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CHAPTER 19 - PATHOLOGY

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BLOOD MANAGEMENT (PD2018_042)

PD2018_042 rescinds PD2012_016

PURPOSE

The purpose of this Policy Directive is to support health services and health service staff to comply with their responsibilities as described in the Australian Health Ministers Conference (AHMAC) Statement on National Expectations for the Supply of Blood and Blood Products1 by:

1. Providing policy and system direction for the use of evidence based best practice blood management guidelines for NSW Health facilities
2. Establishing a consistent, system wide approach to blood management in all facilities providing transfusion therapy
3. Minimising NSW patients exposure to risks associated with the clinical storage, prescribing, handling and administration of blood products in NSW facilities
4. Supporting health facilities to comply with the relevant National Safety and Quality Service Standards, and other accreditation requirements in relation to blood management.

MANDATORY REQUIREMENTS

NSW health services that provide transfusion therapy are responsible for:

1. Developing and maintaining effective systems to ensure safe, effective, appropriate and patient centred blood management processes and procedures
2. Adopting and implementing best practice procedures relating to blood management and the clinical storage, prescribing, handling and administration of blood products
3. Complying with the relevant National Safety and Quality Health Service Standards (NSQHS).

Health service staff involved in blood management and/or transfusion related activities are responsible for:

1. Complying with relevant blood management systems, processes and procedures, including those outlined in this Policy Directive
2. Providing safe, effective, appropriate and patient centred care.

It is recognised that some of the requirements in this policy such as the role of the Local Health Districts/Special health networks are not applicable to private health facilities. Private health facilities are expected to comply with the general principles described in this Policy Directive in compliance with the *Private Health Facilities Act 2007* (NSW) and the *Private Health Facilities Regulation 2017* (NSW).

IMPLEMENTATION

Chief Executives are responsible for:

- Assigning responsibility for implementing and complying with this Policy Directive and reporting on the implementation of this policy document as required
- Monitoring compliance with this Policy Directive by achieving and maintaining accreditation to the relevant NSQHS standard

Health service staff are responsible for:

- Complying with this Policy Directive

Clinical Excellence Commission is responsible for:

- Reviewing and ensuring the currency of this Policy Directive
- Supporting the implementation and evaluation of strategies related to this Policy Directive.

1 Statement endorsed by the Australian Health Ministers' Conference, 12 November 2010 (see attachment 5.1)

Blood Management Procedures

1 BACKGROUND

1.1 About this document

In line with the Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products[2], this Policy Directive provides clinicians; pathology providers; support personnel and health service managers, with direction to ensure safety and quality in blood management related activities.

1.2 Key definitions

Word or Phrase	Definition
Blood Products	Includes fresh blood components (red blood cells, platelets, fresh frozen plasma, cryoprecipitate and cryodepleted plasma) and plasma-derived (fractionated) blood products such (albumin, coagulation factors and immunoglobulins).
Blood Service	The Australian Red Cross Blood Service, responsible for the collection, manufacture and distribution of blood products to NSW hospitals.
Haemovigilance	A set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients, to their follow-up. It includes monitoring, reporting, investigation and analysis of adverse events related to donation, processing and transfusion of blood, as well as development and implementation of recommendations to prevent the occurrence or recurrence of adverse events.
Health care record	Includes a record of the patient's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care.
Traceability	The ability to trace the fate of a blood product from the donor through to the final recipient/s, via accurate documented and/or electronically stored blood service, laboratory and patient records.
Transfusion history	A list of transfusions that a patient has had before presentation, including details of any adverse reactions to the transfusion and any special transfusion requirements. The completeness of the history will depend on the availability of information. It is expected that information will be obtained by reviewing any available referral information and interviewing the patient (and/or their carer).
Transfusion related activity	Transfusion related activity includes but is not limited to: • Prescribing and ordering • Obtaining patient blood samples • Obtaining patient consent for transfusion • Pre transfusion laboratory testing and product issue • Storage • Transport • Administration • Monitoring and patient assessment.

2 Statement endorsed by the Australian Health Ministers' Conference, 12 November 2010 (see attachment 5.1)

1.3 Legal and legislative framework

Blood, blood components and plasma derivatives are regulated under the *Therapeutics Goods Act 1989* (Cth)3.

The *Human Tissues Act 1983* (NSW) sets out the legislative requirements for the collection of blood from donors[4] and the regulation of businesses supplying blood and blood products5.

Under the *National Blood Authority Act 2003* (Cth)6, the National Blood Authority manages and coordinates arrangements for the supply of blood and blood products and services on behalf of the Australian Government and state and territory governments.

Jurisdictional issues relating to the national blood supply, including planning, production, supply and budgeting are managed through the Jurisdictional Blood Committee (JBC). The Deputy Secretary, Population & Public Health is the NSW representative on the JBC.

2 CLINICAL USE OF BLOOD PRODUCTS

2.1 Transportation and Storage

Health services providing transfusion therapy must have procedures in place to ensure the safe storage and where relevant, transport of blood and blood products.

The transport and storage of blood products must comply with the:

- National Pathology Accreditation Advisory Council (NPAAC) Requirements for Transfusion Laboratory Practice or any subsequent versions
- Australia and New Zealand Society of Blood Transfusion (ANZSBT) Guidelines for Transfusion and Immunohaematology Laboratory Practice or any subsequent versions.

2.1.1 Transportation

Transport of blood products between facilities, including packing configurations and the use of validated shipping containers, should be managed in compliance with the:

- Relevant NSW Health Pathology policy directives and procedures[7] (or other accredited pathology provider policy and procedures, see 3.2.2)
- Blood Service Shippers – Receipt and Use by External Institutions8.

2.1.2 Storage

Storage of blood products must comply with:

- Australian Standard AS 3864 - Medical Refrigeration Equipment – for the storage of blood and blood products
- Relevant NSW Health Pathology policy or procedures9 outlining storage requirements of blood products (or other accredited pathology provider policy and procedures, see 3.2.2).

3 Australian Government, Department of Health; Therapeutic Goods Administration, *Therapeutics Goods Act 1989* (Cth)
4 *Human Tissues Act 1983* (NSW) ss19-20H
5 Ibid ss21-21C
6 *National Blood Authority Act 2003* (Cth)
7 NSWHP Policy Red Blood Cell Storage, NSWHP Procedure Retrieval Transfusion Procedure, and any other NSWHP policy directive or procedure related to storage and transport published subsequent to this Policy Directive
8 Australian Red Cross Blood Service Shippers – Receipt and Use by External Institutions (WI-00635; version 1) or any subsequent version
9 Ibid above 7 and Australian Standard AS 3864 - *Medical Refrigeration Equipment –for the storage of blood and blood products* (1997) or any Australian Standard that supersedes this.

This includes:

- Storage in dedicated fridges and/or freezers that are remote from a transfusion laboratory (satellite)
- Storage in facilities without dedicated blood storage equipment, including the use of validated shipping containers for short term storage
- Storage of blood products accompanying transferred patients
- Storage of products for use by emergency retrieval teams.

Blood products delivered to a clinical environment, e.g. ward, operating theatre must:

- Be stored in accordance with this Policy Directive, or
- Be administered to the patient within the appropriate time frame as described in the ANZSBT Guidelines for Administration of Blood Products or any subsequent versions.

A blood product must not be transfused, except at the discretion of the laboratory director, where it is:

- Stored at temperatures outside specified limits
- Stored in non-conforming equipment
- There is doubt regarding storage equipment.

2.2 Consent

Health services providing transfusion therapy must have procedures and processes in place to ensure clinicians are able to obtain and document informed consent for the use of blood products.

These procedures and processes must comply with the requirements for consent as outlined in the NSW Health Policy Directive *Consent to Medical Treatment – Patient Information*, or any subsequent versions, and include:

- The use of the relevant consent forms as described in the above Policy Directive
- Who can obtain consent
- The right to decline any proposed treatment
- Patients who are unable to provide consent (including minors)
- Emergency treatment.

Informed consent requires:

- A discussion of the risks and benefits of the use of blood products
- The availability of other treatment options as relevant to the patient's clinical condition
- The likely outcome(s) if the treatment is not provided or declined
- The documentation of refusal (and associated care planning requirements)

Information for patients on the use of blood products is available to support the consent process at:

- CEC Blood Watch patient information page, including information in multiple languages, and information for children and parents
- Blood Service My Transfusion web site

Where treatment involves the administration of blood products over a period of time for the same clinical indication, it is not necessary to obtain consent for every transfusion episode. Initial consent should be obtained and documented as outlined in the above Policy Directive. It should include the length of time blood products will be required, or the length of time the consent will remain valid for.

Requirements for long term consent should be described in health service procedural documents. For patients with long term transfusion requirements, reviewing and obtaining consent at regular intervals of at least 1 year (but no greater than 2 years) is considered best practice.

A new consent should be obtained if:

- A new treatment is proposed which was not previously explained to the patient
- Where alternative treatments become available
- If new risks associated with the treatment are identified.

2.3 Patient identification

Health services must have systems in place to ensure correct patient identification and procedure verification for transfusion-related activities.

Correct patient identification procedure from the collection of specimens, to the transfusion of blood products, is vital to ensure that all patients receive the correct blood product, for the appropriate indication.

Failure to correctly identify the patient at any stage can lead to serious adverse outcomes.

2.3.1 Pre-Transfusion testing and specimen labelling

Pre-transfusion specimen collection and specimen labelling requirements and related procedures must comply with:

- ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice or any subsequent versions
- NSW Health Pathology NSWHP_PD_009 Minimum Patient Identification requirements for Pre-Transfusion Testing10 (or other accredited pathology provider policy and procedures, see 3.2.2)
- Principles for patient identification, and pre and post procedure matching for level 1 procedures, as outlined in the NSW Health Policy Directive PD2017_032 *Clinical Procedure Safety* or any subsequent versions.

2.3.2 Transfusion verification procedure

Transfusion related patient identification procedures must be implemented for transfusion related activities including:

- The collection of blood products from the transfusion service or appropriate storage (e.g. satellite blood fridge)
- Delivery to the clinical environment
- Administration to the patient.

The purpose of transfusion related patient identification procedures is to ensure the correct blood product is administered to the correct patient. To minimise the risk of error at the final administration check, the administering and checking clinicians must check the required information independently, a process called “double independent checking”.

Procedures must comply with:

- Principles for patient identification and procedure matching as outlined in the NSW Health Policy Directive *Clinical Procedure Safety* or any subsequent versions
- ANZSBT Guidelines for the Administration of Blood Products or any subsequent versions.

2.4 Appropriate use

Health services must have processes in place to support clinicians in their obligations to provide safe, effective and appropriate use of blood products when clinically indicated.

10 NSW Health Pathology NSWHP Policy Minimum Patient Identification requirements for Pre-Transfusion Testing available at https://intranet.pathology.health.nsw.gov.au/tools---resources-/policies-and-procedures/policies

Decisions on whether to prescribe blood products, and the dose or number of units to order should take into account:

- The presence or absence of proven benefit
- Risks associated with the use of blood products
- Other treatment options, including appropriate management of reversible causes of deficiencies[10].

Procedures for appropriate use of blood products must comply with the current and any subsequent versions of:

- National Patient Blood Management Guidelines
- Blood Service Component Information
- ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice including for the selection of modified blood products and:
    - Rh D negative
    - CMV negative
    - Irradiated products

2.5 Safe administration

Health services must have processes in place to support clinicians to safely administer blood products when clinically indicated.

Successful and safe transfusion practice depends on the administration of a quality blood component of the right type, for the right indication, in the right quantity or dose, via the right route, at the right time to the right patient.

Procedures for safe administration of blood products must comply with the current and any subsequent versions of:

- ANZSBT Guidelines for the Administration of Blood Products
- Blood Service Component Information.

2.6 Adverse events

Health services are to have systems and processes in place to support the appropriate identification, management, notification, and follow up of adverse outcomes of transfusion, transfusion reactions, and incidents relating to transfusion activities.

2.6.1 Transfusion reactions

Transfusion reactions are adverse pathophysiological complications associated with the use of blood products. Management of patients who are suspected of having a transfusion reaction should include:

- The initiation of patient assessment and first aid including basic life support and the appropriate escalation as per *Recognition and Management of Patients who are Deteriorating* or any subsequent versions, including obtaining further appropriate clinical consultation if required (e.g. Haematology)
- Notification to the pathology provider responsible for providing the blood product as well as following instructions on follow up investigations and clinical consultation as required
- All adverse reactions are to be entered into the incident management system (see 2.6.3)
- Resources for clinical management of transfusion reactions include:
    - ANZSBT Guidelines for the Administration of Blood Products or any subsequent versions
    - The Blood Service: Adverse Events overview or any subsequent versions.

2.6.2 Transfusion incidents

Transfusion incidents are errors in activities related to the use of blood products including specimen collection, storage, handling, ordering, prescribing, administration and documentation.

Transfusion incidents may cause severe, potentially fatal complications including ABO Haemolytic Transfusion reaction (HTR), and Transfusion Associated Circulatory Overload (TACO). Such complications should be managed as per 2.6.1 in the first instance.

2.6.3 Notification and management of transfusion reactions and incidents

All health services providing transfusion therapy are to have systems in place for the notification and management of transfusion related incidents (including transfusion reactions).

- For NSW Health services, all incidents are to be entered into the incident management system
- Notification and management must comply with NSW Health policy on *Incident Management* or any subsequent versions, including appropriate allocation of a severity assessment code (SAC) and follow up investigation and management
- A Haemolytic Transfusion Reaction (HTR) as a result of ABO (Blood Group) incompatibility, and causing serious harm or death, is a sentinel event, and is a reportable incident requiring a Reportable Incident Brief (RIB)11
- Appropriate open disclosure must occur in compliance with NSW Health policy on *Open Disclosure* or any subsequent versions
- **All** suspected Transfusion Transmitted Infections (bacterial, viral, parasitic or other) must be reported to the Blood Service:
  - 24 hour customer service line: **1300 478 348**
- **All** suspected Transfusion Related Acute Lung Injury reactions must be reported to the Blood Service:
  - 24 hour customer service line: **1300 478 348**
- Consider seeking advice from the Blood Service for the following transfusion reactions where expert advice and/or alternative component or product support may be required. These include:
  - Post transfusion purpura (PTP)
  - Transfusion associated graft-vs-host disease (TA-GVHD)
  - Severe allergic reactions
  - Immediate and delayed haemolytic and serological transfusion reactions
  - Reactions to plasma-derived recombinant products.
- Reactions associated with the use of plasma derived blood products should also be reported to the Blood Service, the product manufacturer, and to the Australian Adverse Drug Reaction Reporting System (AADRS)12.
- The NSW Clinical Excellence Commission, via the Blood Watch Program is responsible for collating and reporting haemovigilance activities in NSW for the National Haemovigilance Program (NBA)13.

2.7 Documentation and medical records

Health services must have in place processes for all models of documentation and management of health care records in compliance with NSW Health policy *Health Care Records – Documentation and Management* or any subsequent versions.

11 NSW Health Incident Management Policy section 3.1 RIB reporting requirements and 3.1.1 The sentinel events
12 Australian Adverse Drug reaction Reporting System (AADRS) as per the Advisory Committee on the Safety of Medicines (ACSOM)
13 NBA, National Haemovigilance Program

NSW Health facilities must comply with the General Retention and Disposal Authority - Public Health Services: Patient / Client Records (GDA 17) 200414.

It is a requirement that there is documentation in place to ensure the traceability (fate) of the blood product is recorded as either transfused, transferred (to another health service) or discarded. This is achieved through accurate documentation in the patient health care record **and** the laboratory information system.

2.7.1 Patient health care record

Documentation of transfusion related activity should be available to all clinical staff and include:

- Transfusion history (including previous complications) if available
- Indication for the use of blood product
- Consent
- Prescription
- Blood product compatibility information or product batch number as applicable
- Administration and completion times
- Patient observations as applicable to the type of blood product
- Outcome of the transfusion
- Occurrence and management of any adverse events or reactions.

2.7.2 Laboratory

Transfusion laboratories must comply with the documentation requirements for blood products, immunohaematology specimens, and patient information as described in the ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice or any subsequent versions.

The fate of fresh blood products, either transfused, transferred or discarded, must be documented in the BloodNet Fate module. If discarded, the reason must be entered, as per the definitions provided.

3 GOVERNANCE

3.1 Blood Management Committee

Health services that provide transfusion therapy must have a process in place for the review of blood product issues. This may be through a Blood Management Committee (BMC) or an equivalent quality or patient safety management committee as relevant to the size and function of the service.

The BMC (or equivalent) responsibilities should include:

- Development and monitoring of local policy, procedures and safe work practices
- Monitoring the clinical use of blood products
- Monitoring wastage of blood products
- Haemovigilance activities, i.e. monitoring, reporting, investigation and analysis of adverse events related to blood product transfusion
- Escalating any concerns or risks associated with transfusion related activities to the relevant authority
- Contingency planning in the event of notified shortages of blood products
- Monitoring education in transfusion related activities to all relevant staff groups.

14 NSW State Records Authority, General Retention and Disposal Authority - Public Health Services: Patient /Client Records (GDA 17) 2004

3.2 Education

Staff involved in transfusion related activities must complete the BloodSafe eLearning Course Clinical Transfusion Practice.

Transfusion related activities include (but are not limited to):

- Pre transfusion laboratory testing and product issuing
- Administration of blood products
- Monitoring and patient assessment
- Prescribing and ordering blood products – Intern medical officers only (Postgraduate Year 1/2) are required to complete Clinical Transfusion Practice
- Health care workers involved in non-clinical handling of blood products, such as hospital porters and orderlies, are required to complete the separate Transporting Blood module only.
- Health care workers employed only to perform phlebotomy or venepuncture are required to complete the separate Collecting Blood Specimens module only.

This mandated requirement to complete these BloodSafe eLearning courses applies only to a one-off completion, Local Health Districts and Special Health Networks may determine to repeat completion and assessment at a frequency deemed by them to meet local needs.

3.3 Roles and responsibilities

3.3.1 Local Health Districts / Special Health Networks

The Local Health District/Special Health Network must monitor compliance with this Policy Directive and ensure that all facilities that provide transfusion therapy (and related activities) are able to report to a BMC (or equivalent), and that all staff are appropriately trained as relevant to their role.

All facilities that provide transfusion therapy must achieve and maintain accreditation to the relevant NSQHS Standard.

3.3.2 NSW Health Pathology

NSW Health Pathology is responsible for the provision of transfusion laboratory services for NSW Health. As required by NSW Health Policy Directive *Accreditation of Pathology Laboratories in NSW Health* (or any subsequent versions) transfusion laboratory services are required to maintain accreditation to the standards developed by the National Pathology Accreditation Advisory Council.

Transfusion laboratory service providers, other than NSW Health Pathology, may be utilised by NSW Health services. Where such agreements are in place, the requirements of this policy apply.

For transfusion laboratories the relevant standard is the National Pathology Accreditation Advisory Council (NPAAC) Requirements for Transfusion Laboratory Practice (3rd Ed) 201715, or any subsequent versions.

3.3.3 Blood Service

The Blood Service is responsible for the collection, manufacture and distribution of blood products to NSW.

The Blood Service operates a 24 hour, 7 day a week phone line for clinical advice and consultation on fresh components, plasma-derived products and recombinant products and on urgent clinical matters including significant transfusion reactions (see 2.6.3 Notification and management of transfusion reaction and incidents).

The contact number is: 24 hour customer service line: **1300 478 348**

15 The Department of Health, NPAAC Requirements for Transfusion Laboratory Practice (3rd Ed) 2017

4 RELATED NSW HEALTH POLICY DIRECTIVES, GUIDELINES AND INFORMATION BULLETINS

- Management of Haemophilia and Related Bleeding Disorders
- National Policy – Access to Government Funded Immunoglobulin Products in Australia
- Maternity – Rh (D) Immunoglobulin (Anti D)
- Maternity – Prevention, Detection, Escalation and Management of Postpartum Haemorrhage (PPH)

5 ATTACHMENTS

5.1 AHMAC stewardship statement

5.2 Implementation checklist

5.1 AHMAC Stewardship Statement

AUSTRALIAN HEALTH MINISTERS' CONFERENCE STATEMENT ON NATIONAL STEWARDSHIP EXPECTATIONS FOR THE SUPPLY OF BLOOD AND BLOOD PRODUCTS

The Australian Health Ministers' Conference (AHMC) has determined that a clear statement is needed on governments' stewardship expectations for the providers of blood and blood products within the health sector. Stewardship, in this context, means responsible, sustainable and appropriate use of blood and blood products.

Blood and blood products are provided under the *National Blood Agreement* 2003 to which all Commonwealth, State and Territory Governments are signatories. Achieving a blood supply that can meet the growing needs of an ageing population at an affordable cost requires the commitment from blood donors to be matched by an equal commitment from other parties in the supply chain.

All governments are committed to:

- Providing an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services; and
- Promoting safe, high quality management and use of blood products, blood related products and blood related services in Australia.

A key component of the blood sector and one which plays an invaluable part is that of the health providers of blood and blood products. Hospitals, doctors, laboratories and other health providers serve a vital role in ensuring these key resources reach the patients in need.

In fulfilling this role, Ministers expect that these health providers will contribute to the sustainability of the blood supply by adopting these stewardship measures for their own organisation and requiring their adoption by any other party to whom they supply blood.

Blood Stewardship Principles

Blood should be managed in ways that ensure:

- All blood products are used in a clinically appropriate manner in accord with relevant professional guidelines and standards;
- Informed patient consent procedures are implemented for all patients;
- Processes, programs and facilities are in place to minimise the wastage of blood products;
- Facilities are accredited with the appropriate bodies to meet all quality and safety obligations; and
- Transfusion related adverse event information is collected and managed according to jurisdictional requirements.

National blood product planning, management and governance are supported by:

- Health providers having an ordering and receipt verification process in place which provides adequate financial accountability as required by governments; and
- Inventory data is provided on a regular and timely basis to assist in supply and demand planning, especially in times of national shortages.

Governments and the National Blood Authority will continue to manage the Australian blood supply to meet the needs of the community. Health providers play a vital role in making sure that products are available to meet clinical need, when and where required. The contribution of these health providers to safe and appropriate use, including minimisation of cost and wastage in the supply, is equally important. Ministers look to health providers to increase their efforts in these areas to ensure that Australia has a sustainable and affordable blood supply into the future.

Statement Approved by the Australian Health Ministers' Conference, 12 November 2010.

5.2 Implementation checklist

LHD/Facility:			
Assessed by:		**Date of Assessment:**	
IMPLEMENTATION REQUIREMENTS	**Not commenced**	**Partial compliance**	**Full compliance**
1. There are procedures and processes in place for blood management activities as outlined in section 2 of this Policy Directive. This includes: a) Transport and storage b) Consent c) Patient identification d) Appropriate use e) Safe administration f) Adverse event management g) Documentation	❑	❑	❑
	Notes:		
2. Procedures and processes are reviewed to ensure they are inclusive of both fresh and fractionated blood products.	❑	❑	❑
	Notes:		
3. Procedures and processes are in place to comply with the requirements for double independent checking.	❑	❑	❑
	Notes:		
4. There is governance in place including a blood management committee and processes for ensuring appropriate and safe use of blood products	❑	❑	❑
	Notes:		
5. There are procedures and processes in place to evaluate compliance with this policy, including: a) Clinical practice or patient blood management audit b) Adverse event reporting c) Haemovigilance analysis and strategies	❑	❑	❑

CORD BLOOD - PUBLIC AND PRIVATE CORD BLOOD BANKING (PD2015_048)

PD2015_048 rescinds PD2005_394

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.

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

2.6.1 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

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.

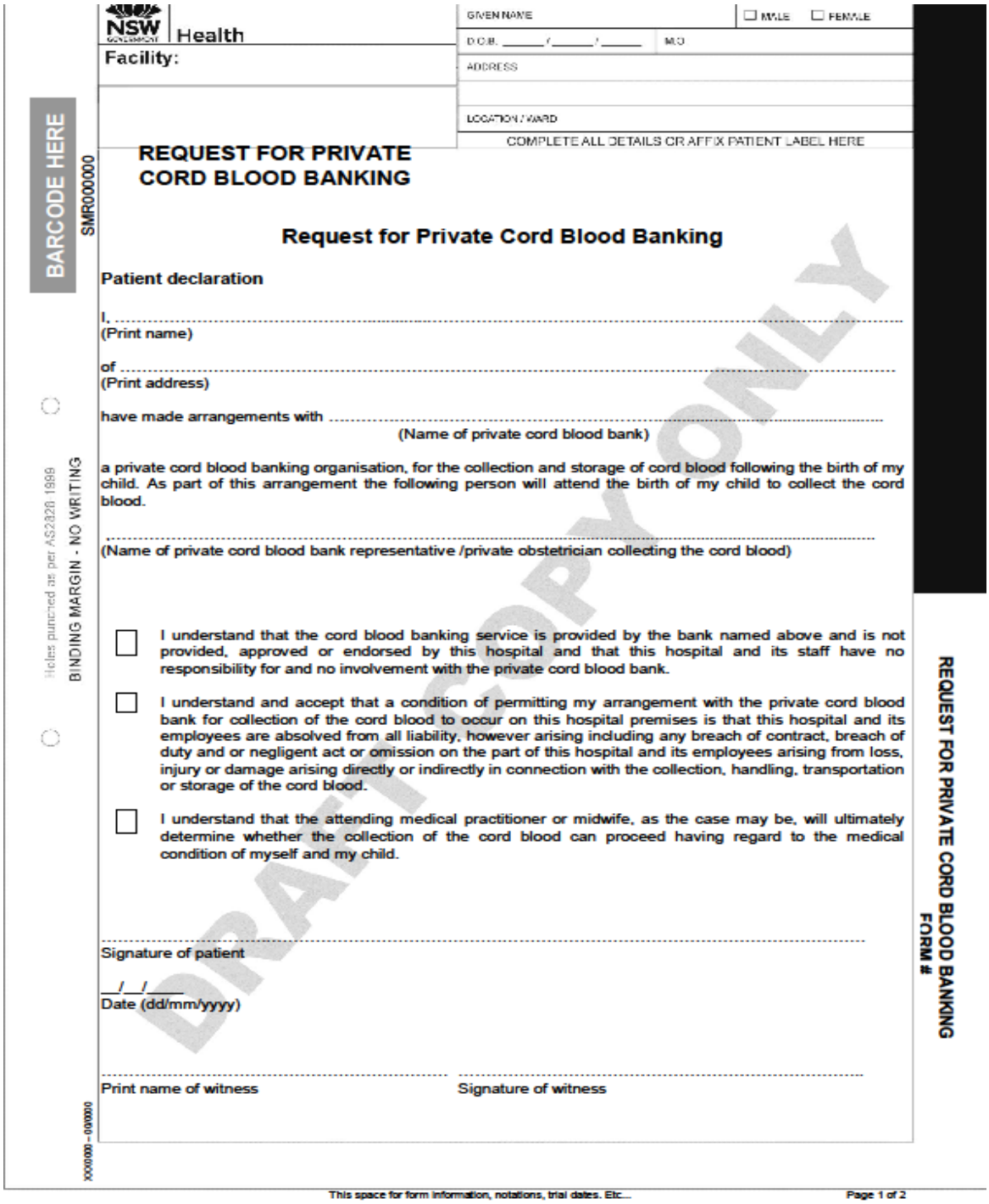
4.1.9 Private Cord Blood Bank visitors to the delivery suite involved in cord blood collection must satisfy the PHO's requirements for identification and must be clearly identifiable and make their presence known to hospital staff. Private Cord Blood Bank visitors will act in accordance with directions 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



NSW Health

Facility:

GIVEN NAME ☐ MALE ☐ FEMALE

D.O.B. ____/____/____ M.O

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

BARCODE HERE

SMR000000

REQUEST FOR PRIVATE CORD BLOOD BANKING

Request for Private Cord Blood Banking

Patient declaration

I, ...
(Print name)

of .....
(Print address)

have made arrangements with .....
(Name of private cord blood bank)

a private cord blood banking organisation, 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)

☐ 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.

.....
Signature of patient

__/__/____
Date (dd/mm/yyyy)

.....
Print name of witness

.....
Signature of witness

DRAFT COPY ONLY

Holes punched as per AS2828 1988

BINDING MARGIN - NO WRITING

REQUEST FOR PRIVATE CORD BLOOD BANKING FORM #

XXXXXX – 0/0000

This space for form information, notations, trial dates, Etc...

Page 1 of 2

RESPONSIBILITIES OF MEDICAL OFFICERS WITH REGARD TO DRIVERS
(IB2013_059)

IB2013_059 rescinds PD2005_028.

PURPOSE

This information bulletin summarises the responsibilities of medical practitioners working in NSW Health with regard to drivers, and outlines the relevant legislation that permits reporting by medical officers of concerns about drivers directly to Roads and Maritime Services (RMS).

This information bulletin replaces PD2005_028 *Drivers – Medical Officers Responsibilities with Regard to Drivers.*

KEY INFORMATION

The Ministry of Health's policy, based on common law and ethical principles, is that the duty of confidentiality owed by medical practitioners to their patients must be preserved except where disclosure of health information occurs with the consent of the patient or where there is a lawful justification for disclosing the information without the consent of the patient.

One context in which disclosure of health information to third parties arises is medical assessment of patients for fitness to hold a licence to drive. This is generally done to assist the relevant licensing authority (Roads and Maritime Services in NSW) to determine whether or not a patient is fit to hold a licence or to hold a conditional licence.

Information regarding this process can be found on the RMS website, which includes a standard "Medical Condition Notification Form". This form can be completed by the medical practitioner in consultation with the patient, and submitted to RMS.

There may be circumstances in which a medical practitioner may hold concerns about a patient's fitness to drive and/or that the patient is a potential danger to the public if permitted to drive in any circumstances, or is permitted to drive without being subject to conditions. In this event where possible medical practitioners should encourage patients to either self-notify the medical condition to RMS or to consent to the medical practitioner notifying RMS of the practitioner's concerns via the submission of a completed "Medical Condition Notification Form".

Where the patient does not comply with the medical practitioner's advice, legislation in NSW provides protections for medical practitioners who directly report the matter to RMS.

Section 275(4) of the *Road Transport Act* 2013 (NSW) provides as follows:

> *An individual does not incur civil or criminal liability for reporting to the Authority [ie RMS], in good faith, information that discloses or suggests that:*
>
> *(a) Another person is or may be unfit to drive*
>
> *(b) It may be dangerous to allow another person to hold, to be issued or to have renewed, a driver licence or a variation of a driver licence.*

The above provisions are **discretionary** reporting requirements only. There is no mandatory reporting requirement for medical practitioners in relation to drivers who may present a risk to the public. In considering whether to make report directly to RMS, medical practitioners should ensure that:

- They are acting in good faith – that is, they are acting out of a bona fide concern for safety concerns regarding the driver concerned.
- The health information they disclose to RMS is limited to information that is relevant to the issue of the driver's fitness to drive or that allowing the person to hold a licence may be dangerous.

Situations that may result in a medical practitioner reporting a patient to the RMS include where the patient is:

- Unable to appreciate the impact of their condition.
- Unable to take notice of the health professional's recommendations due to cognitive impairment.
- Continues driving despite appropriate advice and is considered likely to endanger the public.

In the event that the medical practitioner decides to directly report a patient to RMS, it is good practice to advise the patient that the practitioner is doing so.

Medical practitioners may, if they wish, when directly reporting a patient to RMS, use a copy of the approved "Medical Condition Notification Form". A copy of the form, and more information from RMS, can be found at: http://www.rms.nsw.gov.au/licensing/healthmedicals/health_professionals.html

FORENSIC DRUG AND ALCOHOL SAMPLING IN EMERGENCY DEPARTMENTS (PD2021_010)

PD2021_010 rescinds PD2021_005

POLICY STATEMENT

NSW hospitals are required by the Road Transport Act 2013 (Schedule 3), Marine Safety Act 1998 (Schedule 1), the Rail Safety (Adoption of National Law) Regulation and the Law Enforcement (Powers and Responsibilities) Act 2002 No 103 to provide a service 24 hours per day/7 days per week for the collection of forensic blood and urine samples for drug and alcohol testing. Currently this service is provided in emergency departments (EDs).

This Policy Directive provides additional information for authorised sample takers to assist them to meet the obligations of the stated legislation. Forensic sampling for legislation outside of this (for example sexual assault or drink spiking) is out of scope for this Policy.

SUMMARY OF POLICY REQUIREMENTS

This Policy **does not** replace the requirement for authorised sample takers (please refer to section 1.2 Key Definitions) to ensure they have a detailed understanding of their obligations and comply with legislative requirements.

Two different sampling kits are to be available in all NSW EDs to facilitate sampling– the blood testing for alcohol kit and the blood/urine testing for drugs kit (also known as the 'D' kit as the serial number on the certificate starts with a 'D'). NSW Police will bring an additional kit (also known as/referred to by Police as the 'B' or BAS kit) with them if that is required for sampling.

Authorised sample takers are to ensure the correct sampling kit is used to allow the samples and test results to be used as evidence.

Detailed instructions are available within each sampling kit and must be adhered to. The serial number of the kit is to be documented in the patient's health care record and the sample put immediately in the blue NSW Police security box located in the ED (unless sample is being taken in accordance with Rail legislation please refer to section 6 Rail Legislation).

Circumstances where taking a sample is not required are detailed in the attached procedure document in section 7.1

Appendix 1 provides a quick reference guide for hospitals/EDs in acknowledgement of the complexities of the various pieces of Legislation, sampling kits and sampling requirements.

The complete policy directive is available at:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2021_010

MANAGEMENT OF SUDDEN UNEXPECTED DEATH IN INFANCY (SUDI)
(PD2019_035)

PURPOSE
This Policy Directive outlines the mandatory requirements for management of Sudden Unexpected Death in Infancy (SUDI) in NSW Health facilities. It also outlines the role of NSW Health in the context of the NSW Government response to SUDI which includes the NSW Coroner and Police.

MANDATORY REQUIREMENTS
SUDI is a reportable death under the Coroners Act 2009.1 Most SUDI deaths occur in the community and are brought to their local emergency department, however SUDI can also occur in hospital. NSW Health's role in management of SUDI includes that local health districts and specialty health networks must:

- Ensure that local policies that guide management of SUDI are easily accessible for staff. This includes emergency departments as well as other areas that SUDI may occur such as maternity, paediatrics and intensive care. Information for staff on how to access locally networked paediatric services should be included.
- Ensure that adequate resources and education are provided so that staff can meet the needs of the infant and the parents/carers, and that parents/carers have access to expert medical advice, nursing care and social work. If necessary, these can be accessed via locally networked paediatric services. In some instances the situation may warrant transfer of the infant to a higher level facility.
- Nominate a hospital contact who will coordinate the SUDI response for example a social worker or nurse. This health professional will provide support to the parents/carers and coordinate completion of documentation required by NSW Health. A list of roles and responsibilities of agencies and staff involved in the SUDI response is at Section 6.1 Response to Sudden Unexpected Death in Infancy (SUDI) - Roles and Responsibilities.
- Ensure that the infant's medical history is completed by a senior medical staff member and documented in the health care record. A checklist to support this is at Section 6.2 Medical History Guide – Sudden Unexpected Death in Infancy. A copy of the infant's health care record must be forwarded to Forensic Medicine (NSW Health Pathology) within 24 hours of the infant's death.
- Ensure that support is available for staff who provide care to infants and parents/carers who have experienced SUDI. If necessary, this can be accessed via locally networked paediatric services.
- Ensure there are processes to maintain the quality of care and patient experience of SUDI cases. This includes incident notification, documentation, case discussion that includes the perspective of parents/carers and staff and implementation of any identified improvement opportunities.

IMPLEMENTATION
Local health district chief executives are responsible for:

- Assigning responsibility, personnel and resources to implement this policy.
- Establishing mechanisms to ensure the mandatory requirements are applied, achieved and sustained as usual processes in the instance of a SUDI. This should include nomination of an executive sponsor.
- Ensuring that any local policy reflects the requirements of this policy and is written in consultation with the hospital executive, clinical governance unit and clinical staff.

The complete policy directive is available at:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2019_035

NON-CORONIAL POST MORTEMS (PD2013_051)

PD2013_051 rescinds PD2005_008.

PURPOSE

Non-coronial post-mortems are governed by the *Human Tissue Act 1983* (the Act) which makes specific provisions for obtaining consent and authorisation for the conduct of a non-coronial post mortem and the subsequent use of organs and tissues removed at post mortem and retained for other purposes (eg. for scientific research or teaching purposes).

This Policy Directive provides guidance for Local Health Districts (LHDs) Speciality networks and NSW Health Pathology Services on the procedures that must be in place to support families and clinicians in:

- Providing information to families regarding non-coronial post mortems.
- Obtaining written consent and the authorisation of a designated officer for a non-coronial post mortem and the retention and subsequent use of organs and tissue removed at post mortem for other purposes.
- Disposing of, or returning tissue removed at post mortem to the next of kin for disposal.
- Determining attribution of the costs of post mortems.
- Meeting the requirements relating to the post mortem report including the retention periods for post mortem records.

MANDATORY REQUIREMENTS

Facilities where non-coronial post mortems are undertaken must ensure:

- Compliance with the requirements of the Act in relation to obtaining consent and authorisation prior to post mortem being undertaken and in relation to using tissue taken at post mortem for other purposes (such as scientific research or teaching).

One or more designated officers are available for authorising the post mortem and/or the subsequent use of tissues removed.

- That staff who approach families for consent for the above procedures have appropriate knowledge about the post mortem process and the training to provide that information in a clear and sensitive manner.
- That the standard state-wide forms attached to this policy directive are used wherever indicated by this policy directive.

IMPLEMENTATION

Chief Executives of LHDs and Specialty Networks must ensure that:

- All relevant staff are made aware of their obligations in relation to this Policy Directive.
- Documented procedures are in place to support the Policy Directive.

Staff involved with non-coronial post mortems:

- Must comply with this policy statement as it relates to the work they undertake.

Non-Coronial Post Mortems Procedures

1. BACKGROUND

1.1 About this document

Non-coronial post mortems are performed in a hospital or a forensic pathology facility[16] at the request of a treating clinician, or occasionally at the request of the deceased person's family, when the cause of death is known but there is an interest in determining, for example, the extent of the condition/ disease that caused the death, the effects of therapy or whether any undiagnosed disease of interest might have contributed to the death. These post mortems must not be performed on a person who has, or is suspected of having a prescribed infectious disease as defined in Clause 53 of the *Public Health Regulation 2012*.

Non-coronial post mortems and the use of tissues removed for the purposes of a post mortem examination, are governed by Part 5 *Human Tissue Act 1983* and the principles set out in the Australian Health Ministers' Advisory Council *National Code of Ethical Autopsy Practice and Guidelines* 2002 and the Royal College of Pathologists of Australasia 2011 Policy*: Autopsies and the Use of Tissues Removed from Autopsies*.

Unlike coronial post mortems, a non-coronial post mortem can only be conducted if the deceased or his/her senior available next of kin has consented to it and it has been authorised by a designated officer. The Policy Directive outlines the legal requirements relating to consent and authorization, together with the principles applicable to obtaining consent. It should be read in conjunction with the NSW Ministry of Health PD2013_002 *Designated Officer Policy and Procedures.* The Policy also addresses a number of administrative matters relating to hospital post mortems.

For information about post mortem following stillbirth, see the NSW Ministry of Health's Policy Directive PD2007_025 *Stillbirth - Management and Investigation.*

1.2 Definitions

Authorised/Delegated person: A person who has been authorised in writing by a deceased person's senior available next of kin to exercise his/her functions under the *Human Tissue Act 1983*.

Child: A person who has not attained the age of 18 years and who is not married.

Designated officer means:
(a) In relation to a hospital, a person appointed under s5 (1) (a) of the *Human Tissue Act 1983,* to be a Designated Officer for the hospital.
(b) In relation to a forensic institution, a person appointed under s*5 (1)(a) of the Human Tissue Act 1983,* to be a Designated Officer for the forensic institution.
(c) In relation to a private hospital within the meaning of the *Private Health Facilities Act 2007* a person appointed by the governing body (defined in the Human Tissue Act as the licensee) of the hospital.

Post mortem (non-coronial): A non-coronial post mortem is a medical examination of the body performed after death to:
(a) Confirm the nature of the illness and/or the extent of the disease.
(b) Identify other conditions that may not have been diagnosed.
(c) Assess the effects of treatments and drugs, and identify any complications or side-effects.

[16] In this PD, the term forensic institutions means the Department of Forensic Medicine, Glebe, Sydney, the Department of Forensic Medicine at Wollongong and the Departments of Forensic Medicine, Northern Hub at Newcastle.

Full post mortem: A full post mortem entails a detailed external examination of the body and a gross and histological examination of organs and tissues contained in the abdominal, thoracic and cranial body cavities.

Limited post mortem: A limited post mortem is one in which restrictions are placed on the examination for example, limited to an external examination only with X-rays, computed tomography or magnetic resonance imaging or restricted to an examination of the tissues in only one or two body cavities.

Records: The term record includes consent forms, registers of tissue/organ sources and their disposal. Records may include cards/charts, registers, files, microfilm and microfiche, electronic records including electronic media and photographs, x-rays, scans, film, video, audio and audio-visual recordings. It is expected that the medium or format in which the record is stored will support its retention and maintenance for as long as the record is required.

Senior available next of kin: The order of senior available next of kin is defined in the *Human Tissue Act 1983* in relation to a deceased child as:
(a) Parent of the child.
(b) Sibling of child who is 18 years of age or over where a parent is not available.
(c) Guardian of the child at the time of death where none of the above is available.

and in relation to **any other deceased person** as:
(a) Spouse (which can include a de facto spouse and same sex partner).
(b) Son or daughter of the deceased person (18 years of age or over) where above is not available.
(c) Parent where none of the above is available.
(d) Sibling of the deceased person (18 years of age or over), where none of the above is available.

It should be noted that the list of senior available next of kin for both adults and children is exhaustive and cannot be extended to include other people.

Tissue: In this Policy Directive, the term tissue refers to an organ or part of a human body and any substance extracted from a human body or from part of a human body.

Valid consent: For consent to be valid the following conditions must be met:
(a) The consent must be in writing.
(b) The person giving the consent must be fully informed of the procedures to be undertaken.
(c) The person giving consent must have the capacity to do so.
(d) Consent must be given freely.
(e) Consent must be specific to the procedure.
(see NSW PD2005_406 *Consent to Medical Treatment - Patient Information*).

1.3 Legal, Ethical and Policy Framework

Legislation
Human Tissue Act 1983 (NSW)
Public Health Regulation 2012 (NSW)

National Guidelines and Standards
The Australian Health Ministers Advisory Council (AHMAC) *National Code of Ethical Post Mortem Practice and Guidelines* (2002).
The Royal College of Pathologists of Australasia (RCPA) *Policy on Autopsies and the Use of Tissues Removed from Autopsies* (2011).
National Pathology Accreditation Advisory Council (NPAAC) *Guidelines for Approved Pathology Collection Centres* (2nd Edition, 2012).
Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (2007 Edition); and
NPAAC Standard: *Requirement for the Retention of Laboratory Records and Diagnostic Material* (Fifth Edition 2009).

NSW Policy and Guidelines
NSW Ministry of Health PD2005_406 *Consent to Medical Treatment - Patient Information.*
NSW Ministry of Health PD2013_002: *Designated Officer Policy and Procedures.*
NSW Ministry of Health PD2006_053 *Interpreters – Standard Procedures for Working with Health Care Interpreters.*
NSW Ministry of Health PD2007_025 *Stillbirth - Management and Investigation.*
State Records Authority of NSW *General Retention and Disposal Authority for Public Health Services: Patient/Client Records (GDA 17) (2004)*

2. CONSENT

Valid consents are required for (1) the conduct of a non-coronial post mortem and (2) the retention of tissue taken at post mortem for subsequent use for research or education and training purposes i.e. purposes that are unrelated to the post mortem examination. Consent must be informed and in writing. If the tissue is to be used for research purposes, the proposed research project must have the approval of a properly constituted Human Research Ethics Committee.

2.1 Who can provide consent?

2.1.1 Where the deceased is an adult

Consent may be given by the deceased during his/her lifetime or posthumously by the deceased's senior available next of kin or their delegate.

2.1.2 Where the deceased is a child

The child's senior available next of kin (usually a parent of the child) is required to provide the consent. *The Human Tissue Act 1983* only requires the written consent of one parent; however, if both parents are alive and one refuses to give consent or objects to a post mortem being conducted, a designated officer must not authorise the post mortem (see NSW Ministry of Health PD2013_002 *Designated Officer Policy and Procedures*).

2.2 Delegation of responsibilities of the senior available next of kin

In some cultures and communities, for example, Aboriginal and Torres Strait Islander cultures, it is usual for responsibilities relating to death to be undertaken by a person who is not the deceased's senior available next of kin. The *Human Tissue Act 1983* provides for this situation by allowing the deceased's senior available next of kin to authorise another person (known as a delegate), to exercise their functions. Authorisation must be in writing. The form "Authorisation to delegate responsibilities of next of kin" must be used for this purpose (Appendix 2).

If responsibilities of the senior available next of kin have been delegated, it is the delegate who is included in discussions in which consent is being sought.

2.3 The consent process

The overarching principle for consent for post mortem is that the family of the deceased must be consulted. In relation to non-coronial post mortems the deceased's family has the right to:

- Refuse a post mortem being performed.
- Limit both the extent of the examination and the organs and tissues retained for diagnostic purposes, understanding that such limitations may compromise the information obtained at post mortem.
- Determine the method of disposal of retained tissues.
- Agree or refuse to tissues taken during the post mortem for being subsequently used for therapeutic, medical or scientific purposes.

In hospitals, consent to perform a post mortem should be sought by a senior clinician supported by a staff member with appropriate skills in grief and bereavement counselling. An interpreter should be present, if required. If not readily available, an interpreter can be accessed over the telephone (see NSW Ministry for Health PD2006_053 *Interpreters – Standard Procedures for Working with Health Care Interpreters).*

If the consent of Aboriginal and Torres Strait Islander families is being sought, it is useful to have an Aboriginal Liaison Officer or Aboriginal Health Care Worker present to assist with the discussions.

The consent seeking process should involve an initial discussion about the reason for wanting to perform a post mortem. If the deceased's family raises no objection to a post mortem the discussion should be broadened to include information about:

- Who will perform the post mortem.
- What it involves.
- The option of a limited post mortem.
- The option to agree to tissues removed for the purpose of the post mortem being subsequently used for research purposes.
- Information about costs.
- Viewing arrangements.
- Information about the post mortem report.

The senior next of kin/delegate should also be advised that:

(1) **small pieces of tissue** taken during the post mortem and prepared as blocks and slides for microscopic examination will be retained.

(2) **whole organs** removed from the body during the course of the examination will be returned to the body unless further diagnostic testing is required. In the latter case the family have the option, once the tests are completed, of having the organ(s):

- Returned to the body prior to the funeral (which may result in the funeral being delayed).
- Returned to them after the funeral for separate burial/cremation as required by the family.
- Disposed by the institution.

At the end of the discussions the senior available next of kin or the delegate should be provided with an information sheet (see example provided in Appendix 5) in an appropriate language outlining all the matters discussed and an opportunity to ask questions before signing the consent form (Appendix 1 Consent and Authorisation Form).

2.4 Refusal to have a post mortem conducted

If a deceased's senior available next of kin/delegate refuses to give consent to a post mortem, the requesting clinician must not instead refer the case to the Coroner.

In cases where a post mortem is requested for the purpose of determining compensation entitlement, as in the case of persons who contract dust diseases as a result of their employment, not conducting a post mortem may result in the lack of essential medical evidence required to make a compensation award to dependents of the deceased.

3. AUTHORISATION

Once consent has been obtained, a post mortem **MUST NOT** be carried out until it has been authorised in writing by a designated officer of the facility in which the body is located ie. hospital or forensic institution. The designated officer can only authorise what was consented.

Prior to authorizing a post mortem, a designated officer must be satisfied as to the following:

3.1 In relation to Adults

Where an adult consented during their lifetime, the designated officer must be satisfied that

- Written consent had been given **and**
- The deceased person had not withdrawn their consent before he/she died.

Where the senior available next of kin of a deceased adult has consented, the designated officer must be satisfied that:

- Written consent had been given **and**
- While the deceased was alive he/she had never expressed an objection to having a post mortem or tissue being used for non-diagnostic purposes (if applicable) when they died **and**
- No next of kin of the same or higher order than the senior available next of kin has objected to a post mortem being carried out or tissue used for non-diagnostic purposes.

3.2 In relation to Children

Before a designated officer can authorise a post mortem on a child or a neonate and, where applicable, the use of tissue for subsequent non-diagnostic purposes, they must be satisfied that:

- The child had not during their lifetime expressed an objection to having an post mortem when they died or their tissue being used for non-diagnostic purposes such as teaching and research **and**
- The child's senior available next of kin has given written consent **and**
- No next of kin of the same or a higher class than the child's senior available next of kin objects to the post mortem or, where applicable, the use of tissue for research or teaching purposes.

4. DISPOSAL OF TISSUE

Disposal of tissue removed for the purposes of the post mortem examination must be carried out in accordance with what was consented.

4.1 Procedure to follow where a request had been made for return of tissue for burial/ cremation

If a senior available next of kin or their delegate requests that tissue/body parts be returned to them for cremation or burial[17], the deceased persons clinician or a senior health officer must establish the grounds for the request and explain the relevant public health requirements (see *Public Health Regulation 2012*), the safe handling of human tissue including the requirement that it must not be packed on dry ice, and any of the facility's policy requirements that they must comply with. The hospital should obtain a signed statement from the senior available next of kin/delegate stating that they have had the requirements explained to them and that they have understood the requirements and agree to them. If the request is made for the return of a fetus, the meeting should include a staff member with skills in grief and bereavement counselling and an interpreter if required consistent with the principles outlined in section 2.3.

Once a decision has been made to allow release of the human tissue for disposal, the hospital authorities should provide written instructions for the senior available next of kin/delegate specifying the conditions under which release of the tissue is permitted (including the agreed method of final disposal) and waiving the responsibility of the organisation and its employees if the tissue is subsequently managed in an unauthorised manner. It should be made clear to the person who signs the Tissue Release Form (see Appendix 5) for the receipt of the tissue that they are responsible for the safe and secure storage of the transferred tissue.

The senior available next of kin/delegate should be provided with a copy of a Tissue Release Form (Appendix 5) and a letter (see example Appendix 6) should be given to the person collecting the tissue certifying that they are travelling with human tissue in their possession by the authority of the organisation (in case of accidents etc.).

Tissue that is returned to the senior next of kin or their delegate for separate burial/cremation should be triple packed as required by the National Pathology Accreditation Advisory Council *Guidelines for Approved Pathology Collection Centres (2012).*

4.2 Disposal of the tissue by the institution

If the senior available next of kin or delegate requests that retained organs be disposed of by the institution, the *National Code of Ethical Autopsy Practice 2002* states that the organs must be disposed of by cremation rather than incinerated with surgical waste. Co-cremation of retained organs requires approval from the Director-General, NSW Ministry of Health (*Public Health Regulation 2012).*

5. GENERAL ADMINISTRATIVE MATTERS RELATING TO POST MORTEM EXAMINATIONS

5.1 General matters

Once a post mortem has been authorised, all reasonable efforts should be made to minimise delays in proceeding with it.

At the completion of the post mortem examination, the senior available next of kin/delegate should be contacted and provided with information about the outcome of the post mortem and any associated investigations.

[17] In some cultures tissues expelled from the body such as placentas or tissue removed during treatment such as limbs are similarly required to be returned for cremation or burial and the same principles that apply to tissues returned following post mortem apply in these cases.

If the post mortem shows a different outcome to that listed on the initial certificate as to cause of death, the clinician who provided the initial certificate should prepare a new one and send it to the NSW Registry of Births, Deaths and Marriages together with an explanatory letter.

5.2 Forms

In NSW standardised State Forms must be used for recording of the consent and authority for non-coronial post mortem examination and the delegation of authority of the senior available next of kin. All forms required by this policy may be obtained from Fuji Xerox (previously SALMAT) Electronic Print on Demand (ePOD) at fujixerox.com.au.

5.3 Costs associated with a post mortem

The costs of a post mortem performed at the request of a treating clinician will be borne by the relevant Local Health District. Where a post mortem is requested by the deceased's family, the full costs associated with the post mortem are borne by the deceased's estate. These costs include transport, the post mortem examination and the costs of any tests conducted.

If a post mortem has been requested by the NSW Workers Compensation Dust Diseases Board, the Board will bear the full costs associated with the post mortem.

The full cost of a post mortem on a deceased person who has, or is suspected of having Creutzfeldt-Jakob Disease is borne by the Department of Forensic Medicine, Glebe**.**

5.4 The post mortem report

In the case of non-coronial post mortems the senior available next of kin/delegate has a right to receive a copy of the post mortem report. During the initial consent discussions, the senior available next of kin/delegate should be advised of this together with an explanation that the report is a technical document which they should discuss with the deceased's GP, a GP of their choice or the deceased's hospital treating clinician. Once the post mortem report is available the health facility should post a copy of the report to the address provided by the senior available next of kin/delegate.

In the event that the senior available next of kin/delegate initially declined to have a copy of the report and subsequently changed his/her mind, they should contact the Clinical Information Department of the hospital or facility where the post mortem was conducted to seek a copy.

5.5 Post mortem records

The following documents should be placed on the deceased's medical record file and where relevant or requested a copy given to the senior next of kin/delegate:

- Records of the original discussions that took place between the senior available next of kin/ delegate and family members.
- The post mortem report.
- Signed consent and authorisation forms for the post mortem and any subsequent use of tissue for purposes other than diagnostic purposes.
- A copy of the Delegation of Authority form (if relevant).
- Details of any tissues retained and records relating to method of disposal of tissue including date(s) on which disposed.
- Copies of correspondence, statements and tissue release forms relating to the release of tissue to the senior available next of kin/delegate if applicable (see section 6.1).

5.6 Retention period for tissues and records

The National Pathology Accreditation Advisory Council (NPAAC) *Requirements for the Retention of Laboratory Records and Diagnostic Materials (Fifth Edition2009)* represent the minimum standards for the retention of tissues. Paraffin blocks and slides prepared from adult tissue should be kept for a minimum of 10 years. In the case of children, the retention time of paraffin blocks and slides is the age of majority (18 years) PLUS 7 years. There are specific retention times for samples used for genetic tests/investigations and the *NPAAC guidelines* should be consulted in relation to these.

The NPAAC guidelines and the State Records Authority of NSW *General Retention and Disposal Authority for Public Health Services: Patient/Client Records* require that records of post mortem examinations should be retained for a minimum of 20 years and that genetic reports/records should be kept for a minimum of 100 years. If tissue is retained at post mortem, the records should be kept for a period of 20 years from the date the tissue was disposed of/returned to the senior available next of kin/delegate.

Facilities that maintain integrated patient records should keep the complete record for the longest period required for any part of the record. Electronic records must be accessible for the relevant period (see above) so it is important that the records are migrated across systems if they are changed during that period.

Facilities that keep electronic records rather than hard copy records should ensure that the records are protected so that data cannot be amended without creating an audit trail.

6. ATTACHMENTS

Appendix 1: Consent and Authorisation Form.
Appendix 2: Authorisation to Delegate Responsibilities of Senior Available Next of Kin.
Appendix 3: Authorisation of the Release of Human Tissue Form.
Appendix 4: Example of letter to be issued to a person travelling with human tissue in their possession.
Appendix 5: Information for families about non-coronial post mortems (to print as a folded brochure printer settings should be set to double sided and flipped on short edge).

Appendix 1, 2, and 3 should be obtained from Fuji Xerox (previously SALMAT) Electronic Print on Demand (ePOD) at fujixerox.com.au

APPENDIX 1 - CONSENT AND AUTHORISATION FORM

NSW Health

Facility:

NON-CORONIAL POST MORTEM CONSENT & AUTHORISATION

SMR020032

FAMILY NAME	MRN
GIVEN NAME	☐ MALE ☐ FEMALE
D.O.B. ____/____/____	M.O.
ADDRESS	
LOCATION / WARD	
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	

[Note: This form should be used to obtain consent for the conduct of a non-Coronial post mortem. A copy of the completed form must be (1) retained as part of the post mortem record; (2) placed in the deceased person's notes; and (3) given to the person who provided consent i.e. the senior available next of kin or their delegate].

SECTION 1

DETAILS OF PERSON OBTAINING CONSENT

Family name _____ Given name _____

Institution/Hospital: _____

Person's Position: _____

Contact: Phone _____ Pager _____

ADDITIONAL DETAILS OF THE DECEASED

Date of death of the deceased ____/____/____

Optional: Is the deceased an Aboriginal person or Torres Strait Islander? *[Tick as appropriate]*

- ☐ YES
- ☐ NO
- ☐ UNKNOWN

SECTION 2: PERSON GIVING THE CONSENT

[Tick relevant box and complete as appropriate]

☐ **PERSON GIVING THEIR CONSENT DURING THEIR LIFE TIME TO A POST MORTEM EXAMINATION OF THEIR BODY AFTER DEATH**

I_____ (insert name) consent to a post mortem examination of my body after I have died as detailed in Section 3.

Holes Punched as per AS2828.1: 2012 BINDING MARGIN - NO WRITING

NON-CORONIAL POST MORTEM CONSENT & AUTHORISATION

SMR020.032

111213

NO WRITING

Page 1 of 4

NON-CORONIAL POST MORTEM CONSENT & AUTHORISATION FORM_111213.indd 1 11-12-2013 1:13:44 PM

NSW Health

Facility:

NON-CORONIAL POST MORTEM CONSENT & AUTHORISATION

FAMILY NAME	MRN
GIVEN NAME	☐ MALE ☐ FEMALE
D.O.B. ____/____/____	M.O.
ADDRESS	
LOCATION / WARD	
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	

☐ **SENIOR AVAILABLE NEXT OF KIN**

DETAILS OF SENIOR AVAILABLE NEXT OF KIN

Family name _____ Given name _____

of: _____ *[Insert address]*

Post code: _____

Relationship of senior available next of kin to deceased: _____

☐ **A DELEGATE OF THE SENIOR AVAILABLE NEXT OF KIN**

DETAILS OF DELEGATE OF THE SENIOR AVAILABLE NEXT OF KIN

Family name _____ Given name _____

of: _____ *[Insert address and postcode]*

Telephone Number: _____

Attach written authorisation of delegate

SECTION 3: THE CONSENT

I CONSENT TO THE FOLLOWING BEING CARRIED OUT ON THE ABOVE NAMED DECEASED: *[Tick appropriate box]*

☐ a full post mortem examination of the deceased

☐ a post mortem examination of the deceased **LIMITED** to the following organs, body parts or body cavities:

_____

_____

_____

Holes Punched as per AS2828.1: 2012

BINDING MARGIN - NO WRITING

SMR020032

NO WRITING

NSW Health

Facility:

NON-CORONIAL POST MORTEM CONSENT & AUTHORISATION

SMR020032

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. ____/____/____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

I ALSO CONSENT TO: *[Tick where applicable]*

☐ The retention of organs and other body parts for diagnostic testing.

The following organs or body parts **CAN** be retained: _____

_____

☐ The retention of organs and other body parts for scientific, therapeutic and medical purposes

The following organs or body parts **CAN** be retained: _____

_____

☐ The retention of _____ *[Specify organs or body parts]*

for _____ *[Specify research study]*

I REQUEST that any organs and other body parts be: *[tick as applicable]*

☐ Reunited with the body prior to burial/cremation;

☐ Returned to me or the person nominated by me, if practicable

Name of nominated person: _____

Address of nominated person: _____

Relationship to nominated person: _____

☐ Disposed of in a lawful manner by the hospital

I ALSO REQUEST that:

☐ a copy of the post mortem report be sent to: _____

Address: _____

☐ The body is ready for the funeral which takes place: Date: ___/___/___ Time _____

I HAVE NO REASON TO BELIEVE that the deceased had expressed any objection to this post mortem examination or any use of tissue noted above.

THE NATURE OF THE POST MORTEM EXAMINATION and the way in which the tissue from the deceased's body will be dealt with have been explained to me.

Holes Punched as per AS2828.1: 2012 BINDING MARGIN - NO WRITING

NON-CORONIAL POST MORTEM CONSENT & AUTHORISATION SMR020.032

111213

NO WRITING

Page 3 of 4

NON-CORONIAL POST MORTEM CONSENT & AUTHORISATION FORM_111213.indd 3 11-12-2013 1:13:44 PM

NSW Health

Facility:

NON-CORONIAL POST MORTEM CONSENT & AUTHORISATION

FAMILY NAME	MRN
GIVEN NAME	☐ MALE ☐ FEMALE
D.O.B. _____/_____/_____	M.O.
ADDRESS	
LOCATION / WARD	
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	

I have had the opportunity to ask questions and I am satisfied with the explanation and the answers to my questions.

SIGNATURE of the person giving consent in their lifetime _____

SIGNATURE of the senior available next of kin or authorised delegate _____

SIGNATURE of doctor/health professional _____ **Date:** _____/_____/_____

INTERPRETER present: NO/ YES **SIGNATURE** of Interpreter: _____

AUTHORISATION BY A DESIGNATED OFFICER

I, _____ hereby authorise: *[tick where applicable]*
[Full name of Designated Officer]

- ☐ the full post mortem examination of the deceased's body
- ☐ the limited post mortem examination of the deceased's body
- ☐ the retention of organs or other body parts for diagnostic testing
- ☐ the retention of tissue, organs and body parts removed for the purposes of the post-mortem examination for scientific, therapeutic, and medical purposes as set out in the above consent.

I _____ declare that I do not have a personal interest in the deceased and I have not had a clinical involvement with the deceased.
[Name of the Designated Officer]

SIGNATURE of the Designated Officer: _____

DATE: ____/____ / ____

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BINDING MARGIN - NO WRITING

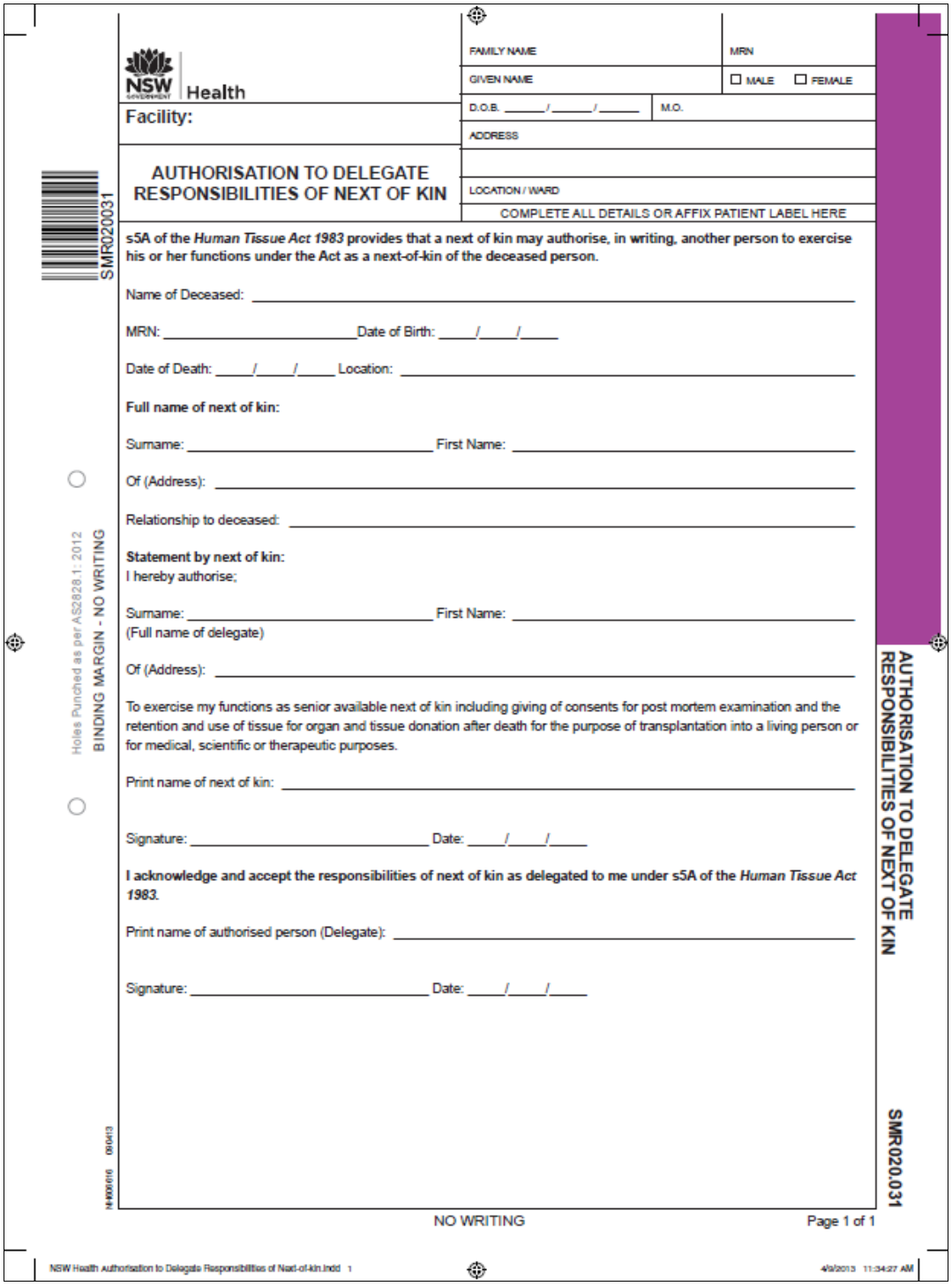
SMR020032

Page 4 of 4

NO WRITING

NON-CORONIAL POST MORTEM CONSENT & AUTHORISATION FORM_111213.indd 4 11-12-2013 1:13:46 PM

APPENDIX 2 - AUTHORISATION TO DELEGATE RESPONSIBILITIES OF NEXT OF KIN



NSW Health

Facility:

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. ____/____/____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

SMR020031

AUTHORISATION TO DELEGATE RESPONSIBILITIES OF NEXT OF KIN

s5A of the *Human Tissue Act 1983* provides that a next of kin may authorise, in writing, another person to exercise his or her functions under the Act as a next-of-kin of the deceased person.

Name of Deceased: _____

MRN: _____ Date of Birth: ____/____/____

Date of Death: ____/____/____ Location: _____

Full name of next of kin:

Surname: _____ First Name: _____

Of (Address): _____

Relationship to deceased: _____

Statement by next of kin:
I hereby authorise;

Surname: _____ First Name: _____
(Full name of delegate)

Of (Address): _____

To exercise my functions as senior available next of kin including giving of consents for post mortem examination and the retention and use of tissue for organ and tissue donation after death for the purpose of transplantation into a living person or for medical, scientific or therapeutic purposes.

Print name of next of kin: _____

Signature: _____ Date: ____/____/____

I acknowledge and accept the responsibilities of next of kin as delegated to me under s5A of the *Human Tissue Act 1983*.

Print name of authorised person (Delegate): _____

Signature: _____ Date: ____/____/____

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AUTHORISATION TO DELEGATE RESPONSIBILITIES OF NEXT OF KIN
SMR020.031

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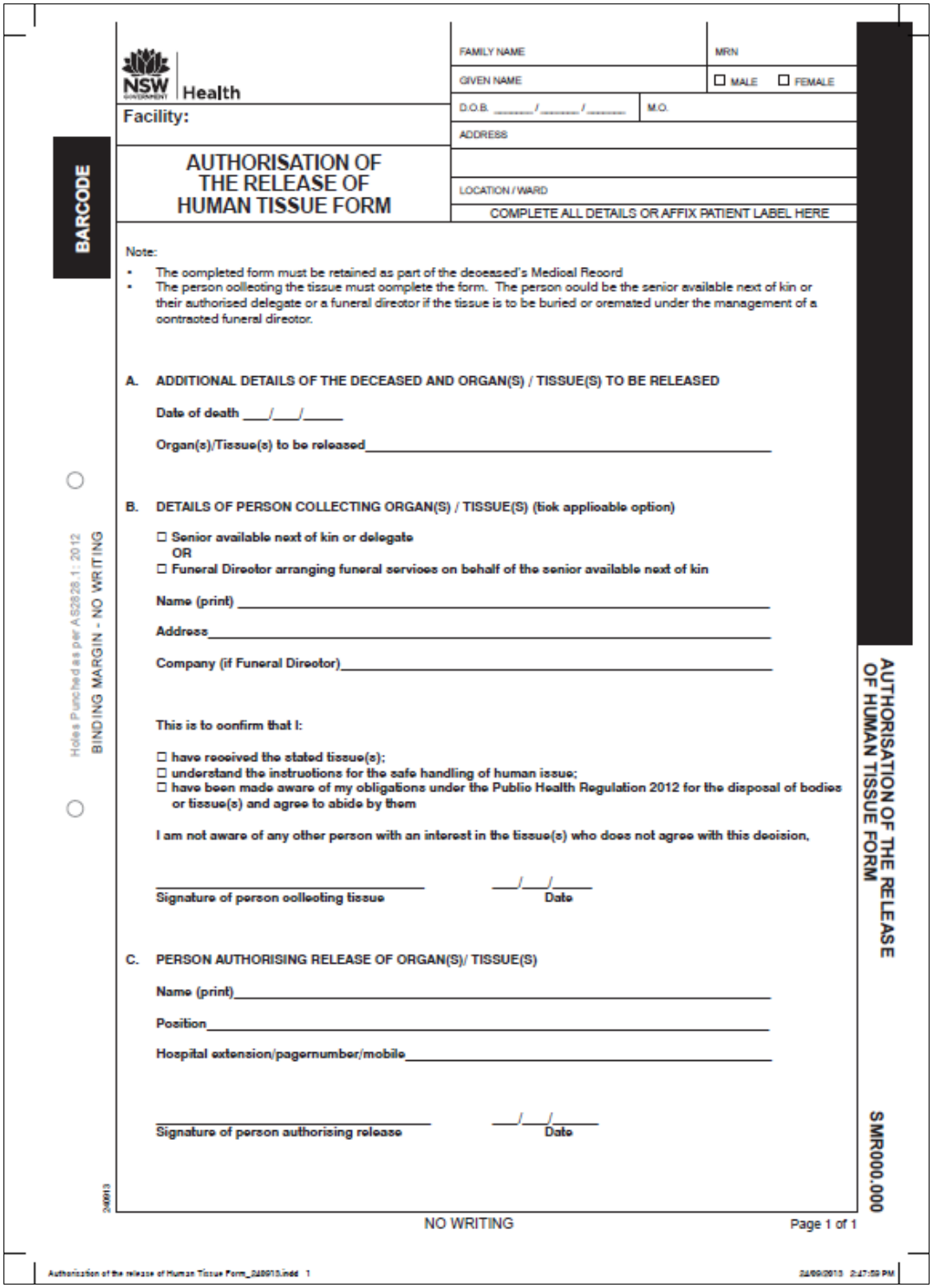
NO WRITING

Page 1 of 1

NSW Health Authorisation to Delegate Responsibilities of Next-of-kin.indd 1 4/3/2013 11:34:27 AM

APPENDIX 3 - AUTHORISATION OF THE RELEASE OF HUMAN TISSUE FORM



NSW Health

Facility:

AUTHORISATION OF THE RELEASE OF HUMAN TISSUE FORM

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. ____/____/____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

BARCODE

Note:

- The completed form must be retained as part of the deceased's Medical Record
- The person collecting the tissue must complete the form. The person could be the senior available next of kin or their authorised delegate or a funeral director if the tissue is to be buried or cremated under the management of a contracted funeral director.

A. ADDITIONAL DETAILS OF THE DECEASED AND ORGAN(S) / TISSUE(S) TO BE RELEASED

Date of death ___/___/_____

Organ(s)/Tissue(s) to be released_____

B. DETAILS OF PERSON COLLECTING ORGAN(S) / TISSUE(S) (tick applicable option)

☐ Senior available next of kin or delegate
OR
☐ Funeral Director arranging funeral services on behalf of the senior available next of kin

Name (print) _____

Address_____

Company (if Funeral Director)_____

This is to confirm that I:

☐ have received the stated tissue(s);
☐ understand the instructions for the safe handling of human issue;
☐ have been made aware of my obligations under the Public Health Regulation 2012 for the disposal of bodies or tissue(s) and agree to abide by them

I am not aware of any other person with an interest in the tissue(s) who does not agree with this decision.

_____ ___/___/_____
Signature of person collecting tissue Date

C. PERSON AUTHORISING RELEASE OF ORGAN(S)/ TISSUE(S)

Name (print)_____

Position_____

Hospital extension/pagernumber/mobile_____

_____ ___/___/_____
Signature of person authorising release Date

Holes Punched as per AS2828.1: 2012
BINDING MARGIN - NO WRITING

AUTHORISATION OF THE RELEASE OF HUMAN TISSUE FORM

SMR000.000

24913

NO WRITING

Page 1 of 1

Authorisation of the release of Human Tissue Form_24913.indd 1 24/09/2013 2:47:59 PM

APPENDIX 4 - EXAMPLE OF LETTER TO BE ISSUED TO PERSON TRAVELLING WITH HUMAN TISSUE IN THEIR POSSESSION

To whom it may concern,

This is to certify that _____
(Name of person authorised to travel with human tissue in their possession)

Is travelling with human tissue in their possession.

The tissue is hermetically sealed inside a container and there is no risk associated with transporting the tissue stored in this manner.

Person certifying the packaging of the tissue:

Name: _____

Designation: _____

Institution/Hospital: _____

Contact: _____

Signature of authorising person: _____
Date: ____/_____/_____

Can I consent to retaining organs for use for other (therapeutic, medical and scientific) purposes?
When you are asked to give consent for a post mortem, you may also be asked to consider allowing the use of your deceased relative's organs or tissue for other purposes that are not an essential part of the post mortem examination. This includes research and teaching.

You do not have to consent to the use of organs or tissue for these other purposes. A post mortem can still be carried out.

What about training?
Medical students and specialists in training need to attend and sometimes assist in performing post mortems as part of their ongoing medical education. In these circumstances the post mortem is always supervised by a fully qualified pathologist.

Will I have to pay for a post mortem examination?
There may be costs associated with the post mortem examination. It is important you discuss this with your doctor or hospital representative before you give consent.

What happens after consent is given for a post mortem?
The post mortem will be carried out as soon as possible after consent has been given. If you wish to see the body prior to the post mortem, let the doctor know and arrangements will be made.

When and how will I find out the results of the post mortem?
A preliminary post mortem report will be available within a few days of the examination but the final report will be prepared only after all test results are returned and may take some months. You can decide whether you want the report to be sent to you, your family doctor or the doctor(s) who cared for your loved one. As the report contains technical language, you should make a time with one of these doctors to discuss the report and any implications it may have for you or your family.
If you have any further questions please contact:
Name……
Phone……..Pager…….
INFORMATION FOR FAMILIES ABOUT

NON-CORONIAL POST MORTEMS
Deciding about a post mortem for your deceased family member can be very difficult. After reading this information, you may find it helpful to discuss the examination with a doctor who has cared for your relative or hospital social worker.

What issues should be considered?
It is important that you make the decision that is right for you and your family. It can be helpful to consider what the deceased person would have wished in the circumstances. It may also help to think about whether a post mortem would help you and your family understand and come to terms with your loved one's death.

What is a post mortem?
A post mortem (also known as an autopsy) is a medical examination of a body after death by a doctor who is a pathologist or by a doctor training in pathology under the supervision of a pathologist. Pathologists are doctors who specialise in the study of disease.

A post mortem can be a full or limited post mortem.

A full post mortem will involve:
- an external and internal examination of the organs and tissues within the head, abdomen and chest cavities
- taking of small samples of tissues from the major organs for later testing
- possible retention of some specific organs for more detailed analysis

A limited post mortem means that you, as the next of kin, may set limits on the extent of the post mortem examination, for example:
- an external examination only;
- an external examination and some testing on small samples of tissue or
- an internal examination limited to certain areas of the body.

A post mortem examination does not always provide all the answers about a person's death.

What information can a post mortem provide?
- More information about the medical conditions that may have caused or contributed to your relative's death

- Information that may confirm or rule out a suspected or unsuspected medical condition. This may be important for you or other members of your family, for example, if the condition might be inherited; and
- Information that may help improve care of people in the future

When is consent needed for a post mortem?
A non coronial post mortem is a post mortem that is not legally required by the Coroner. It is either recommended to you by a doctor or sometimes requested by the family in order to find out, for example, the extent of the condition that caused the death or whether any undiagnosed disease might have contributed to the death. These are **non-coronial or hospital** post mortems and they require written consent from either the deceased (given when they were alive) or from the deceased's senior available next of kin (which is determined by the *Human Tissue Act 1983)* after death.

Who can consent to a post mortem?
As the senior available next of kin, you may be approached by a health care worker and asked for your consent to the post mortem examination. You are free to choose whether or not to give your consent for the post mortem examination. Your consent must be given in writing.

I am the senior next of kin but in my culture it is not my role to make these decisions. Can someone else do it for me?
It is recognised that in some cultures arrangements around the death of a person may traditionally be performed by someone other than the senior available next of kin. The *Human Tissue Act* allows a senior available next of kin to authorise another person, in writing, to exercise their functions. This 'authorised person' also known as a 'Delegate' can then give written consent for a non-coronial post mortem. There is a form you will be asked to complete if you wish to authorise someone to be your delegate.

What happens at a post mortem?
The pathologist who will be performing or supervising the post mortem will review the deceased's medical records before undertaking a thorough examination of the body. A full post mortem will include:

- an examination of the outside of the person's body looking for marks or other abnormalities that might indicate injury or disease;
- an **internal** examination which is a surgical procedure like a large operation. The pathologist will usually make two incisions, one across the back of the head and another on the front of the body. This allows the pathologist to examine all the major organs including the brain if necessary. Small samples of tissue or body fluids will usually be taken for later microscopic examination.
- a **laboratory** examination, which may involve microscopic examination of the tissue samples taken during the internal examination or other testing looking for evidence of disease.

What happens after the post mortem?
Once the examination is complete the incisions are closed like a surgical operation and the body cleaned. In most cases, once the body has been clothed, the effects of the post mortem are not very noticeable. Normally, you will be able to see the body after the post mortem.

Why would the Pathologist need to retain organs?
It is often important for the pathologist to retain an organ (usually the brain or heart) in order to test for signs of disease or injury that are not immediately apparent. Usually this will be discussed as part of the consent but the need to retain a particular organ may not be known until the post mortem has begun.

If the pathologist does need to retain organs you may be able to delay the funeral arrangements for a short time so these organs can be returned to the body before it is released for burial or cremation. If this is not possible, you can decide whether you would like the organs returned to you or your funeral director for separate burial or cremation or disposed of by the facility where the post mortem was conducted (usually by cremation). Small samples of tissue and fluids taken during the internal examination will not be returned to the body.

DESTITUTE PERSONS - CREMATION OR BURIAL (PD2008_012)

PD2008_012 rescinds PD2007_051.

1. Introduction

This policy directive rescinds Policy Directive PD2007_051 due to the inclusion in that Policy Directive of Police forms, and references to them, which are no longer to be used. This Policy Directive deals with the cremation or burial of the bodies of deceased destitute persons in the State of New South Wales for services as set out in this document.

Definitions:

For the purposes of this policy directive the following terms mean:

"Destitute Persons" - deceased persons with no money or assets and whose relatives and friends are unable to pay the costs of cremation or burial.

"Still Birth" - means the birth of a child that exhibits no sign of respiration or heartbeat, or other signs of life, after birth and that:

a) is at least 20 weeks' gestation; or
b) if it cannot be reliably established whether the period of gestation is more or less than 20 weeks, has a body mass of at least 400 grams at birth.

"Public Health Unit" - please see the attached list (attachment I).

2. Cremation/Burial generally

Funeral procedures and rites are helpful for the resolution of grief and the bereavement process. This is no less true for the families and friends of people who are destitute when they die. The conditions for the cremation or burial of deceased destitute persons should take equal account of the emotional needs of any relatives or friends of the deceased.

Cremation will generally be the preferred method of disposal, provided that:

- there is no objection set out in the Will of the deceased;
- there is a written agreement of any known relatives or friends;
- it is not contrary to the direction of the State Coroner;
- all necessary cremation certificates have been completed.

In all Areas Health Services and Public health facilities it should be noted that only the contracted funeral director will be contacted to provide the service. A list of these can be obtained from the Department of Commerce, Office of Government Business and Procurement.

3. Responsibility for Burial or Cremation of Destitute Persons

Public Health Units are responsible for the administration of the process related to the cremation and burial of destitute persons within their Area Health Service boundaries and are to provide assistance and advice to interested parties to ensure all requirements are adhered to.

The cost of cremation or burial of deceased destitute persons is the responsibility of the Area Health Service.

4. Procedure for Burial or Cremation

4.1 Where the death occurs in a public hospital, State Government nursing home, or other facility under the control of a public health organisation under the *Health Services Act* (in this policy referred to as a 'public health facility') and a medical practitioner has issued a death certificate:

- The social worker at that facility shall make all reasonable inquiries to locate any relatives, friends or members of organisations that may wish to arrange for a cremation or burial of the body at their own expense.
- Where no one is able to pay for the cremation or burial of the body:
  1. issue an order to the contracted funeral director for a funeral and cremation or burial to be conducted in accordance with the contract requirements;
  2. arrange for an officer of the public health facility to attend the service;
  3. forward the duly certified invoice to the Area Health Service for payment.

The assistance of the Police may be obtained if the facility's own enquiries fail to locate any relatives, friends, or others who may wish to arrange a cremation or burial at their own expense. This will help to avoid causing unnecessary distress to people who may have wished to make other funeral arrangements and been willing to pay the funeral costs.

4.2 Where the death of a destitute person occurs outside of a public health facility, does not fall within the Coroner's jurisdiction, a medical certificate as to the cause of death has been issued, and the Police have determined that the State is ultimately responsible for the burial or cremation then:

- Police will complete forms P372 (attachment 2);
- the form is then forwarded to the Director of the Public Health Unit for the relevant Area Health Service;
- an Environmental Health Officer will complete form HEALTH373 (attachment 3) and contact the contracted funeral director to arrange for the burial or cremation; and
- after the burial or cremation, the contracted funeral director will forward the invoice to the Public Health Unit to arrange payment by the appropriate Area Health Service.

4.3 Where the death of a person comes within the Coroner's jurisdiction, or when a medical certificate as to the cause of death has been not been issued, and the Police have determined that the State is ultimately responsible for the burial or cremation then:

- Police will complete form P372 (attachment 2) and forward it to the Coroner;
- in all cases the Coroner will issue an Order for Disposal of a Destitute Person;
- the Coroner will forward the form to the Director of the appropriate Public Health Unit and request the burial or cremation to be conducted; and
- an Environmental Health Officer will complete Form HEALTH 373 (attachment 3), contact the contracted funeral director and request to arrange the burial or cremation.

5. Contracts for Destitute Cremation and Burial

Contracts for the cremation or burial of deceased destitute persons are under the control of the Department of Commerce, Office of Government Business and Procurement. Contract details and information about them may be obtained from the Office of Business and Procurement. Such contracts are generally reviewed every three years.

Each contract may cover one or more police regions/local areas/towns, and includes services to all public health facilities in that police region/local area/town. Public health facilities and Area Health Services **must** use the contracted funeral director for all funerals, cremations or burials paid for by Area Health Service under these arrangements.

Contracts generally provide for separate rates of payment, whether it is a burial or cremation, for:

- adult - burial including ground fee and burial rites and relevant certificates;
- child under 1.1 metres - burial including ground fee and burial rites and relevant certificates;
- still-born neo-nate (not less than 20 weeks gestation or 400 grams in weight) - burial including ground fee and burial rites and relevant certificates;
- adult - cremation including cremation fee and relevant certificates;
- child under 1.1 metres - cremation including cremation fee and relevant certificates; and
- still-born neo-nate - cremation including cremation fee and relevant certificates.

6. Complaints about Contractors

Any complaints by family or friends about the performance of a contracted funeral director should be taken up in the first instance with the Department of Commerce, Office of Business and Procurement which has the primary responsibility for contracted funeral directors.

7. Responsibility of the Police

The Police are responsible in all cases for:

- determining whether a death is reportable to the Coroner and whether any person is able to pay for the cost of the burial or cremation;
- determining whether the deceased has any assets or estate.
- completion of Forms P372 (attachment 2) and forwarding the form to the Public Health Unit (or to the Coroner in coroner's cases) as is appropriate and required in the particular case.

8. Records of Burial or Cremation

Under the Public Health (Disposal of Bodies) Regulation the cemetery or cremation authority is required to maintain records of the name, date, location of the grave, section and record number, or the location of the ashes, of the deceased. The ultimate burial/cremation site location details will generally also form part of the information recorded by the Registrar of Births, Deaths and Marriages. Public Health Units are also required to keep records of the name of the deceased, and place of burial/ cremation and the contracted funeral director used.

9. Assistance to Relatives and Friends of the Deceased

Appropriate staff in the public health facilities should be made aware of this policy to enable information to be supplied to relatives of destitute persons where there is an obvious need of assistance with funeral expenses. Family members should be directed to the social worker who will assess the situation and provide appropriate advice.

A register is to be maintained at the Public Health Unit and notation made in that register in the event that relatives, after being provided details of destitute burial/cremation, decline the service. Any subsequent ex gratia request for contribution to the funeral arrangements for that particular person will then not be accepted (see Section 12 for ex gratia payments generally).

Where an ex gratia claim is made from non-family members the hospital is to examine carefully the bona fides of the claim as generally the full cost of the funeral is the responsibility of those persons.

Bereaved relatives and friends of a destitute person should, regardless of their inability to meet the cost of cremation or burial, be informed of funeral arrangements by the contracted funeral director and encouraged to attend the funeral service. They will, however, be entirely responsible for their own transportation to and from the service.

10. Death in a Hospital Remote from Residence

When the deceased destitute person has been transported from their normal area of residence to a "remote hospital" for treatment not available at their local hospital, and has died at the remote hospital, the reasonable costs of returning the body to the area of residence may be paid if:

- the burial/cremation in their local area is requested by relatives of the deceased; and
- approval was arranged prior to the transfer of the body.

In these cases, the cost of transport back to the local area will be met by the remote hospital where the person dies. The costs of the actual destitute funeral will be met by the local Area Health Service covering the deceased's normal place of residence.

11. Australian Ex-Service Man or Woman

The Department of Veterans' Affairs will pay a certain amount towards the funeral expenses of an Australian ex-service man or woman who dies in destitute circumstances. The Department of Veteran Affairs should be contacted for the current details of the benefit payable in a particular case.

12. Requests for Financial Assistance after the Funeral has been performed

Where the funeral service has already been conducted, and persons otherwise responsible for the funeral arrangements claim financial difficulty, a petition may be submitted to the relevant Area Health Service for an ex gratia contribution to that cost. Chief Executives have limited delegation to approve the provision of financial aid to impoverished families to assist with already incurred burial costs of relatives. All other ex gratia payments are to be referred to the Department of Health.

The petition should take the form of a covering letter requesting assistance and the circumstances for the request. In addition all petitioners must supply a signed statutory declaration witnessed by a Justice of the Peace, which states:

- a complete listing of the assets of the deceased;
- a complete listing of assets, income, expenditure of the remaining relatives;
- a copy of the funeral director's invoice. If the invoice has been fully paid, it would be in very exceptional circumstances that any assistance would be offered;
- a copy of the death certificate;
- details of any financial assistance provided by charities, Centrelink or any other source; and
- details of any arrangement made with the funeral director to pay off the debt.

It should be noted, as per the Combined Delegations Manual (Delegation F91), that the Chief Executives of all Area Health Services are authorised to approve of ex gratia payments under this delegation within specified limits. Chief Executives are required to submit an annual return each financial year of the actual payments made to the Chief Financial Officer, Department of Health. The return for each year must include the following details;

- recipient;
- value of ex gratia payment;
- full cost of funeral as claimed by recipient; and
- number of claims rejected without any ex gratia payment made.

The Department will therefore no longer have primary administrative and financial liabilities associated with destitute burials and ex gratia payments. To facilitate the management by Area Health Services of all future claims for destitute burials and ex gratia payments the Department is providing annualised budget supplementation to Area Health Services from 1 July 2007 based on average annual costs over the previous 3 years.

Attachment 1

Public Health Unit	Mailing Address	Phone contact (work hours)	Fax contact (work hours)	After hours contacts
Greater Southern AHS	**Goulburn Office**	02 4824 1837	02 4824 1831	02 6021 4799 (diverts to Albury Base Hospital) - ask for the Environmental Health Officer on call
Public Health Unit	Locked Bag 11 Goulburn 2580		02 4824 1838 (secure)	
	Queanbeyan Office	02 6124 9934	02 6124 9946	02 6021 4799 (diverts to Albury Base Hospital) - ask for the Environmental Health Officer on call
	PO Box 1845 Queanbeyan 2620			
	Albury Office PO Box 3095 Albury 2640	02 6021 4799	02 6021 4899	02 6021 4799 (diverts to Albury Base Hospital) - ask the Environmental Health Officer on call
	Wagga Wagga			02 6021 4799 (diverts to Albury Base Hospital) - ask the Environmental Health Officer on call
	PO Box 201 Wagga Wagga 2650	02 6923 5755	03 6923 5751	
Greater Western AHS	**Broken Hill Office**	08 8080 1499	08 8080 1683	08 8080 1333 (Broken Hill Base Hospital) - ask for the Senior Environmental Health Officer on call
Centre for Population Health	PO Box 457 Broken Hill 2880		08 8080 1196 (secure)	or on call mobile 0417 685 259
	Dubbo Office	02 6841 5569	02 6841 5571 (secure)	02 6885 8666 (Dubbo Base Hospital) - ask for the Senior Environmental Health Officer on call
	PO Box 739 Dubbo 2830			or call 0418 866 397 - ask for the Senior Environmental Health Officer on call
	Bathurst Office	02 6339 5601	02 6339 5173 (secure)	0428 400 526 - ask for the Senior Environmental Health Officer on call
	PO Box 143 Bathurst 2795			
Hunter/New England AHS	**Newcastle Office**	02 4924 6477	02 4924 6490 (secure)	02 4924 6477 (diverts to John Hunter Hospital) - ask for Public Health Officer on call
Hunter Population Health	Locked Bag 10 Wallsend 2287			if no answer, phone 016301965 and ask for Public Health Physician on call
	Tamworth Office	02 6767 8630	02 6766 3003	02 6767 8630 (diverts to Tamworth Base Hospital) - ask for Public Health Officer on call
	PO Box 597 Tamworth 2340			if no answer, phone 016301965 and ask for Public Health Physician on call
Justice Health Service	PO Box 150 Matraville 2036	02 9214 6229	02 9289 2494 (secure)	02 9311 2707 - ask for Nurse Manager
Public Health Unit		(Public Health coordinator/CNC)		
North Coast AHS	**Port Macquarie Office**	02 6588 2750	02 6588 2837	0407 271 498 - ask for Public Health Officer on call
Public Health Unit	PO Box 126 Port Macquarie 2444			if no answer, phone 0417 244 966
	Lismore Office	02 6620 7500	02 6622 2151	132222 pager number 397635
	PO Box 498 Lismore 2480		02 6620 2252 (secure)	if no answer, phone 0417 244 966

Northern Sydney/Central Coast AHS	**Hornsby Office**	02 9477 9400	02 9482 1650	02 9477 9123 (Hornsby Hospital) - ask for the Environmental Health Officer on call
Public Health Unit	c/- Hornsby Hospital Palmerston Rd Hornsby 2077		02 9482 1358 (secure)	
	Gosford Office	02 4349 4845	02 4349 4850 (secure)	02 4320 2111 (Gosford Hospital) - ask for the Environmental Health Officer on call
	PO Box 361 Gosford 2250			
South Eastern Sydney/ Illawarra AHS	**Randwick Office**	02 9382 8333	02 9382 8334	02 9382 2222 (Prince of Wales Hospital) - ask for Public Health Nurse on call
Public Health Unit	Locked Bag 88 Randwick 2031		02 9382 8314 (secure)	
	Wollongong Office	02 4221 6700	02 4221 6722	02 4222 5000 (Wollongong Hospital) - ask for Public Health Officer on call
	Locked Bag 9 Unanderra 2526		02 4221 6759 (secure)	
Sydney South West AHS	**Eastern Zone**	02 9515 9420	02 9515 9440	02 9515 6111 (Royal Prince Alfred Hospital) - ask Public Health Officer on call
Public Health Unit	(Camperdown Office)		02 9515 9467 (secure)	
	PO Box 374 Camperdown 2050			
	Western Zone	02 9828 5944	02 9828 5955	02 9828 3000 (Liverpool Hospital) - ask for Public Health Officer on call
	(Liverpool Office)			
	Locked Mail Bag 7017 Liverpool BC 1871			
Sydney West AHS	**Penrith Office**	02 4734 2022	02 4734 3300	02 9845 5555 (Westmead Hospital) - ask for Public Health Officer on call
Centre for Population Health	PO Box 63 Penrith 2751		02 4734 3444 (secure)	
	Parramatta Office	02 9840 3603	02 9840 3608	02 9845 5555 (Westmead Hospital) - ask for Public Health Officer on call
	Locked Bag 7118 Parramatta BC 2150		02 9840 3591 (secure)	

Attachment 2

P. 372

BURIAL/CREMATION OF A DECEASED DESTITUTE PERSON

_____Police Station

_____20__

Full name of deceased _____ _____
(Surname) (Christian or given name/s

Address _____

Age _____ Date of Birth _____ Native of _____

Date of Death _____Time am/pm _____ Place _____

Circumstances of death _____

_____

Death certificate issued by Dr _____

Was the deceased -

(a) a pensioner/ ** YES/NO. If yes, type of pension _____
(Repatriation, Invalid,Age, etc)

(b) a returned or an ex-serviceman or woman? ** YES/NO

(c) a member of any trade union, friendly society or other organisation
Interested in defraying burial expenses? **YES/NO

(d) insured? **YES/NO

Did the deceased have any -

(e) money? **YES/NO Details _____

(f) property? ** YES/NO Details _____
(If insufficient space attach report)

Religion of deceased _____

Name and address of next of kin _____

_____Relationship to deceased _____

Next of kin notified of the death by _____

Will the next of kin or other person defray burial expenses? **YES/NO

Does the next of kin desire -

(g) a religious ceremony? *YES/NO If yes, details _____

(h) the body to be interred or cremated? * INTERRED/CREMATED

_____Signature

_____ Name

_____ Rank

THIS FORM IS TO BE COMPLETED IN DUPLICATE AND SUBMITTED TO THE PUBLIC HEALTH UNIT, OR THE CORONER (IF A CORONER CASE)

*CROSS OUT WORDS WHICH DO NOT APPLY
** CROSS OUT WORDS WHICH DO NOT APPLY. IF ANSWER TO ANY QUESTIONIS 'YES' ATTACH A REPORT GIVING DETAILS

Attachment 3
HEALTH 373

AUTHORITY FOR BURIAL/CREMATION
OF DECEASED DESTITUTE PERSON

Public Health Unit: …….…… Phone No …….

Report Date: …….……..

Police Officer: …….….... Morgue Register/Book No: …….

The Authority given for Cremation/Burial indicated below is based on Information received by the NSW Police Service.

To: ……..…….(Undertaker's Name)

You are hereby requested to provide a coffin and conveyance of the body of a ……(sex)

person, named ……..…… lying dead at ….……..(morgue),

and to arrange for …….…….(Cremation/Interment) without delay.

The account for the Department of Health is to be delivered to …….

(Director, Public Health Unit) of ……...

…….(Area Health Service).

Authorised: …….…….…….(Signature)

(Senior Environmental Health Officer)

Payment of Account No: ……

Approved: ……..…….. Not Approved: ……..……..

Note: This Authority must be returned to the Director, Public Health Unit as shown above.

I hereby certify that the remains of the late ……

were buried/cremated on …….(date) and place in Grave No: ……...

OR ……(other).

Signature: …….. Date: …….……

Address: ……..

CORONER'S CASES AND THE *CORONERS ACT 2009* (PD2010_054)

PD2010_054 rescinds PD2009_083.

PURPOSE

To provide:

- medical practitioners, health care workers and managers in the public health system with specific information about the *Coroners Act 2009*; and
- medical practitioners, nurses and midwives, health care workers and administrators with direction and guidance about reportable deaths to the NSW Coroner.

MANDATORY REQUIREMENTS

Each NSW Health Agency must have effective systems and procedures in place to report deaths to the Coroner in accordance with the *Coroners Act 2009* and this Policy Directive.

IMPLEMENTATION

Roles and Responsibilities

Chief Executives must ensure that:

- the principles and requirements of this policy are applied, achieved and sustained;
- all staff are made aware of their obligations regarding this Policy Directive;
- documented procedures are in place supporting the Policy Directive;
- there are documented procedures in place to effectively respond to and investigate alleged breaches of this Policy Directive.

Hospital Managers and Staff have responsibility to:

- report Anaesthetic deaths to the Director-General via the Report of Death Associated with Anaesthesia/Sedation form (section 7.1);
- provide copies of medical records to the pathologist or medical officer conducting a post mortem (section 9.3);
- provide the Coroner's Office with a completed "Report of Death of a Patient to the Coroner" (form A) along with original or copies of medical records (sections 6; 9.3).

1. BACKGROUND

1.1 About this document

The policy directive *Coroner's Cases and the Coroner's Act 2009* provides specific information about *Coroners Act 2009* (the Act) and the implications for medical practitioners, health care workers and managers in the public health system.

A number of key changes have been enacted in the *Coroners Act 2009* which are relevant to health care workers. These include changes in the categories of cases which must be reported to the Coroner, and changes to coronial autopsy procedures.

Current versions of the *Coroners Act 2009* and the *Coroners Regulation 2010* are accessible at www.legislation.nsw.gov.au

2. DEFINITIONS

The *Coroners Act 2009* defines the following terms that are used in this Policy Directive as follows:

Child: means a person who is less than 18 years old.

Child in care means a child or young person who is less than 18 years old:
(a) who is under the parental responsibility of the Minister administering the *Children and Young Persons (Care and Protection) Act 1998*, or
(b) for whom the Director-General of the Department of Community Services or a designated agency has the care responsibility under section 49 of the *Children and Young Persons (Care and Protection) Act 1998*, or
(c) who is a protected person within the meaning of section 135 of the *Children and Young Persons (Care and Protection) Act 1998*, or
(d) who is the subject of a out-of-home care arrangement under the *Children and Young Persons (Care and Protection) Act 1998*, or
(e) who is the subject of a sole parental responsibility order under section 149 of the *Children and Young Persons (Care and Protection) Act 1998*, or
(f) who is otherwise in the care of a service provider.

parental responsibility, in relation to a child or young person, means all the duties, powers, responsibilities and authority that, by law, parents have in relation to their children.

service provider has the same meaning as it has in the *Community Services (Complaints, Reviews and Monitoring) Act 1993*.

Coronial proceedings: Defined in the Act as any proceedings conducted by a Coroner or assistant Coroner for the purposes of the *Coroner's Act 2009* concerning the investigation of a death, suspected death, fire or explosion. Without limiting the definition, coronial proceedings include the following:
(a) the holding of an inquest or inquiry
(b) proceedings to determine whether or not to hold, or to continue to hold, an inquest or inquiry,
(c) proceedings of an interlocutory or similar nature (including proceedings to deal with evidential matters or case management issues).

Health related procedures see section 5.3, 5.3.1 & 5.3.2.

Reportable deaths see section 5.1.

Senior next of kin: This is defined in section 4 of the *Coroners Act* to mean:
(a) the deceased's person spouse; or
(b) if (a) is not available, any of the deceased's adult children; or
(c) if (a) and (b) are not available, either of the deceased's parents; or
(d) if non of (a), (b) or (c) are available, the deceased person's adult brothers or sisters; or
(e) if none of the above are available, the executor named in the deceased's will or the deceased's legal representative immediately prior to death.

Remains: of a deceased person means the body or remains of the body (or any part of the body) of the person.

Tissue: includes an organ, or part, of a human body, including bodily fluids.

Whole organ: of a deceased person means the whole or a substantial part of a visibly recognisable structural unit of the person's body.

In the context of this Policy Directive the terms Nursing Unit Manager (NUM) is interchangeable between Director of Nursing, Midwifery Unit Manager or any other nursing and midwifery position that is responsible for the management of a service or unit.

3. LEGAL AND LEGISLATIVE FRAMEWORK

Births, Deaths and Marriages Registration Act 1995
Children (Detention Centres) Act 1987
Children and Young Persons (Care and Protection) Act 1998
Community Services (Complaints, Reviews and Monitoring) Act 1993
Coroners Act 2009
Coroners Regulation 2005
Crimes (Administration of Sentences) Act 1999
Disability Services Act 1993
Human Tissue Act 1983 (part 7)
Mental Health Act 2007
Public Health (Disposal of Bodies) Regulation 2002
Public Health Act 1991

4. JURISDICTION OF THE CORONER

A Coroner has jurisdiction to hold an inquest concerning the death or suspected death of a person if it appears to the Coroner that:

(a) the person's death is (or there is reasonable cause to suspect that the person's death is) a reportable death, or
(b) a medical practitioner has not given (or there is reasonable cause to suspect that a medical practitioner has not given) a certificate as to the cause of death.

5. CIRCUMSTANCES IN WHICH A MEDICAL PRACTITIONER SHOULD NOT ISSUE A CERTIFICATE AS TO CAUSE OF DEATH

A medical practitioner must not issue a certificate as to the cause of the death under the *Births, Deaths and Marriages Registration Act 1995* if the death is a **REPORTABLE** death (s6 *Coroners Act 2009*), i.e.

(a) the person died a violent or unnatural death;
(b) the person died a sudden death the cause of which is unknown;
(c) the person died under suspicious or unusual circumstances;
(d) the person died in circumstances where the person had not been attended by a medical practitioner during the period of six months immediately before the person's death;
(e) the person died in circumstances where the person's death was not the reasonably expected outcome of a health related procedure carried out in relation to the person (see below);
(f) the person died while in or temporarily absent from a declared mental health facility within the meaning of the *Mental Health Act 2007* and while the person was a resident at the facility for the purpose of receiving care, treatment or assistance.

OR

if the death is a death under s23 *Coroners Act 2009*, i.e. a death in custody case where the person died:

(a) while in the custody of a police officer or in other lawful custody; or
(b) while escaping, or attempting to escape, from the custody of a police officer or other lawful custody;or
(c) as a result of, or in the course of police operations; or
(d) while in, or temporarily absent from, any of the following institutions or places of which the person was an inmate:
  (i) a detention centre within the meaning of the *Children (Detention Centres) Act, 1987*
  (ii) a correction centre within the meaning of the *Crimes (Administration of Sentences) Act 1999*
  (iii) a lock-up; or
(e) while proceeding to an institution or place referred to in paragraph (d), for the purpose of being admitted as an inmate of the institution or place and while in the company of a police officer or other official charged with the person's care or custody.

OR

if the death is a death under s24 *Coroners Act*, i.e.

(1) the death of a child who was:
  (a) a child in care; or
  (b) a child in respect of whom a report was made under Part 2 of Chapter 3 of the *Children and Young Persons (Care and Protection) Act 1998* within the period of 3 years immediately preceding the child's death; or
  (c) a child who is a sibling of a child in respect of whom a report was made under Part 2 of Chapter 3 of the *Children and Young Persons (Care and Protection) Act 1998* within the period of 3 years immediately preceding the child's death; or
  (d) a child whose death is or may be due to abuse or neglect or that occurs in suspicious circumstances.

OR

(2) the death of a disabled person

(a) a person (whether or not a child) who, at the time of the person's death, was living in, or was temporarily absent from, residential care provided by a service provider and authorised or funded under the *Disability Services Act 1993* or a residential centre for disabled persons, or

(b) a person (other than a child in care) who is in a target group within the meaning of the *Disability Services Act 1993* who receives from a service provider assistance (of a kind prescribed by the regulations) to enable the person to live independently in the community.

5.2 Changes to the categories of cases that were previously reportable in the *Coroners Act 1980*

(a) Deaths during, within 24 hours, or as a result of anaesthesia are no longer reportable to the Coroner unless they are captured under one of the other sections of the Act listed above. For example, if death occurred following anaesthesia and this was not a reasonable expected outcome of the procedure, the death is still reportable. (See also S7.1)
(b) The period where the person had not been attended by a medical practitioner for three months prior to death has been increased to six months.
(c) The limitation whereby a death need be reported only if it occurred within a year and a day of an accident has been removed.

(d) A death is not reportable if it follows an accident attributable to old age, if the person is older than 72 years (as opposed to 65 years in the previous legislation). The provision covers accidents that occur in a nursing home, hospital or at home. The medical practitioner **MUST STATE** on the certificate that it is given in pursuance of S38(2) of the *Coroners Act 2009*. Note that if a relative of the deceased person objects to a medical practitioner issuing a death certificate in these circumstances, the death must be reported to the Coroner (s38(3) of the Act).

5.3 NSW DEPARTMENT OF HEALTH GUIDELINES FOR DETERMINING WHETHER A DEATH IS A REASONABLY EXPECTED OUTCOME OF A HEALTH-RELATED PROCEDURE

5.3.1 What is a health-related procedure?

For the purposes of this section, the *Coroner's Act* defines a health-related procedure as a medical, surgical, dental or other health-related procedure (including the administration of an anaesthetic, sedative or other drug). Procedure in this circumstance is taken to mean health care provided to a patient.

5.3.2 What is meant by the term 'reasonably expected outcome'?

The *Coroners Act 2009* does not define the term '*reasonably expected outcome*'. This is a matter for medical practitioners to decide based upon the facts of the case. Guidelines to assist the medical practitioner determine whether or not the death should be reported to the Coroner are below (however, the examples are not exhaustive and factors individual to each case must be considered).

In determining whether the death is a reportable death?

Consider:
- did the health related procedure cause the death, and
- was the death an unexpected outcome of the procedure?

IF THE ANSWER TO BOTH OF THESE QUESTIONS IS YES, THEN THE DEATH IS REPORTABLE.

In determining whether the health procedure caused the death consider:
- was the health related procedure necessary to improve the patient's medical condition, rather than an elective or optional procedure; and
- with regards to the death, would your peers consider the health related procedures performed to be consistent with competent professional practice?

IF THE ANSWER TO BOTH OF THESE QUESTIONS IS *YES,* THEN *THE DEATH MAY NOT BE REPORTABLE.*

In determining whether the death was an unexpected outcome of the health related procedure consider:
- whether the patient's condition (factoring in their age and co-morbidities) at the time they underwent the health or health related procedure was such that death was likely to occur if they did not undergo the procedure;
- was death recognised as being a significant risk of the procedure given the patient's medical condition, but the patient, family and/or medical practitioner believed the potential benefits of the procedure outweighed the risk;
- with regards to the death, would your peers consider the health related procedures performed to be consistent with competent professional practice?

IF THE ANSWER TO EACH OF THESE QUESTIONS IS YES THEN THE DEATH MAY NOT BE REPORTABLE.

The factors to consider in each particular case will be different and doctors should use their professional judgement to determine whether the death is reportable. If the medical practitioner is uncertain about whether the death is reportable then s/he should contact the NSW State Coroner's Office on the numbers located at the end of this Policy Directive.

6. OBLIGATION TO REPORT DEATHS OR SUSPECTED DEATHS THAT ARE EXAMINABLE BY THE CORONER

Under the Act, hospitals and medical practitioners *or* any other person, who has reasonable grounds for believing that a death or a suspected death would be examinable by the Coroner must report the death or suspected death to the police (who will then report it to the Coroner) or a Coroner or assistant Coroner as soon as possible (ss35 and 38 of the Act).

All reports by medical practitioners and hospitals to the Coroner should be on the prescribed Form "*Report of Death of a Patient to the Coroner*" annexed to this Policy Directive. Reports on this form should be prepared in triplicate; the original and a duplicate copy should be handed to the police (a copy for the police and a copy for the police to give to the Coroner), the third copy should be retained by the hospital in the medical record of the deceased patient.

Medical, nursing and midwifery staff requiring further advice

If there is doubt as to whether the death is reportable, contact **must** be made with a senior medical team member or senior nurse manager or in their absence the NSW Police or the Office of the NSW State Coroner on 02 8584 7777 (business hours).

7 NSW DEPARTMENT OF HEALTH REQUIREMENT TO REPORT OTHER KINDS OF DEATHS

7.1 Anaesthetic deaths

The *Coroners Act 2009* does not specifically identify anaesthesia related deaths as being reportable to the Coroner. The requirement of the 1980 *Coroners Act* to report to the Coroner deaths occurring while under, or as a result of, or within 24 hours after the administration of anaesthesia enabled these deaths to be reviewed by the Special Committee Investigating Deaths Under Anaesthesia (SCIDUA) who then ensured that policies and practices were put in place to help reduce the number of such deaths.
In order to ensure the continued monitoring of anaesthetic related deaths, the *Public Health Act* and Regulation have been amended to make a death occurring 'while under, or as a result of, or within 24 hours after the administration of, an anaesthetic administered in the course of a medical, surgical or dental operation or procedure or an operation or procedure of a like nature (other than a local anaesthetic administered solely for the purpose of facilitating a procedure for resuscitation from apparent or impending death)' ("Anaesthesia Related Deaths") a Category 1 Scheduled Medical Condition.

Category 1 Scheduled Medical Conditions must be reported to the Director-General in accordance with the *Public Health Act* and Regulation. In relation to Anaesthesia Related Deaths, medical practitioners are required to notify SCIDUA via the "Report of Death Associated with Anaesthesia/ Sedation" ("SCIDUA Notification Form").

The SCIDUA Notification Form is annexed to this Policy Directive. Copies of the SCIDUA Notification Form are available from the Department of Anaesthesia at each hospital. The form can also be downloaded from the NSW Clinical Excellence Commission's website: http://www.cec.health.nsw.gov.au/programs/scidua

The completed Notification Forms are to be mailed to:

Secretary NSW Health,
C/o Special Committee Investigating Deaths Under Anaesthesia
Clinical Excellence Commission
Locked Bag 8
HAYMARKET NSW 1240

It should be noted that it is possible that a death might require notification to both the Coroner and SCIDUA, for example, if death occurred following anaesthesia and this was not a reasonable expected outcome of the procedure. In such cases Form A should be completed and sent to the Coroner and SCIDUA should be notified using the notification form "Report of a Death Associated with Anaesthesia/Sedation".

7.2 Certain other deaths

The NSW Department of Health has other Policy Directives for reporting deaths that may not be part of the *Coroner's Act*, such as reporting to:

- NSW Reportable Incident Review Committee
- NSW Maternal and Perinatal Committee, and
- Collaborating Hospitals Audit of Surgical Mortality (formally known as the Special Committee Investigating Deaths Associated with Surgery).

Staff should be familiar with these Policy Directives and note that they have a responsibility to report to these Committees.

8 GUIDELINES FOR MEDICAL, NURSING AND MIDWIFERY STAFF ON CORONERS' CASES DYING IN HOSPITAL

8.1 General considerations

The guidelines should be followed by medical, nursing and midwifery staff in dealing with Coroners' cases dying in hospital. In general nothing should be done to a body after death if it is a Coroner's case.

All intra-venous cannulae, needles, endotracheal and intragastric tubes, all drains and airways should be left in situ. Attached drip bags, bottles and feed lines must accompany the body. All sharps or items of equipment left in situ should be firmly taped or secured to the body in such a way that the risk of sharps injury or leakage is minimised. The immediate area should be checked and any sharps or equipment not required to remain in situ should be removed for disposal or reprocessing.

The body should be placed only in a plastic body bag. The body should not be washed even if the surface is soiled so that all surface contamination can be observed by the forensic pathologist and duly assessed. For instance, when death occurs shortly after injury by impact with a vehicle or by violent assault, washing may remove vital trace evidence such as an offender's blood and hairs or such things as paint flakes, glass chips or other finely divided material, which may be matched later against similar material obtained from another source.

Limbs and jaws must not be tied and orifices should not be plugged with cotton wool as these activities can leave marks, which cause problems especially about the face and neck.

Any material sucked from the stomach and/or any vomitus from suspected poisoning cases, should be retained and placed in screw-capped container(s), appropriately labelled and forwarded with the body for chemical analysis.

8.2 Removal of surgical apparatus

Generally, surgical and other apparatus are removed from the body during an autopsy. Such apparatus will be returned to the hospital if requested. However, not all deaths reported to the Coroner undergo an autopsy and in these circumstances surgical apparatus and similar equipment will not necessarily be removed from the body. If the hospital would like the surgical and other apparatus returned, written application should be made to the Coroner so that the equipment can be removed from the body.

8.3 Infectious diseases

Prior to death, if the deceased had or may have had one of the infectious diseases listed under "List A" or "List B" in section 3 of the *Public Health (Disposal of Bodies) Regulation 2002*, then a label stating clearly and indelibly only either "Infectious Disease List A - Handle With Care" or "Infectious Disease List B - Handle With Care" should be attached to the body and the body should be placed only in a plastic body bag. The body should then be placed in a second plastic body bag with a second label with the same information affixed outside. Neither label should specify the condition. The body should **not** be washed with antiseptic solution.

Infectious Diseases:
List A

- Creutzfeldt-Jakob disease
- Hepatitis C, and
- Human Immunodeficiency Virus Infection (HIV)

List B

- Diphtheria
- Plague
- Respiratory Anthrax
- Smallpox
- Tuberculosis
- Any viral haemorrhagic fever (including Lassa, Marburg, Ebola and Congo-Crimean fevers)

8.4 Custody of body

The hospital in whose care the body of the deceased is, is responsible for the safe custody of the body until a Coroner's order for burial has been issued or, when directed by the Coroner, it is removed by members of the Police Force. This implies safe custody of the correct body in the same condition as when death occurred, i.e.no interference with incisions, dressings, equipment in situ etc. and orifices must not be plugged.

8.5 Education purposes

Occasionally, medical staff of a teaching hospital might have a coronial case that they would like to use for the specific purpose of informing clinical staff or teaching students. For example, they might wish to conduct the post mortem at the teaching hospital in order that students can attend; alternatively, they might wish to take photographs of the body for future teaching purposes. In these cases, a senior medical practitioner or hospital administrator must first obtain the written consent of the deceased person's senior next of kin and then obtain the approval of the Coroner.

8.6 Relatives

Relatives are at times caused distress because they are questioned by police and asked to carry out the necessary identification formalities without having been advised in advance of the reason for police enquiries. Where deaths are reported to the Coroner, whether immediately after death or at anytime thereafter, a senior Hospital Officer should make all reasonable efforts to contact and, where possible, to interview relatives to explain to them the formalities required by the *Coroner's Act*.

- Access to bodies for identification purposes should be appropriately authorised and supervised by the police.
- Access to bodies for any other reason including compassionate reasons should be appropriately authorised and supervised by a staff member such as a Nursing/Midwifery Unit Manager or Acting Nursing/Midwifery Unit in the ward or manager or social worker employed by the Area Health Service.
- In any death considered suspicious or where criminal charges relating to the death are possible, any access to the body should be appropriately authorised and supervised by the police.

9 CORONIAL POST MORTEMS

9.1 Power to dispense with a post mortem

The Coroner has powers to dispense with a post mortem if after obtaining advice from police officers and medical practitioners, s/he is satisfied that the person died from natural causes and the senior next of kin (see Definitions section of PD) indicates the family does not wish to have a post mortem conducted to ascertain the precise cause of the person's death.

9.2 Dignity of deceased person to be respected

Under the terms of the 2009 Act the dignity of the deceased person is to be respected.

Medical practitioners undertaking post mortems are to endeavour to use the least invasive procedures that are appropriate in the circumstances. Examples of procedures that are less invasive than a full post mortem examination of the remains of a deceased person include (but are not limited to) the following:

(a) an external examination of the remains;
(b) a radiological examination of the remains;
(c) blood and tissue sampling; and
(d) a partial post mortem examination.

9.3 Transfer of medical records to forensic pathologists for post mortem

Where a post mortem is to be conducted under the direction of the Coroner, the pathologist or medical officer conducting the post mortem must have access to a copy of the medical records. The hospital is responsible for providing a copy of the medical records. The following procedure is recommended for the handling of records:

(a) the release of all medical records should be handled by the Medical Records Section or designated responsible officer of the hospital. All hospitals must maintain a Register of Deceased Persons. It is recommended that the movement of medical records of deceased persons be recorded either in a specific register or in the Register of Deceased Persons. If a separate register is kept it should contain the following information:
    - **Area Health Service Unique Patient Identifier (medical record number)**. This is a registered number given to the patient.
    - **Patient's full name**
    - **Date of death**
    - **Hospital autopsy**. This column should be notated if the medical staff of the hospital are seeking to conduct a post mortem within the hospital.

- **Report to Coroner complete.** This column should be notated to signify that the statutory form A "*Report of Death of a Patient to the Coroner*" has been completed.
- **Report to SCIDUA.** This column should be notated to signify that the form "*Notification of Death Associated with Anaesthesia/Sedation*" has been sent to the Clinical Excellence Commission, if relevant.

(b) Medical records may be sent with the deceased but should be collated and packaged prior to dispatch. The records should be forwarded in a sealed envelope to the Coroner. (If the original documents are forwarded to the Coroner, the hospital must retain a copy of the medical records.)

(c) A signed receipt should be obtained for all records from the Coroner's Court. The receipt may be a simple card bearing the following:

Received from.....Hospital

Package Number:.....

.....signed

.....date
The Coroner, Coroner's Court

(d) Records should be forwarded within 24 hours of the death.
(e) Records should be forwarded and collected by the hospital courier where practical.

Records will generally be available for collection within seven (7) days of delivery to the Coroner's Court.

Police requesting information and/or medical records from frontline staff should be advised to make a formal request to the Area Health Service Chief Executive.

9.4 Discharge type summaries for coronial cases in hospitals

For coronial cases involving deaths in hospitals, it is the responsibility of hospitals to provide the Coroner's Office with originals or copies of the deceased person's medical records and completed Form A.

Hospitals should provide a discharge type summary upon the written request of the Coroner. This summary should outline the care and treatment received by the deceased person at the hospital and specifically answers the questions raised by the Coroner's Office in its request. This will enable any issues of concern to be addressed in the first instance without the intervention of the police.

9.5 Information for relatives of a deceased person whose death has been referred to the Coroner

This section provides information that should be given to the relatives of a deceased person, irrespective of whether that person was a public or private patient, whose death has been referred to the Coroner.

9.5.1 The right to object to the exercise of post mortem investigative function

The senior next of kin of a deceased person whose death has been referred to a Coroner may object in writing to the conduct of a post mortem investigation including the retention of whole organs during the conduct of such investigations. If the Coroner decides that a post mortem examination is necessary or desirable in the public interest, the Coroner must notify the senior next of kin in writing of this decision. The senior next of kin may apply to the Supreme Court within 48 hours of receiving the notice for an Order that the post mortem examination not be conducted or a whole organ not be retained.

9.5.2 Coronial Information and Support Program - Objections

The Coronial Information and Support Program (CISP) at the Office of the NSW State Coroner manages all objections throughout New South Wales. The CISP staff are trained to deal with acutely bereaved families and will speak to the senior next of kin regarding any objection to the autopsy. Tel. 02 8584 7777.

The website for the Office of the NSW State Coroner contains important information and links to other supportive information. The address is: http://www.coroners.justice.nsw.gov.au/.

In addition the State Coroner's Court and the Department of Forensic Medicine, Glebe has produced an information leaflet. The leaflet provides information about the coronial system and informs next of kin of their right to object to a post mortem examination. Copies of the leaflet can be obtained from the State Coroner's Court at Glebe on (02) 8584 7777 or the Department of Forensic Medicine, Glebe on (02) 8584 7800.

9.5.3 The availability of Grief Counselling

Forensic grief counsellors are employed on a full-time basis at the NSW Department of Forensic Medicine, Glebe on (02) 8584 7800 and at the Department of Forensic Medicine at Newcastle on (02) 49223700.

The counsellors are available to assist relatives of the deceased person (who are coronial cases). They provide the bereaved with information, support and counselling.

10. CORONIAL INVESTIGATIONS

10.1 Power to obtain documents and things for purposes of coronial investigation.

For the purposes of assisting a Coroner in her/his investigation, s53 of the Act gives the coroner the power to direct a person to produce a document or other thing. The power to give direction includes:

(a) power to direct that a document be produced relating to the medical care or treatment of a person;
(b) the power to direct a person to provide any tissue in the person's possession or under the person's control that was taken from the deceased before his or her death.

However, the Coroner must withdraw a direction if it appears to the Coroner that:

(a) any person would be entitled on the grounds of privilege to refuse to produce the document or other thing in a court of law; and
(b) the person does not consent to compliance with the direction.

The production of a copy of a document is taken to be sufficient compliance with the direction unless the direction expressly requires the production of the original document.

10.2 Cross border coronial assistance

Under the Act (s102) the State Coroner may request in writing that the person holding a corresponding office in another State or Territory provide assistance in relation to a matter that is the subject of an investigation. Likewise the State Coroner, at the written request of a person holding a corresponding office in another State or Territory, provide assistance in relation to that person or a Coroner of that State or Territory in connection with the exercise of power under the law of that State or Territory.

In practice this section allows the NSW State Coroner to request assistance from an Area Health Service (AHS) (this could be a request for clinical records or statements from staff) in relation to an Inquest that is been held in another State, at the request of a Coroner from another State.

11. CORONERS RECOMMENDATIONS

The role of the State Coroner in New South Wales is to ensure all deaths, suspected deaths, fires and explosions, which come under the Coroner's jurisdiction are properly investigated and concluded.

Where an inquest or inquiry is held, the *Coroners Act* allows NSW Coroners to make any recommendation that they consider necessary or desirable in relation to a death, suspected death, fire or explosion.

When a Coroner addresses a recommendation to the Minister for Health or to NSW Health, the Department's Corporate Governance and Risk Management Branch is responsible for ensuring a response is provided to the Coroner. Corporate Governance and Risk Management Branch liaise with relevant areas within the NSW Health System, particularly those areas responsible for implementing recommendations, to prepare the response.

The Department's Corporate Governance and Risk Management Branch is also responsible for reporting to the Department of Attorney-General as referred in the Department of Premier and Cabinet memorandum M2009-12 Responding to Coronial Recommendations.

The Department's Corporate Governance and Risk Management Branch can be contacted on telephone 9391 9654.

Form - "Report of Death of a Patient to the Coroner" and SCIDUA Notification form "Report of Death Associated with Anaesthesia/Sedation: can be downloaded from http://www.health.nsw.gov.au/policies/pd/2010/PD2010_054.html

102(02/09/10)

CORONIAL CHECKLIST (IB2010_058)

PURPOSE

To advise the NSW Health system of a checklist that has been drawn up for use in determining whether a death should be reported to the coroner.

KEY INFORMATION

The NSW Health Department has recently issued Policy Directive PD2010_054 Coroners Cases and the *Coroners Act 2009*. A Coronial Checklist has been developed for optional use as an aid in determining whether a death should be reported to the coroner. All forms (those annexed to the Policy Directive PD2010_054 and the Coronial Checklist) can be obtained from SALMAT either by Electronic Print On Demand (ePOD) or by purchase order from Health Support Services, Better Health Centre.

Please go to http://www.health.nsw.gov.au/policies/ib/2010/IB2010_058.html to view the Coronial Checklist forms.

113(02/12/10)

ACCREDITATION OF PATHOLOGY LABORATORIES IN NSW HEALTH
(PD2017_011)

PD2017_011 rescinds PD2006_064

PURPOSE
NSW Health Pathology is required to ensure that the accreditation of pathology laboratories is maintained. By maintaining accreditation it is expected that laboratories will meet uniform standards of practice, competently perform tests / examinations and produce accurate and reliable results for the tests for which they are accredited.

MANDATORY REQUIREMENTS
The Commonwealth requires that for a pathology service to attract Medicare benefits the pathology laboratory is to be accredited for the kinds of services that are being provided.

The standards used to assess accreditation for pathology laboratories are Standards for Pathology Laboratories developed by the National Pathology Accreditation Advisory Council ("NPAAC"). These set out the minimum standards acceptable for good pathology practice in Australia. It should be noted that the NPAAC Standards also require the laboratory to be certified to *AS ISO 15189: Medical laboratories – Requirements for quality and competence* and other Australian and International Standards.

The Commonwealth has chosen the National Association of Testing Authorities (NATA) to act on its behalf to undertake the accreditation and certification of laboratories.

Full information on the Commonwealth's requirements for obtaining accreditation are in the Medical Benefits Schedule Category 6 – Pathology Services which can be obtained from http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/Downloads-201605

IMPLEMENTATION
- The NSW Health Pathology Chief Executive is responsible for ensuring pathology laboratories in NSW Health are accredited.
- The Sydney Children's Hospitals Network Chief Executive is responsible for ensuring pathology laboratories at The Children's Hospital at Westmead are accredited.

MANAGED POINT OF CARE TESTING (POCT) SERVICE (PD2018_028)

PD2018_028 rescinds PD2015_028

PURPOSE

The purpose of the Managed Point of Care Testing (PoCT) Service Policy Directive is to describe the requirements for a quality assured pathology service using devices located near the patient.

More rapid access to test results provided through the use of PoCT devices can increase clinical effectiveness and contribute to improved patient outcomes. However the result provided by the devices must be accurate, reliable and relevant.

This Policy Directive outlines the requirements for the safe and effective management and use of PoCT. Devices must be fit for their intended purpose and be used by competent individuals on the correct patient. Results become part of the patient record.

The expected outcomes for this Policy Directive are to ensure that:

- PoCT pathology testing is deployed in NSW Health facilities in an accurate, effective and clinically reliable manner supporting safe and optimal care for patients.
- clear standards for the introduction and management of PoCT that maximise patient care and patient safety are provided.
- any associated medico-legal and financial risks are minimised by supporting all operators in implementing PoCT appropriately including those without a laboratory background.
- patients and staff do not suffer avoidable harm or loss.
- staff using PoCT are trained, competent and use safe work practices.
- equipment including facilities and environmental conditions are safe for users.
- compliance with International Standards ISO 15189 and ISO 22870 and any other relevant regulatory requirements so that supervising laboratories achieve and maintain National Association of Testing Authorities Australia (NATA) accreditation for PoCT.
- principles of quality management and continuous improvement for PoCT are applied.

MANDATORY REQUIREMENTS

The mandatory requirements are described in the Procedures at Attachment 1.

IMPLEMENTATION

Effective clinical governance is an essential component of PoCT. This Policy Directive describes a co-operative framework involving both NSW Health Pathology services and local healthcare facility staff.

The multidisciplinary PoCT Clinical Advisory Committee provides governance oversight.

The NSW Health Pathology Operational Team where the PoCT device is situated provides operational oversight of the PoCT Service including laboratory assigned supervision. The local healthcare facility performs testing at the point of care.

Customer Service Charters must specify:

- appropriate use of devices.
- roles and responsibilities for managing the PoCT service.
- measures for compliance with the requirements of this Policy Directive and any other relevant requirements.

NSW Health Pathology provides an electronic management solution for PoCT devices to support clinical governance and accreditation objectives by:

- electronically transmitting a patient result to the Laboratory Information System (LIS) in which they then become part of that patient medical record.
- monitoring both operator and device performance.
- allowing for remote management of devices including preventing device operation if the competency of the operator has not been assessed or reassessed within appropriate intervals.
- supporting e-learning for ongoing competency assessment.

Public Health Organisations (PHOs) and NSW Health Pathology must ensure that all relevant staff comply with this Policy Directive.

Managed Point of Care Testing (PoCT) Service: Procedures

1 BACKGROUND

The driving forces increasing the demand for PoCT include clinician demand for best practice treatments, the need for more rapid results and advances in technology resulting in new devices.

PoCT is performed in many locations throughout NSW Health facilities including Emergency and ICU departments and clinics and other settings.

Advantages of PoCT include:

- improved equity of access
- greater satisfaction for patients who require care in rural and remote communities or who are unable to travel from home
- improved patient compliance with testing due to the convenience of PoCT and, in some instances, more simple sample collection
- more rapid provision of test results particularly the reduced time between collection and analysis.

This ensures more timely treatment reducing the risk of harm and increasing the likelihood of more effective healthcare outcomes.

1.1 About this document

This document applies to all approved PoCT services and equipment incorporated into the NSW Health Pathology's Managed PoCT Service and covers the management and use of these devices irrespective of who performs the test.

The process for approval of devices is detailed in the PoCT Device Commissioning Flowchart (Attachment 1).

1.2 Key definitions

Point of Care Testing (PoCT) is defined as pathology testing performed in close proximity to a patient by a healthcare worker and usually outside the precincts of a traditional laboratory. Other terms commonly used to describe PoCT include:

a) Near patient testing (NPT)

b) Bedside testing

c) Physician office testing

d) Extra-laboratory testing

e) Disseminated laboratory testing.

Managed PoCT Service is defined as an organisational framework that delivers an integrated PoCT service according to defined standards to provide results in a short period of time because of clinical urgency.

Operator refers to registered medical practitioners, nurses, midwives, and other healthcare workers including laboratory staff.

Quality Assurance is the process of assuring that diagnostic services have been performed in an appropriate and approved manner adequate to meet an agreed standard of medical care.

1.1 Abbreviations

APA	Approved Pathology Authority
APP	Approved Pathology Provider
ARTG	Australian Register of Therapeutic Goods
eMR	Electronic Medical Record
EQA	External Quality Assurance
ISO	International Organization for Standardization
ISO 15189	International Standard -Medical Laboratories – Requirements for quality and competence - Requirements for quality and competence
ISO 22870	International Standard - Point-of-care testing (POCT) - Requirements for quality and competence
IT	Information Technology
KPI	Key Performance Indicator
LIS	Laboratory Information System
NATA	National Association of Testing Authorities,Australia
NPAAC	National Pathology Accreditation Advisory Council
NPT	Near Patient Testing
NSWHP	New South Wales Health Pathology
PHO	Public Health Organisation
PoCT	Point of Care Testing
QA	Quality Assurance
QC	Quality Control
RCPA	Royal College of Pathologists of Australasia
SLA	Service Level Agreement
TGA	Therapeutic Goods Administration
WH&S	Workplace Health and Safety

1.2 Regulatory Framework

NSW Ministry of Health requires that NSW Health staff comply with all approved jurisdictional policies and legislation regulating and assuring the quality of pathology results.

The Accreditation of Pathology Laboratories in NSW Health Policy Directive PD2017_011 states that accreditation of NSW Health Pathology laboratories is required by the Commonwealth to meet uniform standards of practice, competently perform tests and examinations, and produce accurate and reliable results in order to attract Medicare benefits.

2 MANDATORY REQUIREMENTS FOR A MANAGED PoCT SERVICE

2.1 General

2.1.1 Pathology testing that is performed on approved PoCT devices must conform to this Policy Directive.

2.1.2 PoCT will only be approved for use as an alternative to a laboratory based service if there is a significant demonstrable benefit to patient care or clinical outcomes.

2.1.3 The Managed PoCT Service must comply with all relevant NPAAC Standards and International Organization for Standardization (ISO) Standards ISO 15189 Medical laboratories – Requirements for quality and competence and ISO 22870 Point-of-care testing (POCT) Requirements for quality and competence.

2.1.4 The service must review all requests to establish PoCT and must approve all such services and the devices to be used before PoCT is implemented.

2.1.5 Testing locations performing PoCT must be authorised to provide PoCT testing by the Local Health District (LHD).

2.1.6 Each staff member performing PoCT tests must be trained and assessed as competent. This training and assessment must occur before commencing testing.

2.1.7 PoCT devices must be periodically evaluated for their ongoing suitability.

2.1.8 PoCT devices may be withdrawn and PoCT services suspended if:

- PoCT service testing locations fail to comply with this Policy Directive
- a significant safety issue has occurred
- the instrumentation is misused or operator accreditation or certification is deficient
- there are concerns in relation to accuracy of results
- there is a lack of clinical effectiveness
- the expected benefits for using PoCT are not realised.

Services may be reinstated if evidence of remediation or resolution is provided.

2.2 Service Introduction

2.2.1 Applications to introduce, modify or change POCT services or devices must be submitted on the Application Form for PoCT Service Form.

2.2.2 Implementation of PoCT by NSW Health Pathology must be in collaboration with the LHD or relevant clinical service team and the supporting NSW Health Pathology Operational Team and must be integrated into the clinical framework of the health service.

2.2.3 The application must:

a) identify if PoCT will replace, or will be in addition to, laboratory testing

b) identify how PoCT will be integrated in to clinical pathways and guidelines

c) address the benefits to clinical need and effectiveness

d) define quality key performance indicators (KPIs).

2.2.4 Only approved devices will be endorsed and supported by this policy and procedure, irrespective of how the devices are financed, for example, purchased, loaned, gifted, leased, etc.

2.2.5 Devices will be commissioned once adequate numbers of competent operators have been trained, assessed and accredited. 'Adequate numbers' of operators will be determined by the management at the requesting test location.

2.2.6 A Customer Service Charter must be agreed and signed before implementation of PoCT services.

2.3 Accreditation

2.3.1 All PoCT services must be accredited by National Association of Testing Authorities, Australia (NATA).

2.3.2 Under Commonwealth legislation, all PoCT devices must be approved for use by the Therapeutic Goods Administration.

2.4 Patient Results

2.4.1 All patient results must be entered into, or transferred to, the appropriate LIS so they become part of the electronic medical record (eMR).

2.4.2 Results from PoCT devices must be clearly distinguishable in the LIS and eMR from results derived from laboratory analysers.

2.5 Networking

2.5.1 All new PoCT devices included in the Managed PoCT service must be:

a) capable of transferring patient results electronically to the LIS.

b) linked to NSW Health Pathology's PoCT Management System.

2.6 Supporting Documentation

2.6.1 A copy of the operational procedure for each device must be readily available near the PoCT instrument. Electronic copies are available from the NSW Health Pathology internet.

2.6.2 The procedure must contain:

- principle of examination
- sample requirements
- reagent storage
- calibration procedure (if appropriate)
- testing procedure and use of all related equipment

- maintenance and troubleshooting procedures including device error messages
- result interpretation including critical alert limits and reference ranges
- competency assessment criteria
- response to abnormal or unexpected results
- limitations of procedure including known interferences and limits of detection
- Quality Control (QC) and External Quality Assurance (EQA) procedures and Quality Control Record Sheets
- safe work practice and infection control information
- requirements and processes for recording results
- storage of documentation relating to testing ie printed test results.

2.7 Safety

2.7.1 Only PoCT devices and associated equipment that have satisfied Workplace Health & Safety requirements may be commissioned.

2.7.2 Specimens, reagents and other consumable supplies must be handled and disposed of according to safe work practices.

2.7.3 Devices and associated equipment must be located/stored, used and managed according to safe work practices.

2.8 Quality Control and External Quality Assurance

2.8.1 Prescribed quality control and quality assurance must be performed on all devices for all analytes as specified by the Managed PoCT Service to achieve compliance with the NATA Medical Testing Field Application Document Requirements for Accreditation (2013).

2.8.2 All devices must be enrolled in an EQA program for every analyte/test performed. If a commercial EQA is not available, an internal "interlab" program is mandatory.

2.8.3 Quality control and external quality assurance must be performed by certified operators. It is recommended that a representative sample of staff who use the device participate in the EQA program. All results must be recorded and retained for a period according to NPAAC Requirements.

2.9 Device Maintenance

2.9.1 Maintenance of devices is the responsibility of staff employed at the testing location performing PoCT.

2.10 Training and Competency Assessment

2.10.1 Initial training for devices must include 'face-to-face' training.

2.10.2 Training must be undertaken by an approved trainer. Knowledge/skill training requirements must include:

- the ability to demonstrate appropriate use of the device.
- pre-analytical requirements such as sample collection, reagent storage requirements, safety and infection control practices.
- the ability to identify results that fall outside of reference ranges.
- device maintenance.
- an understanding of Quality Control (QC) and Quality Assurance Program (QAP).

2.10.3 All staff performing PoCT must be initially assessed for competence by an approved trainer, for all devices they use.

2.10.4 All staff performing PoCT must be reassessed for competence periodically. The interval between All staff performing PoCT must be reassessed for competence periodically. The interval between re-certification of competency will be dependent on the device type, testing frequency and may be varied if there is any deficiency in performance of PoCT at the testing location. Minimum intervals for re-certification are to be specified in service level agreements.

2.10.5 All training will be followed by competency assessment.

2.10.6 Competency assessment records must be stored on site and retained in accordance with NPAAC Requirements.

2.11 Incident Reporting

2.11.1 Any incident involving PoCT devices must be reported in the NSW Health Incident Information Management System (IIMS) in accordance with the Incident Management Policy.

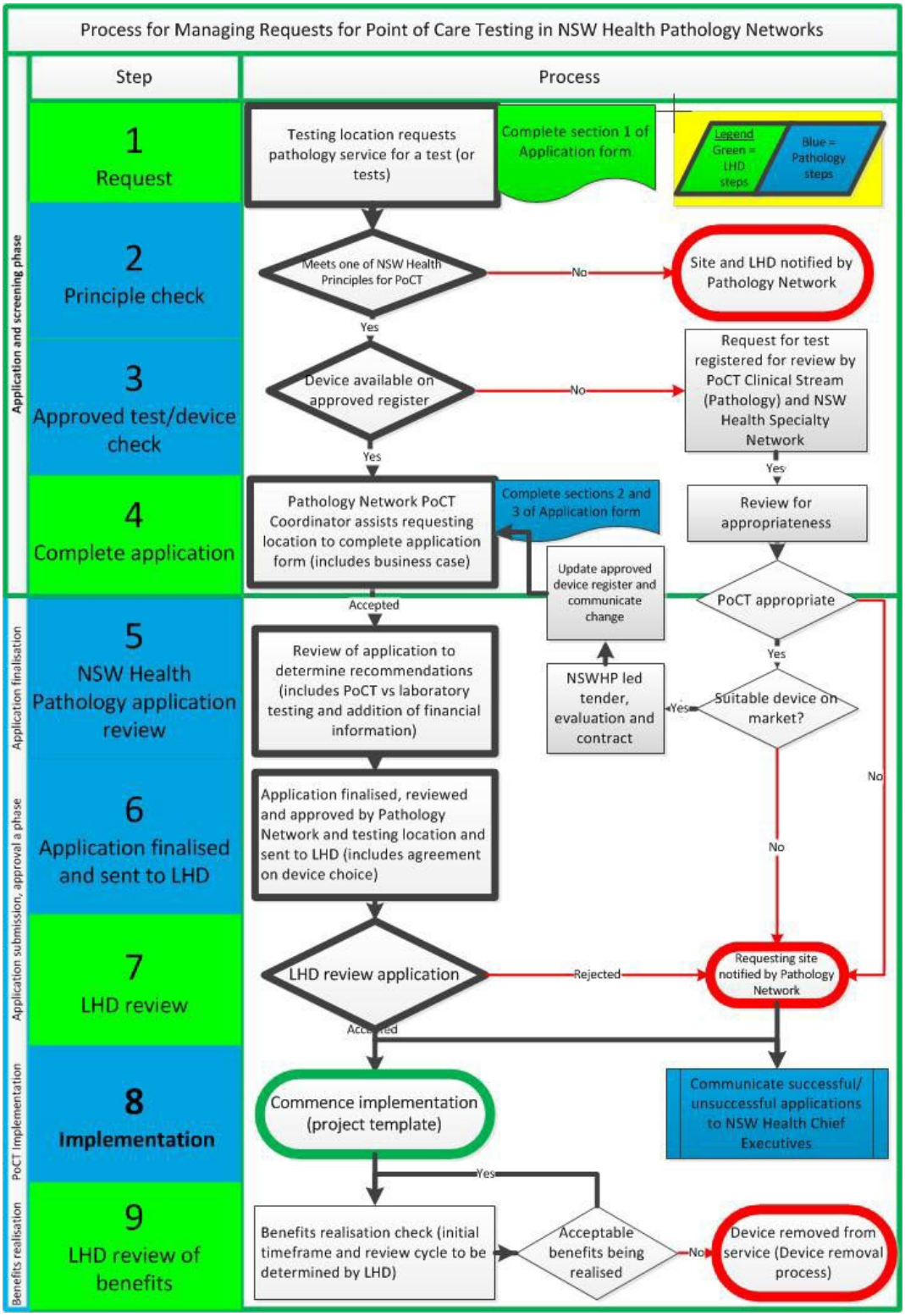
2.11.2 Any non-clinical issue relating to reagents, devices, quality control, EQA must be reported to the management at the testing location and be made the subject of a corrective action report in accordance with current standards.

2.12 Internal and External Audit

2.12.1 PoCT Services are subject to internal and external audits to assure quality and compliance with accreditation requirements**.**

3 APPENDIX

Attachment 1: PoCT Device Commissioning Flowchart



TRANSPORT OF PATHOLOGY SPECIMENS TO LABORATORIES (PD2023_001)

PD2023_001 replaced PD2018_020

POLICY STATEMENT

NSW Heath Pathology provides specialist pathology services for NSW Health organisations, NSW Police, private pathology providers, community based medical practitioners and private hospitals. It ensures a consistent state-wide approach to the safe and timely transport of all pathology and forensic specimens in compliance with relevant regulatory requirements.

SUMMARY OF POLICY REQUIREMENTS

Pathology specimens must be transported by the NSW Health Pathology Transport Service to NSW Health Pathology's on-site laboratory or to the appropriate laboratory providing the required diagnostic testing.

Other transport services can only be used to transport specimens to the appropriate laboratory providing the required diagnostic analysis in the following circumstances:

- Where the NSW Health Pathology Service is not operating
- Where there is no on-site NSW Health Pathology laboratory
- When the NSW Health Pathology laboratory is closed.

To ensure the integrity of specimens and the safety of staff and transport personnel, specimens must be appropriately handled, prepared, stored, packaged, labelled and transported in compliance with all legislative and regulatory requirements and this Policy.

To download the full Transport of Pathology Specimens to Laboratories policy to to:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2023_001