Cord Blood - Public and Private Cord Blood Banking

Summary This Policy Directive outlines the requirements for consent to and collection of cord blood in public hospitals for donation to a either a public cord blood bank or for collection for private cord blood banking.

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CORD BLOOD - PUBLIC AND PRIVATE CORD BLOOD BANKING

PURPOSE

Collection, storage and processing of cord blood in NSW is governed by the NSW Human Tissue Act 1983 and regulated by the requirements of the Therapeutic Goods Administration.

This document provides direction to health services regarding public and private cord blood banking. It outlines the procedures to be followed by NSW Health staff for obtaining a woman’s consent for and collection of cord blood for either donation to a public cord blood bank, directed donation to a family member requiring a haemopoietic stem cell transplant or for private storage for future personal use.

Failure to comply with the requirements of the NSW Human Tissue Act 1983 may constitute an offence.

There are a number of options for cord blood banking available to women in NSW. It is important that women have access to relevant information on these options preferably in the antenatal period so that an informed choice can be made.

MANDATORY REQUIREMENTS

1. All consents to the donation of cord blood for its use in transplantation or other medical, scientific or therapeutic purposes (including research) must meet the requirements of the NSW Human Tissue Act 1983.
2. The collection of cord blood must not interfere with the delivery of the baby or placenta or any emergency procedure required.
3. If public or private patients in public hospitals wish to utilise a private cord blood bank, they must make their own arrangements for the collection of cord blood.
4. As a condition of permitting a private cord blood bank to undertake the collection of cord blood in a Public Health Organisation’s premises, a mother is required to sign the request form provided at Attachment 1.
5. No employee of a Public Health Organisation may be involved in the collection of cord blood for private blood banking. Public Health Organisations must not be involved in the collection, storage or transplantation of cord blood for private blood banks.

IMPLEMENTATION

Chief Executives of Local Health Districts are responsible for:

- Ensuring that the contents of this policy are brought to the attention of relevant staff.

Cord blood bank collection staff (both public and private) must:
• Obtain consent to the collection and / or donation of cord blood by the woman (preferably in the antenatal period) and provide a copy to be placed on the woman’s medical record at the commencement of labour

• Make their presence known to hospital staff when attending for collection and satisfy the Public Health Organisation’s (PHO’s) security requirements by presenting their company employee identification on arrival and

• Await the instruction of the doctor / midwife conducting the delivery for an indication that cord blood collection can proceed.

Individual patients who wish to have private collection of cord blood are responsible for:

• Making arrangements for the collection, storage and transfer of cord blood, with a collector from the private cord blood bank, a private obstetrician with visiting practitioner appointment to the hospital or another suitably qualified person and

• Ensuring that the private cord blood bank collection staff are notified of the commencement of labour.

Individual medical practitioners exercising their rights of private practice:

• May make arrangements with a private cord blood bank for the collection of cord blood at the request of their patients.

Private cord blood bank staff are responsible for:

• Ensuring that women complete the Request for Private Cord Blood Banking form (Attachment 1) antenatally and providing a copy to be included in the woman’s medical record before the commencement of labour.

REVISION HISTORY

<table>
<thead>
<tr>
<th>Version</th>
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<tr>
<td>December 2015 (PD2015_048)</td>
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1 BACKGROUND

1.1 About this document

This document relates to cord blood banking. Cord blood is the blood remaining in the umbilical cord vessels and placenta after the umbilical cord has been cut after the birth of a baby. Normally, the umbilical cord and placenta, together with the approximately 100 millilitres of cord blood, are disposed of after birth. Cord blood collection is the collection of cord blood from the umbilical vein after birth. Cord blood is rich in stem cells and can be frozen and banked for many years and subsequently used as an alternate source of stem cells to bone marrow.

Requests for cord blood collection and / or banking are not routine but are becoming more common. Currently, in NSW, there are three circumstances in which cord blood collection may take place:

1. Public donation
2. Family donation or
3. Private collection and use / banking.

1.2 Key definitions

Public cord blood donation: the collection of cord blood for anonymous donation through the Sydney Cord Blood Bank (SCBB) at one of its collection centres. The SCBB has collection centres at a number of hospitals in NSW including Royal Hospital for Women Randwick and Royal Prince Alfred Mothers and Babies Hospital, Camperdown.

Family cord blood donation: the collection of cord blood for donation and use where there is a family member (e.g. a biological sibling) with a disease such as leukaemia who is in immediate need of a bone marrow transplant.

Private use cord blood banking: the collection of cord blood for storage for private use either for the child following whose birth the cord was collected or for another family member in case there is ever a medical need in the future.

1.3 Legal and legislative framework

The Human Tissue Act 1983 regulates the process by which consent can be given to the donation of human tissue such as cord blood for the purpose of its transplantation into the body of another person or for medical, therapeutic or scientific purposes.

The Human Tissue Act 1983 expressly prohibits trade in donated human tissue. This includes any agreement or offer to enter into any agreement for any valuable consideration to the sale or supply of tissue from a person’s body.

Failure to comply with the requirements of the Human Tissue Act 1983 may constitute an offence.

All public and private cord blood banks must meet TGA regulatory and / or manufacturing licensing requirements to operate as cord blood banks.
2 PUBLIC CORD BLOOD DONATION

2.1 The Sydney Cord Blood Bank (SCBB)

In NSW public donation of cord blood is managed through the SCBB located at the Sydney Children’s Hospital Randwick. The SCBB is part of a national network of public cord blood banks. NSW Health supports the activities of the SCBB which collects and stores cord blood for the use of all patients, free of charge, on the basis of need.

This network collects and banks cord blood from voluntary donors for anonymous use by patients needing a stem cell transplant. Donating mothers give informed consent and are screened for blood borne viruses and for any historical risk of transmitting genetic disorders.

Collected cord blood that meets strict acceptance criteria is processed, frozen, stored and distributed for transplant and is identified only by a unit number so that the donor remains anonymous.

The SCBB arranges for cord blood to be collected by its own staff, or obstetricians and midwives who have been trained and accredited by the SCBB.

Public cord blood donations can only be collected in facilities licensed by the Therapeutic Goods Administration. Information on current collection sites for public cord blood donation is available at www.abmdr.org.au

2.2 Information on Public Cord Blood Collection and Banking

Public and private patients attending maternity units in hospitals with public bank collection sites should be informed that public cord blood donation is available. Information should be made available to expectant parents in the antenatal period about the option to collect and donate their cord to the public cord blood bank. If parents wish to donate the woman should be encouraged to discuss this intention with her midwife or obstetrician in the antenatal period.

2.3 Procedures for Public Cord Blood Banking in NSW Public Health Organisations

The following procedures apply for public cord blood collection and banking:

2.3.1 Informed consent to the collection of cord blood for the purpose of public cord blood banking should be obtained preferably during the antenatal period. The consent is archived by the SCBB and a copy of the consent will be provided to the public health facility. A copy of the consent is also given to the woman intending to donate.

2.3.2 It is important to confirm that the woman understands she is consenting to public cord blood donation for anonymous use by anyone in need of a stem
cell transplant and that the cord will not be available and / or released for uses other than for purposes for which it has been banked (stem cell transplantation).

2.3.3 All SCBB staff employed to collect cord blood at designated collection sites must satisfy the PHO’s requirements for identification and must be clearly identifiable and make their presence known to hospital staff. SCBB visitors will act in accordance with the PHO’s work health and safety policies at all times whilst present.

2.3.4 Obstetricians and midwives of the public health organisation may be involved in the collection of cord blood for public cord blood banks upon voluntary completion of training and accreditation offered by the SCBB.

2.3.5 Facilities of public health organisations (i.e. materials, documents or staff) may be provided as part of a contractual arrangement with the SCBB for the purpose of cord blood collection and temporary storage.

2.3.6 The collection of cord blood must not interfere with the delivery of the baby or placenta or any emergency procedure required. The doctor / midwife conducting the delivery will indicate if the collection can proceed.

3 FAMILY CORD BLOOD COLLECTION AND DONATION

A family cord blood donation (also known as directed cord blood donation) is the donation of cord blood for use where there is an identified sibling with a disease that may require a bone marrow transplant. In NSW directed cord blood donation is only available through the Sydney Children’s Hospitals Network.

A decision to use a directed donation of cord blood for transplantation will be made by the treating doctor of the family member needing a transplant.

As with all cord blood donation the consent of the mother to the donation, collection, screening and testing of the cord blood unit will be required.

If the decision is to proceed with directed donation, the donating mother will be responsible for the making the arrangements for the collection and transportation of the cord blood in collaboration with her obstetric team.

For further information on family (directed) cord blood donation contact the Sydney Children’s Hospital Bone Marrow Transplant Unit.

4 PRIVATE USE CORD BLOOD BANKING

A number of private cord blood banks have been established in Australia. These banks provide a service whereby mothers can have their newborn baby’s cord blood collected and stored indefinitely for the purpose of private future use by the baby, sibling or other family member. Private cord blood banks charge an initial collection fee and an annual storage fee.

Information may be made available to expectant parents in the antenatal period about the option to collect and store their cord blood in a private bank. If the expectant parents wish
to have the cord blood collected and stored in a private bank the expectant woman should be encouraged to notify her obstetrician or midwife in the antenatal period.

4.1 Procedures for Private Cord Blood Banking in NSW Public Health Organisations

The following procedures apply for private cord blood collection and banking:

4.1.1 If a patient (either a public patient or a private patient in a public hospital) wishes to utilise a private cord blood bank for the collection of cord blood, they must make their own arrangements with a private cord blood bank representative for the collection.

4.1.2 Informed consent to the collection of cord blood for the purpose of private cord blood banking must be obtained by the private cord blood representative during the mother’s antenatal period. A copy of this consent should be provided to the hospital where the woman plans to give birth and should be placed on the woman’s medical record prior to the commencement of labour.

4.1.3 The mother must make a private arrangement for the collection, storage and transfer of cord blood with a collector from the private cord bank, a private obstetrician holding a visiting practitioner appointment to the hospital or another suitably qualified person.

4.1.4 No employee of the public health organisation may be involved in the collection of cord blood for private blood banks.

4.1.5 It is a matter for individual medical practitioners, exercising their rights of private practice, as to whether they make arrangements with a private cord blood bank for the collection of cord blood at the request of their patients.

4.1.6 Facilities (i.e. materials, documents or staff) of public health organisations are not to be used for the collection, storage or transplantation of cord blood for private blood banks.

4.1.7 As a condition of permitting a private blood bank to undertake the collection of cord blood in a public health organisation’s premises, a mother is required to sign a request form (Attachment 1) in the ante-natal period. The form is to be placed on the medical record prior to the commencement of labour. This form confirms that she understands that the cord blood service is not provided by the public health organisation or its employees and that the hospital is not responsible for the collection, transport and storage of the cord blood.

4.1.8 The woman seeking private cord blood banking services is responsible for ensuring that the private cord blood banking service is notified when she commences labour.
4.1.9 Private Cord Blood Bank visitors to the delivery suite involved in cord blood collection must satisfy the PHO’s requirements for identification and must be clearly identifiable and make their presence known to hospital staff. Private Cord Blood Bank visitors will act in accordance with directions by PHO staff and otherwise in accordance with the PHO’s work health and safety policies at all times whilst present.

4.1.10 The doctor / midwife conducting the delivery will indicate if and when the cord blood collection can proceed. Cord blood collections undertaken by private cord blood bank collectors must take place after the delivery of the baby and placenta (ex-utero).
5 LIST OF ATTACHMENTS

Request and Release for Private Cord Blood Banking
## Attachment 1: Request and Release for Private Cord Blood Donation

**Request for Private Cord Blood Banking**

**Patient declaration**

I, [Name], am the parent of [Child's name], who was born on [Date of birth].

I have made arrangements with [Name of private cord blood bank] for the collection and storage of cord blood following the birth of my child. As part of this arrangement, the following person will attend the birth of my child to collect the cord blood:

[Name of private cord blood bank representative/private obstetrician collecting the cord blood]

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I understand that the cord blood banking service is provided by the bank named above and is not provided, approved or endorsed by this hospital and that this hospital and its staff have no responsibility for and no involvement with the private cord blood bank.

I understand and accept that a condition of permitting my arrangement with the private cord blood bank for collection of the cord blood to occur on this hospital premises is that this hospital and its employees are absolved from all liability, however arising including any breach of contract, breach of duty and or negligent act or omission on the part of this hospital and its employees arising from loss, injury or damage arising directly or indirectly in connection with the collection, handling, transportation or storage of the cord blood.

I understand that the attending medical practitioner or midwife, as the case may be, will ultimately determine whether the collection of the cord blood can proceed having regard to the medical condition of myself and my child.

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Signature of patient: [Signature]

Date (dd/mm/yyyy): [Date]

Print name of witness: [Name]

Signature of witness: [Signature]

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This space for form information, notations, the dates, etc.