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 the Hospitals.

<u>Stem cells</u> – 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.

### 2. Introduction

This policy has been developed to guide SA Health employees on their limited role in the collection of autologous cord blood for the purposes of private cord blood banking.

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

A number of privately operated cord blood banks provide services in South Australia. Women may ask for their newborn baby's cord blood to be collected and stored for future use. Private cord blood banks charge an initial collection fee and/or an annual storage fee for this service.

A private blood bank is able to recruit SA Health employees to undertake cord blood collection during the periods that the SA Health employee is 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 Outside Employment Policy (Reference # D0083) or in accordance with the South Australian Department of Health Part-time Work Policy (Reference # G0059).

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.

### 3. Aim

To provide women and SA Health employees with appropriate information in relation to managing the collection of cord blood for the purposes of private cord blood banking.

To ensure all SA Health employees are aware that they are 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 undertaking work related to their employment within SA Health.

# 4. 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 adults.

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

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.

### 5. Outcome Statement

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

# 6. Standard Requirements

- 6.1 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.
- 6.2 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.
- 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. This includes obtaining informed consent for, and the collection, storage and transfer of, a baby's cord blood for the purposes of private cord blood banking. The 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.
- All private cord blood bank representatives who collect a baby's cord blood for the purposes of private cord blood banking must have appropriate separate private insurance for these activities.

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

A private cord blood bank 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.

- 6.5 The woman seeking private cord blood bank services must sign a release form permitting a private cord blood bank 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. The form 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.
- 6.6 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.
- 6.7 SA Health and its employees are responsible for processes 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 cord blood collector and their accreditation status with SA Health is available at the hospital.
  - > 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 representative acting on behalf of the privately operated cord blood banking service, present at the birth to collect the cord blood for the purposes of private cord blood banking, only proceeds with the exutero cord blood collection at the instruction of the medical practitioner/midwife involved with the birth.
  - > SA Health hospitals are not used for the storage of cord blood for privately operated blood banks.
- 6.8 Private cord blood banks are not permitted to refer to SA Health hospitals in promotional material.
- 6.9 Private cord blood banks will be required to:
  - > Submit information on each potential private cord blood bank collector's professional background, their criminal history and photographic identification; verifying the named person as a private cord blood bank - cord blood collector.
  - > 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.
- 6.10 The Executive Officer of the SA Health hospital where cord blood has been collected for the purposes of private cord blood banking, must inform SA Health Insurance Services on a monthly basis of the number of collections which have occurred as a means of monitoring activity.

### 7. Procedural Guidelines

- 7.1 SA Health employees, whilst on duty in the employment of SA Health have no role in any of the processes including obtaining informed consent, the collection, labelling or storage of cord blood for the purposes of private cord blood banking.
- 7.2 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.

# 8. References

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## For more information

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