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**Patient Matters Manual**

**CHAPTER 26 – TISSUE/ORGAN**

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DONATION, USE AND RETENTION OF TISSUE FROM LIVING PERSONS
(PD2016_001)

PD2016_001 rescinds PD2005_341 and PD2012_014

PURPOSE
This policy directive outlines requirements for and restrictions on:

- Consent to remove regenerative or non-regenerative tissue from a living adult during medical, dental or surgical treatment and to use and / or retain the tissue for scientific, therapeutic or medical purposes
- Consent and certification to remove regenerative tissue from a living child for its transplantation into a parent or sibling
- Consent and certification to remove regenerative tissue from a very young living child for its transplantation into a sibling
- Assessing requests for the return of tissue to a patient / next of kin.

MANDATORY REQUIREMENTS

- Written consent for the removal, retention or use of tissue for therapeutic, scientific or medical purposes (apart from diagnostic / treatment purposes) must be obtained in line with the requirements of the Human Tissue Act 1983 and this policy directive.
- All restrictions and conditions on the use of tissue removed from living adults and children are observed.
- Under the Human Tissue Act 1983 tissue removed during treatment can be retained for up to 72 hours in order to obtain consent, including consent from the senior available next of kin where the patient dies subsequent to tissue removal.
- Requests for the return of tissue removed / expelled during the course of medical, dental or surgical treatment must be assessed according to the guidelines at Attachment 1. A decision to release tissue to a patient / next of kin must be documented on the form at Attachment 7.

IMPLEMENTATION
Chief Executives of Local Health Districts / Specialty Networks and NSW Health Pathology must ensure that:

- Relevant staff are made aware of their obligations under this policy directive.

Clinicians involved in the donation of tissue from a living person for transplantation or other therapeutic uses must ensure that:

- All necessary consents and certificates are obtained in line with the requirements of the Human Tissue Act 1983 and this policy directive.

Researchers and staff of tissue or biobanks must ensure that:

- Consent to the removal, use and / or retention of tissue for medical or scientific purposes is obtained in line with the requirements of the Human Tissue Act 1983 and this policy directive.

Hospital and pathology service staff involved in the retention and release of human tissue must ensure that:

- Tissue is released to a patient / next of kin in line with the requirements of this policy directive.
DONATION, USE AND RETENTION OF TISSUE FROM LIVING PERSONS PROCEDURES

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1.  BACKGROUND

About this document

This policy directive supersedes sections 4.1 to 4.4 of PD 2005_341 Human Tissue - Use / Retention of Including Organ Donation, Post Mortem and Coronial Matters and PD 2012_014 Human Tissue – Consent for Donation of Regenerative Tissue by Young Children & Consent Form.

This policy directive outlines the requirements for obtaining consent to the removal, collection, use and retention of regenerative and non-regenerative tissue from living persons for medical, scientific or therapeutic purposes (including research or educational purposes) and any restrictions on the removal and use of this tissue.

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Key definitions

Child

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

Child in care

A child or young person under the age of 18 years who is in any of these categories:

a) Under the parental responsibility of the Minister administering the *Children and Young Persons (Care and Protection) Act 1998*

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*

c) A protected person within the meaning of section 135 of the *Children and Young Persons (Care and Protection) Act 1998*

d) Subject of an out-of-home care arrangement under the *Children and Young Persons (Care and Protection) Act 1998*

e) Subject of a sole parental responsibility order under section 149 of the *Children and Young Persons (Care and Protection) Act 1998*

f) 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 child.

Designated Officer

A Designated Officer is a person who in relation to a:

a) Hospital, is appointed under s5(1) (a) of the *Human Tissue Act 1983* to be a Designated Officer for the hospital

b) Forensic institution, is appointed under s5(1)(a) of the *Human Tissue Act 1983* to be a Designated Officer for the forensic institution

c) Private hospital within the meaning of the *Private Hospitals and Day Procedure Centres Act 1988* – is appointed by the governing body (defined in the Act as the licensee) of the hospital.

Medical dental or surgical treatment

Any medical, dental or surgical treatment carried out by or under the supervision of a medical practitioner or dentist with respect to a living person in the interests of the health of that person.

Medical or Scientific purpose

Under the *Human Tissue Act 1983* use of a body or tissue for medical or scientific purposes includes educational purposes connected with medicine or science. This may also include research and other therapeutic purposes.
Person Responsible (Guardianship Act 1987)
When a person lacks decision making capacity and it is not an emergency, all health care practitioners are required under law to consult and seek consent to treatment from the Person Responsible. For persons 16 years and older, the Person Responsible is determined according to the hierarchy within the Guardianship Act 1987 (NSW):

a) An appointed guardian (including enduring guardian) with the function of consenting to medical and dental treatment (or if there is no-one in this category)

b) A spouse or de facto spouse (including same sex partner) who has a close and continuing relationship with the person, where the spouse is not a person under guardianship (or if there is no-one in this category)

c) The carer or person who arranges care regularly or did so before the person went into residential care, and who is unpaid (the carer’s pension does not count as payment) (or if there is no-one in this category)

d) A close friend or relative.

Senior Available Next of Kin
For a living child, the senior available next of kin is determined according to the hierarchy within the Human Tissue Act 1983:

a) Parent of the child (or, if not available)

b) A person who is a guardian of the child.

Tissue
Tissue includes an organ or part of a human body and any substance extracted from a human body or part of a human body. There are two types of tissue:

a) Regenerative tissue is tissue that after injury or removal is replaced in the body of a living person by natural processes of growth or repair (e.g. bone marrow)

b) Non-regenerative tissue is tissue other than regenerative tissue.

1.3 Legal and legislative framework

1.3.1 Human Tissue Act 1983 (the Act)
This policy directive describes requirements for the operation of Part 2 of the Human Tissue Act 1983 which regulates donations of tissue by living persons. Donation of ova, semen or foetal tissue is covered under different provisions within the Act or other legislation and is therefore excluded. In the Act, reference to:

a) The transplantation of tissue includes transplantation of any part of the tissue or any substance obtained from the tissue

b) Tissue that is removed from the body of a living person in the course of medical, dental or surgical treatment includes tissue expelled from the body of the person in the course of treatment, including where the person dies during the course of the treatment.
1.3.2 Guardianship Act 1987

Part 5 of the Guardianship Act 1987 allows that when a person aged 16 years or older lacks decision making capacity and medical or dental treatment is not an emergency, consent for medical and dental treatment may be given by the Person Responsible.

For the purposes of this policy directive the Guardianship Act 1987 allows a Person Responsible who is consenting to the medical, surgical or dental treatment of a patient to consent to other uses of the tissue that is removed or expelled from a living person.

1.4 Policy framework

NSW Health policy documents relevant to this policy directive:

- PD 2005_406 Consent to Medical Treatment – Patient Information
- PD 2015_04 Kidney Donation - Living (including Directed and Non-Directed Donation)
- PD 2013_002 Designated Officer Policy and Procedures
- GL2006_021 Human Tissue - Requirements of the Human Tissue Act 1983 in relation to research & use of tissue
- GL 2007_016 Human Research Ethics Committees- Standardised Patient Information Sheets (PIS)
- GL2008_019 Adult-to-Adult Living Donor Liver Transplantation Guidelines.

NSW Health State Forms relevant to this policy directive:

- Consent and certification for the donation of tissue by a living adult (SMR 020.035)
- Consent and certification for the donation of regenerative tissue by a living child (SMR 020.036)
- Consent and Certification for regenerative tissue donation: Child not capable of understanding
- Consent and authority for the retention and use of tissue removed or expelled during treatment of a deceased patient (SMR 020.034)
- Authorisation to delegate responsibilities of next of kin (SMR 020.031)
- Authorisation for the release of human tissue to a patient or next of kin. (SMR 020.033)

2. CONSENT TO THE USE OF TISSUE REMOVED DURING MEDICAL DENTAL OR SURGICAL TREATMENT

2.1 Consent requirements

2.1.1. Consent by a person with capacity

Where a person has capacity, their written consent is required if regenerative or non-regenerative tissue removed from their body during medical, surgical or dental treatment is to be used for any medical, therapeutic or scientific purposes (apart from the diagnostic purpose associated with the removal).

The consent must specify the purpose for and any conditions under which the tissue is to be used. For example, the patient should be given a description of the sort of uses to which their tissue may be put, such as scientific and medical research, biobanking, teaching or study. 
26. TISSUE/ORGAN

The consent / request for medical treatment form issued through Policy Directive (PD) 2005_406 Consent to Medical Treatment - Patient Information includes an option for consent for the use of tissue removed during the course of treatment. A copy of this consent should also be available to the agency / facility or researcher who receives the tissue for inclusion in their records.

The patient must be informed that consent to the use of tissue is separate from consent to treatment and that treatment procedures are in no way affected by a decision not to consent to use of tissue.

2.1.2 Consent for tissue removed from living persons under guardianship

Attachment A of Policy Directive 2005_406 Consent to Medical Treatment – Patient Information sets out the requirements for establishing a person’s ability to consent under the Guardianship Act 1987.

Where the person from who the tissue is to be removed is under guardianship, the guardian who is consenting to the medical, surgical or dental treatment may also consent to the subsequent use of tissue.

2.1.3 No consent required for tissue blocks and slides

Specific consent is not required to retain tissue in the form of tissue blocks/slides.

2.1.4 Use of tissue removed in the course of medical, dental or surgical treatment

The Human Tissue Act 1983 allows small samples of tissue that have been lawfully removed from a living person to be used without specific consent for purposes such as testing as part of a quality assurance / quality control program, audit or evaluation or pathology samples retained which are necessary for the accreditation of a hospital, forensic institution, laboratory or research institution.

2.2 Consent Options for Tissue Use

The Human Tissue Act 1983 allows consent to be general. Unless otherwise stated, such as in the specific uses described below, the patient should be informed that the term “therapeutic, medical and scientific purposes” has wide meaning and allows tissue to be used for a large variety of purposes.

Where a person places limitations on their consent, the tissue may not be used outside the scope of the consent.

2.2.1 Research

Where tissue is removed from a living person as part of a medical, dental or surgical procedure:

a) Written consent for use of the tissue for research must be obtained from the person whilst alive (or the person with parental authority if they are a child) or, if the person has died, from their senior available next of kin after their death

b) Consent must be sought in accordance with the research protocol. Research participants should provided with an information sheet outlining the period of retention and the storage and disposal arrangements and copy of the consent form. See GL 2007_016 Human Research Ethics Committees- Standardised Patient Information sheets (PIS)

c) The project must have been approved by a Human Research Ethics Committee constituted in accordance with the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research.
2.2.2 Tissues donated to tissue banks and biobanks

The person from whom the tissue is removed must consent to its retention and use in a pathology tissue collection, research tissue bank or biobank for uses such as education, training or research. Many research tissue banks or biobanks have their own specific consent forms. Banking of tissue for these purposes may require collection of the person’s personal health information (See 2.2.3).

2.2.3 Consent to the collection and use of personal health information related to the retained tissue

If the purpose for which the tissue has been collected requires the collection, storage, linkage or potential disclosure of the person’s personal health information this must be acknowledged in the consent documentation.

3. PROCEDURE FOR OBTAINING CONSENT TO THE DONATION OF TISSUE FROM LIVING PERSONS FOR TRANSPLANTATION

3.1 Consent and certification for the removal of the tissue from a living person for transplantation in to another person

Consent should follow the normal consent procedures outlined in PD 2005_406 Consent to Medical Treatment - Patient Information. The usual consent / request for medical treatment form should first be completed by the clinician (or their delegate) who will be performing the removal of tissue.

For certain living tissue donations the clinician responsible for the patient will need to ensure that the appropriate consent certificate is completed (see Attachments 2, 3 and 4). All consent forms attached to this policy include the relevant certificates. Restrictions apply where it is proposed to remove tissue from a child (Sections 3.2.2, 3.3.1, 3.3.3, 3.4 and 3.5).

3.2 Certification requirements

3.2.1 Removal of tissue from a living adult

A medical officer who is not involved in the removal of the tissue should issue a certificate stating that
- The nature and effect of the tissue removal were explained before consent was given
- Written consent was given in the presence of the officer.

3.2.2 Removal of tissue from a living child

If tissue is to be removed from a child then the medical officer must state that this has been explained to the parent and the child and that the:
- Options for the use of tissue removed during the procedure have been explained and consented to by the patient/next-of-kin/child (if appropriate)
- Medical officer is satisfied that the patient or the parent / guardian and child were of sound mind and the consent was freely given
- Patient or parental authority has not subsequently revoked the written consent
- Child remains in agreement with the proposed tissue removal and transplantation.

3.3 Restrictions on the use of tissue from living persons
3.3.1 Mandatory 24 hour cooling off period
In all cases the removal of tissue cannot take place until 24 hours after the written consent was given.

3.3.2 Use of non – regenerative tissue from an adult
Apart from removal in the course of treatment carried out for the benefit of the adult, non-regenerative tissue may only be removed from the body of an adult person for transplantation purposes.

3.3.3 Use of non – regenerative tissue from a child
Non-regenerative tissue may not be removed from a living child unless removed during the course of treatment carried out for the benefit of the child.

3.4 Use of regenerative tissue from a child
The senior available next of kin may consent in writing to the use of regenerative tissue from a child only for transplant to a parent or sibling.

A senior available next of kin / guardian cannot give consent to or authorise the use of the tissue if it appears (after reasonable inquiry) that the child objects to the use of or purposes for which the tissue is to be used.

Consent to use the tissue may not be given if there is another next of kin of the same or higher degree of kinship who objects to the use of the tissue or to the purpose(s) for which the tissue is to be used.

3.5 Use of regenerative tissue from a child not capable of understanding the procedure
Section 11A of the Human Tissue Act 1983 allows for bone marrow to be removed from a child donor who is too young to understand the procedure, where it is intended for transplantation into the child’s sibling. The following conditions must be met before removal of bone marrow in this setting may proceed:

A medical practitioner must certify that:

a) Parental consent was given in the presence of the medical practitioner

b) Before consent was given, the medical practitioner explained the nature and effect of the removal of tissue from the child’s body and the intended effect of the proposed transplantation

c) At the time of the consent, the medical practitioner is satisfied that the parent was of sound mind, understood the nature and effect of removal of the tissue, and that consent was freely given

d) The medical practitioner is of the opinion that the pre-conditions for child tissue donation (in this setting) are satisfied:
   ○ The child, by reason of his or her age, is not capable of understanding the nature and effect of the removal of the tissue and the intended effect of its proposed donation
The brother or sister of the child is likely to die or suffer serious and irreversible damage to his or her health unless the tissue to be removed from the child is used in their treatment of that brother or sister.

Any risk to the child’s health (including psychological or emotional health) caused by removal of tissue is minimal.

The above certification is effective only if a second medical practitioner, who is a specialist in paediatric medicine or paediatric transplantation certifies that:

a) He / she is of the opinion that the ‘pre-conditions for child tissue donation’ are met

b) He / she is acting as an independent medical practitioner, meaning their primary role in providing this opinion is to ensure the health of the child from whom tissue is being removed

c) He / she is not responsible for care of the sibling in whose treatment the tissue is to be used.

As an alternative to the procedure set out under the Human Tissue Act 1983, the Family Court of Australia may authorise the removal of tissue when it has found that the removal of tissue is in the child’s best interests. The Family Court is empowered by federal law and is not subject to the limitations set out in the Human Tissue Act 1983. For example, the Family Court may authorise donations to others apart from siblings, such as first cousins, as was the case in Re Inaya (Special Medical Procedure) [2007] FamCA 658.

Public hospitals that carry out bone marrow transplantation must ensure that the provisions in the NSW Human Tissue Act 1983 or the orders of the Family Court are followed and that local policy supports these provisions.

Should there be a difference of opinion between the Bone Marrow Transplantation specialist and the independent assessor of the patient, a second independent assessment of the donor should take place at another campus.

It should be noted that the Family Court may make orders with respect to donation of regenerative tissue by minors that may override parental and / or medical consensus in some circumstances.

4. ROLE OF DESIGNATED OFFICER – REVOCATION OF CONSENT

If the donor indicates that they wish to revoke their consent or in the case of child if the child no longer agrees with removal and transplantation of tissue, the Designated Officer for the hospital must be informed and act on this. For further information on the role of the Designated Officer see Policy Directive PD 2013_002 Designated Officers, Policy and Procedures.

5. CONSENT TO THE USE OF TISSUE REMOVED FROM LIVING PERSONS WHO SUBSEQUENTLY BECOME DECEASED

5.1 Consent for use of tissue removed from a person who subsequently dies

As outlined elsewhere in this policy it is best to obtain the consent of the person themselves, their senior available next of kin / person responsible / guardian as appropriate for the retention and future use of tissue to be removed during treatment before the prior to treatment commences.

The Human Tissue Act 1983 allows for tissue removed during treatment to be retained for up to 72 hours in order to obtain consent. These situations may arise for example, where the person was an emergency patient who did not have the opportunity to consent before treatment and died during the course of their treatment.
Where a person was living when the tissue was removed and subsequently dies, only a senior available next of kin (or their delegate) may consent to the use of the deceased person’s tissue. Consent must be recorded using the form Consent and authority for the retention and use of tissue removed or expelled during treatment of a now deceased patient (Attachment 5).

5.2 Restrictions on the use of tissue from children in the care of the State

Where tissue was removed from a living child who subsequently dies and the child immediately before their death was in care of the State, the tissue may not be used for any medical, therapeutic or scientific purposes other than donation for transplantation.

Where a clinician is unsure about the status of the child, he / she should make an application to the Department of Family and Community Services to ascertain the child’s status before obtaining consent.

6. CONSENT OPTIONS FOR DISPOSAL OF TISSUE OR RETURN TO PATIENT OF TISSUE REMOVED DURING MEDICAL, SURGICAL OR DENTAL TREATMENT

If a patient consents to the use of their tissue for medical, therapeutic or scientific purposes, information should be provided at the time of obtaining consent as to how the tissue may be disposed of after the therapeutic, medical or scientific use has expired.

A patient may request that the tissue removed during their medical, surgical or dental treatment be returned to them for disposal. This request is often made in relation to foetal tissue under 20 weeks gestation and in some cultures to other tissues removed during treatment or expelled from the body such as placentas and amputated limbs.

Legally there is no ownership in excised body parts. However, if certain conditions are met there may be no objection to the patient taking home tissue removed or expelled from their body while they are in hospital.

A responsible medical practitioner should be satisfied that the arrangements for returning the tissue to the patient and the eventual method of retention or disposal do not present a public health risk. This will require the provision of additional information to the patient / senior available next of kin on the public health requirements as set out in Appendix 1 and completion of the Authorisation for the release of human tissue to a patient or next of kin form (Attachment 7).

If a patient does not consent to their tissue being used for other medical, therapeutic or scientific purposes and does not request its return, the tissue should be disposed of in accordance with usual waste management procedures.

Tissue returned to the patient / senior available next of kin or their delegate for appropriate storage or disposal should be triple packed as required by the National Pathology Accreditation Advisory Council’s Guidelines for Approved Pathology Collection Centres (2012).

7. FORMS

In NSW standardised State Forms must be used for recording consent to the removal, collection, storage and use of human tissues. All forms in this policy may be obtained through your Local Health District/Specialty Network facility print manager.
8. LIST OF ATTACHMENTS

1. Procedures for the return of human tissue to the patient / next of kin
2. Consent and certification for the donation of tissue by a living adult (SMR 020.035)
3. Consent and certification for the donation of regenerative tissue by a living child (SMR 020.036)
4. Consent and Certification for regenerative tissue donation: Child not capable of understanding
5. Consent and authority for the retention and use of tissue removed or expelled during treatment of a deceased patient (SMR 020.034)
6. Authorisation to delegate responsibilities of next of kin (SMR 020.031)
7. Authorisation for the release of human tissue to a patient or next of kin (SMR 020.033)
8. Letter for travel with human tissue
Procedures for the Return of Tissue to Patient / Next of Kin

The patient / next-of-kin may request that tissue be returned to them for disposal. This request may be made in relation to tissue removed during treatment or expelled from the body for example, foetal tissue under 20 weeks gestation, placentas and amputated limbs. For many patients this request will be made for cultural or religious reasons relating to bodily integrity and / or the appropriate disposal of remains.

Legally, there is no ownership in excised body parts and whilst there may be no objection to the patient wishing to take home tissue removed or expelled from their body while they were in hospital, a responsible medical practitioner or health professional should be satisfied that the arrangements for returning such tissue to the patient / next of kin do not present a risk to public health. This requires an assessment of the request by the health organisation and the provision of additional information to be given to the patient / next of kin.

The following guidelines describe the minimum requirements organisations should cover including the assessment process which should be undertaken and the information to be given to the patient / next of kin before the organisation agrees to return the tissue.

Assessment of Requests

Requests for the return of human tissue to the patient / next of kin for disposal should be assessed by the relevant senior medical or health care professional caring for the patient. Any request made for the release of foetal tissue should be referred for assessment in conjunction with a social worker or counsellor. Staff should facilitate discussion about what the patient / next of kin intends to do with the tissue and assessment should include:

- The grounds for the request
- The proposed storage and / or final disposal method for the material (which must be in keeping with the requirements of these guidelines)
- Whether the intended disposal method constitutes a public health or other safety risk (see below).

Where a patient indicates that they wish to bury a body on private land specific conditions apply (see below).

The patient / next of kin should be informed of the requirements of this policy and given the opportunity to clarify the requirements.

No trade in tissue

It should be made clear to the patient / next of kin that section 32 of the Human Tissue Act 1983 makes it an offence to sell or supply (or offer to sell or supply) human tissue to another person for anything of valuable consideration.

Public health and safety requirements

Human tissue cannot be released where

a) It may be contaminated with cytotoxic, chemical or radioactive waste
b) It is reasonably believed to be infected with a prescribed infectious disease as defined in Clause 53 of the Public Health Regulation 2012.
Prior to disposal or transfer to another private storage arrangement the human tissue must not to be removed from the container in which it is released.

Disposal or other appropriate storage must take place within eight hours of the tissue being removed from the health organisation.

**Documentation**

Careful documentation of the assessment and discussion with the patient / next of kin should be made in the patient’s medical record.

If a decision is made to release the human tissue for disposal, the form *Authorisation of the Release of Human Tissue to a Patient or Next of Kin* is to be completed by the patient / next of kin who is taking possession of the tissue. The original form should be filed in the medical record. A copy of the form and a letter certifying that the person is travelling with human tissue in their possession (see Attachment 6) should accompany the person with the tissue.

It must be clear to the person who receives the tissue that they are responsible for the safe and secure storage of the transferred tissue.

If the tissue to be returned is from a deceased person, the senior available next of kin should be asked to provide copies of appropriate identification for documentation. The senior available next of kin hierarchy can be found in the *Human Tissue Act 1983*.

**Minimum requirements for the preparation and release of tissue**

The officer who is preparing the human tissue for release for private disposal should have regard to their organisation’s local protocol on the handling, storage and preparation of human tissue for transportation.

The tissue may be immersed in formalin but must be drained and must not be released in formalin. It is important in some cultures that placental tissue IS NOT placed in formalin.

The National Pathology Accreditation Advisory Council’s Guidelines on the *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials* recommend triple packaging for the transport of all human tissues and substances.

A label identifying the tissue should be affixed to the container. The outer container should be marked “Tissue for collection by” and include the name of patient / next of kin / mother (for foetal tissue under 20 weeks gestation) and the date of the procedure / miscarriage / death.

The container containing the tissue should be stored in a refrigerated unit by the organisation pending collection by the patient / next of kin / other delegated person who will collect the tissue.

If the tissue is to be transported by the patient / next of kin it should be placed on ice in a waterproof container when released to the patient / next of kin. Dry ice cannot be used as it has potential hazards. Refrigerated transport must be used where the journey is more than eight hours.

**Options for tissue disposal for discussion with patient / families**

Patients / next of kin may ask what alternative disposal methods the organisation might offer. Staff should give honest information on their organisation’s protocol for the disposal of human tissues.

**Burial or cremation of tissue at the patient / next of kin’s expense**

This option is often the choice for patients from cultures where it is important that all bodily remains are eventually reunited at death. Fees for cremation of individual tissues may be expensive and families should be encouraged to check these costs before making a decision.

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Crematoriums require a letter from a medical officer certifying that the tissue is the “tissue / limb / etc. of patient x”. A letter will also be required from the patient stating that they request cremation of the tissue (limb etc.).

The patient will need to organise transport of the tissue to the crematorium.

**Burial or cremation of foetal tissue**

Some families may choose to arrange their own funeral service and cremation or burial of fetal tissue (less than 20 weeks gestation), which is at their own expense. Crematoriums require a letter from a medical officer certifying that the tissue is the fetal tissue and noting the gestational age. The family may transport the appropriately packaged tissue to the funeral director / crematorium themselves.

Some Local Health Districts / Specialty Networks offer a service that provides group cremation of fetal tissues and the scattering of the ashes in a memorial garden as an alternative to private arrangements.

**Burial on private land**

In addition to the public health requirements set out above, burial of a body on private land or in a garden will require council consideration. GL2013_016 Guidance on Burying a Body on Private Land - Public Health Regulation 2012 outlines the requirements that must be considered. These include:

- The total landholding must be equal to or exceed five hectares
- Bodies must be buried at a minimum depth of 900 millimetres
- Bodies must be placed in a coffin prior to burial
- A geotechnical investigation may be considered if there is any likelihood of contamination of ground waters and/or surface waters.

Full details are available within the guideline.
ATTACHMENT 2:
Consent and Certification for the Donation of Tissue by a Living Adult

This form is to be completed by living adults who are donating either regenerative or non-regenerative tissue from their body for the purposes of transplantation to another person under Part 2 of the Human Tissue Act 1963 or for donation of tissue removed or expelled from their body during treatment for its use for medical, scientific or research purposes, under part 3C of the Human Tissue Act 1963. Consent to the removal of regenerative and non-regenerative tissue must be certified by a medical practitioner. The Certificate is on the reverse of this form.

Details of the Donor
Title ____________________
Surname ____________________
First Name ____________________
Address ____________________
Date of Birth ____________________
Date ____________________ Post Code ____________________

Statement of Consent
I consent to the removal and donation of ____________________
(type of tissue)
being *regenerative / *non regenerative tissue from my body for:

☐ transplantation to the body of another living person or
☐ other therapeutic purposes or for medical or scientific purposes or
☐ use in ethically approved research ____________________ (specify research study)

Dr ____________________ (name of certifying Doctor)

has explained the nature and effect of the removal of the tissue to me. I have had the opportunity to ask questions. I have received answers to my satisfaction.

Name ____________________
Signature ____________________ Date ____________________

* delete if not applicable
ATTACHMENT 3:
Consent and Certification for the Donation of Regenerative Tissue by a Living Child

This form is for the donation of regenerative tissue from a living child for the purpose of its transplantation to a parent or sibling under s 26 of the Human Tissue Act 1983. This form is to be completed by a person with parental authority for the child. Consent to the removal of regenerative tissue must be certified by a medical practitioner. The certificate is on the reverse of this form.

Details of the Donor
Surname ____________________________
First Name __________________________
Address _____________________________
State ___________________________ Post Code __________
Date of Birth ________________________

Parent's Consent

I ___________________________ (name of parent)
of ___________________________ (name of parent)
being the mother/father/paternal authority of the above named child, consent to the removal of:

______________________________ (type of tissue)
being regenerative tissue from the body of the above mentioned child for the purpose of transplanting the tissue to the body of:

______________________________ (name of recipient)
who is the ___________________________ of the donor
(state relationship - sibling/mother/father)
Or ___________________________ (name of certifying Doctor)

has explained the nature and effect of the removal of the tissue and the intended transplantation to me. I have had the opportunity to ask questions. I have received answers to my satisfaction.

Name ___________________________
Signature _________________________ Date ____________

This certificate is to be signed by a person with parental authority for the child, or a medical practitioner if the procedure is to be performed under a medical practitioner's authority, or by a person with parental authority for the child if the procedure is to be performed under a person's authority other than a medical practitioner or a medical practitioner's.

302(15/02/16)
26. TISSUE/ORGAN

ATTACHMENT 4

Consent and Certification for Regenerative Tissue Donation: Child Not Capable of Understanding

Facility:

CONSENT TO REGENERATIVE TISSUE DONATION – CHILD INCAPABLE OF UNDERSTANDING

This form is for the donation of regenerative tissue from a child not capable of understanding for the purpose of its transplantation to a sibling under section 11A of the Human Tissue Act 1963. This form is to be completed by a person with parental authority for the child. Consent to the removal of the regenerative tissue from a young child must be certified by 2 medical practitioners. The Certificate is on the reverse of this form.

Details of the Child Donor

Given Name

Family Name

Address

State

Post Code

Date of Birth

Parental Consent

I ________________ (mother / father / parental authority)

of ________________ (address)

being the mother/father/parental authority of the above named child, consent to the removal of:

________________________

(type of tissue)

being regenerative tissue from the body of the above named child for the purpose of transplanting the tissue to the body of:

________________________

(name of recipient)

who is the sibling of the donor.

Dr. ________________ (name of certifying removal practitioner)

has explained the nature and effect of the removal of the tissue and the intended transplantation to me. I have had the opportunity to ask questions. I have received answers to my satisfaction.

Name

Signature __________________________

(mother / father / parental authority)

Date / /
ATTACHMENT 5:

Consent and Authority for the Retention and use of Tissue Removed or Expelled During Treatment of a Now Deceased Patient

Human Tissue Act 1983

This form is to be completed by the next of kin of a deceased patient where tissue had been removed or expelled from the patient following medical, surgical or dental treatment and is to be retained for its subsequent use for medical, scientific or research purposes under part 5C of the Human Tissue Act 1983. A Designated Officer for the health facility must authorise the subsequent retention and use of the tissues. The Designated Officers Authority is on the reverse of this form.

Details of the person giving consent

Title: ____________________________

Family Name: _____________________

Given Name: _____________________

Address: __________________________

State: ____________________________

Post Code: _______________________

Relationship to Deceased

Statement of Consent

I consent to the retention and donation of ________ (type of tissue) being tissue removed from the body of ________ (family name) ________ (given name) for: ________ (check box)

☐ for other therapeutic purposes, or

☐ for medical or scientific purposes, or

☐ for use in ethically approved research

(specify research study)

I have no reason to believe that the deceased has expressed an objection to the removal of the above mentioned tissue.

I have no reason to believe that an equal or more senior next-of-kin to the deceased has an objection to the removal of the above mentioned tissue for such purposes.

Name: ___________________________

Signature: _______________________

Date: __________________________
ATTACHMENT 6

Authorisation to Delegate Responsibilities of Next of Kin

[Form Image]

NAME: ___________________________ DATE OF BIRTH: __/__/____

ADDRESS: ___________________________

RELATIONSHIP: ___________________________

STATEMENT BY SENOIR AVAILABLE NEXT OF KIN:

I hereby authorise:

Surname: ___________________________ First Name: ___________________________

FULL NAME OF SENIOR AVAILABLE NEXT OF KIN:

I acknowledge and accept the responsibilities of next of kin as delegated to me under s3A of the Human Tissue Act 1989.

PRINT NAME OF AUTHOURED PERSON (DELEGATE):

SIGNATURE: ___________________________ DATE: __/__/____
ATTACHMENT 7

Authorisation for the Release of Human Tissue to a Patient or Next of Kin

<table>
<thead>
<tr>
<th>Facility:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorisation for the Release of Human Tissue to a Patient or Next of Kin</td>
<td></td>
</tr>
</tbody>
</table>

**A. DETAILS OF THE TISSUE(S) TO BE RELEASED**

Date of procedure / / or date of death of patient / / 

Tissue(s) to be released ____________________________

**B. DETAILS OF PERSON COLLECTING TISSUE(S) (Pick applicable option)**

- Patient
- Senior available next of kin or delegate
- 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 tissue;
- 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 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) OR TISSUE(S)**

Name (print) ____________________________

Designation ____________________________

Hospital extension/pager number(s) ____________________________

Signature of person authorising release ____________________________ Date / /
ATTACHMENT 8
Example of Letter to be Issued to Person Travelling
With Human Tissue in Their Possession (On Facility Letterhead)

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 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: ____/_____/_____

302(15/02/16)
PD2013_001 replaces Chapter 5 of PD2005_341.

PURPOSE

Deceased organ donation is governed by the Human Tissue Act 1983. The Human Tissue Act 1983 makes specific provisions for obtaining consent and authorisation for the removal of organs and tissues for the purposes of donation and subsequent transplantation to a living person or for other therapeutic, medical or scientific use of those donated organs and tissues.

This document provides guidance to Local Health Districts (LHDs), Specialty networks and NSW Health Pathology Departments and Institutes of Forensic Medicine on protocols and procedures that must be in place in health facilities to support organ donation including the identification of potential donors, the determination of death, the scope and format of consent (including the specific requirements of the Human Tissue Act 1983 as to who may consent), authorisation of the designated officer, obtaining Coronal authorisation for donation to proceed when relevant and donor maintenance.

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

MANDATORY REQUIREMENTS

- Written consent or consent by other prescribed means (as outlined in the Human Tissue Regulation 2010) must be obtained prior to the removal of tissue for its use for medical, scientific or therapeutic use.
- In the absence of a written consent from the deceased, consent must be obtained from the senior available next of kin or their delegate.
- Designated specialists must be appointed in health facilities by the Chief Executive in Local Health Districts and Specialty Networks, and the Licensee in private facilities to certify death by brain death criteria.
- A designated officer must be appointed by the Chief Executive of the LHD/Specialty Network or Governing Authority of a private facility to legally authorise, in writing, the removal of tissue after death for its use for donation and transplantation to a living person or for other therapeutic, medical or scientific purposes.
- Where a family objects to the donation of organs from a deceased contrary to the known wishes of the donor, the requesting clinician must document the reasons for family objection on the standard form provided and have this documentation signed by the designated officer.
- The policy mandates the use of standard forms including those for consent and authorisation of the removal of tissue from a deceased, certification of brain death and certification of cardiac (circulatory) death for the purposes of organ donation. These forms are attached to this policy directive.

IMPLEMENTATION

Chief Executives of LHDs are responsible for ensuring that:
- All staff are made aware of their obligations in relation to this Policy Directive.
- Documented procedures are in place to support the Policy Directive.
The NSW Organ and Tissue Donation Service (NSW OTDS) is responsible for:

- The coordination of organ and tissue donation and retrieval within NSW.
- The provision of education and training on organ and tissue donation for LHD/Specialty Network staff.
- The development of clinical and operational protocols for organ and tissue donation to be adopted in LHDs/Specialty Networks across NSW.

Donation Specialist Staff in LHDs and Specialty Networks are responsible for:

- Management of multi-organ and tissue donation at LHD/Specialty Network level.

Designated specialists in health facilities are responsible for:

- Certification of brain death according to criteria outlined in the attached procedures.

Designated officers in hospital and forensic facilities:

- Must authorise the removal of tissue after death for its use for donation and transplantation.
- Must review and confirm that the reasons for a family’s objection to donation proceeding contrary to the known wishes of the potential donor have been documented by the requesting clinician.

1. BACKGROUND

1.1 About this document

This Policy Directive establishes the minimum requirements for a process to be undertaken to obtain consent for organ and tissue donation including:

- Guidance on obtaining consent by audio or audio-visual recording or other prescribed means under the Human Tissue Regulation 2010;
- Consent for organ and tissue donation for a child in the care of the state; and
- Consent for organ and tissue donation from the authorised; and person/delegate of the senior available next of kin.

This Policy Directive also establishes requirements for:

- The minimum documentation and maintenance of confidential records and consent forms relating to organ and tissue donation for transplantation;
- The documentation required when a family objects contrary to the consent of the potential donor;
- The role of the Designated Officer in assessing information with regard to the most recent decision of the deceased;
- Privacy issues related to organ and tissue donation;
- Donor billing;
- Disposal/return of unallocated organs to the next of kin; and
- Documentation required when recording family objection to organ donation.

Under section 27A of the Human Tissue Act 1983, the Director-General may issue guidelines relating to the removal of tissue after death, including recording reasons for not proceeding with the removal of tissue from the body of a deceased person, where the deceased person has given consent but the family has objected. This Policy Directive will establish such guidelines.
This Policy Directive should be read in conjunction with the following NSW Ministry of Health policies and guidelines:

- PD2005_406 Consent to Medical Treatment - Patient Information
- GL2005_057 Guidelines for End-of-Life Care and Decision-Making
- GL2014_008 Organ Donation After Circulatory Death: NSW Guidelines
- PD2010_054 Coroners Cases and the Coroners Act 2009
- PD2013_002 Designated Officer Policy and Procedures

1.2 Key definitions

**Authorised Person** (*Delegate of the senior available next of kin*)

*Section 5A of the Human Tissue Act 1983* allows a senior available next of kin to authorise another person, in writing, to exercise their functions as senior available next of kin under the *Human Tissue Act 1983.* This ‘authorised person’ or delegate may give written consent for organ and tissue donation. Evidence of authorisation must be attached to the consent form.

**Child**

A person who has not obtained the age of 18 years and who is not married.

**Child in care**

A child or young person under the age of 18 years:

- Who is under the parental responsibility of the Minister administering the *Children and Young Persons (Care and Protection) Act 1998,* or
- 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
- Who is a protected person within the meaning of Section 135 of the *Children and Young Persons (Care and Protection) Act 1998,* or
- Who is the subject of an out-of-home care arrangement under the *Children and Young Persons (Care and Protection) Act 1998,* or
- 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
- 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.

**Death**

The *Human Tissue Act 1983* defines death as:

(a) Irreversible cessation of all function of the person’s brain, or
(b) Irreversible cessation of circulation of blood in the person’s body.
**Designated Officer**

A Designated Officer is:

- 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, or
- In relation to a forensic institution, a person appointed under s5(1)(a) of the *Human Tissue Act 1983*, to be a Designated Officer for the forensic institution, or
- In relation to a private hospital within the meaning of the *Private Hospitals and Day Procedure Centres Act 1988* – a person appointed by the governing body (defined in the Act as the licensee) of the hospital.

**Designated specialist**

The *Human Tissue Act 1983* authorises the governing body of each hospital, whether public or private to appoint designated specialists. For the purposes of the Act medical practitioners with the following qualifications are automatically eligible for appointment as designated specialists:

- Fellows of the Australasian College of Emergency Medicine.
- Fellows of the Australian and New Zealand College of Anaesthetists.
- Fellows of the College of Intensive Care Medicine of Australia and New Zealand.
- Fellows of the Royal Australasian College of Physicians.
- Fellows of the Royal Australasian College of Surgeons.
- Fellows of the Royal Australian College of Obstetricians and Gynaecologists.

Medical specialists with equivalent overseas qualifications are also eligible for appointment as designated specialists subject to approval in each case by the Chief Executive of the Local Health District (as a delegate of the Director-General of the Ministry of Health).

Other appropriately qualified and experienced medical practitioners who hold specialist registration but are not a member of the one of the colleges listed above (such as those who have been granted specialist registration by the Medical Board of Australia) may be considered by the Chief Executive of the Local Health District (as a delegate of the Director-General of the Ministry of Health).

**Medical or scientific purpose**

A reference in the *Human Tissue Act 1983* to the use of a body or organ and tissue for medical or scientific purposes includes educational purposes connected with medicine or science.

**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.

**Requesting health professional**

A requesting health professional is an appropriately qualified health professional who has experience in conducting sensitive conversations with patients and families. The requesting health professional’s role is to empower the family to make fully informed decisions. The requesting clinician will offer the option of donation to the family, or discuss donation with them, but does not necessarily manage the entire donation process.
26. TISSUE/ORGAN

Senior Available Next of Kin

The order of Senior Available Next of Kin is defined in S4 of the Human Tissue Act 1983 in relation to a deceased child:

- Parent of the child;
- Sibling of child who is 18 years of age or over where a parent is not available; or
- Guardian of the child at the time of death where none of the above is available.

However, where the child is in the care of the state specific provisions for consent to organ and tissue donation apply (see section 2.3).

In relation to any other deceased person a Senior Next of Kin may be a:

- Spouse (which can include a de facto spouse and same sex partner);
- Son or daughter of the deceased person (18 years of age or over) where above is not available;
- Parent where none of the above is available; or
- Sibling of the deceased person (18 years of age or over), where none of the above is available.

Tissue

In this policy the term tissue refers to an organ or part of a human body and a substance extracted from a human body or from part of a human body. It does not include tissue blocks and slides, which may be retained without specific consent.

1.3 Legal and legislative framework

The current policy is underpinned by the requirements of:

- The Human Tissue Act 1983;
- The Human Tissue Regulation 2010; and
- The Coroners Act 2009.

2. CONSENT FOR DECEASED ORGAN AND TISSUE DONATION

Specific consent requirements apply when dealing with the removal of organ and tissue from the deceased.

There are defined legal parameters on who may give consent and who may authorise procedures on a deceased body. There are also specific requirements in relation to organ and tissue donation from deceased persons whose deaths are reported to the Coroner.

Seeking and obtaining consent is a sensitive issue. Staff seeking consent should have a good understanding of the activities for which they are seeking consent. They should also be in a position to answer questions that donors or their families may ask. The NSW Organ and Tissue Donation Service (OTDS) co-ordinates training for selected healthcare professionals to develop the skills to discuss organ and tissue donation with families and to seek and obtain consent.

Any consent relied upon must be a valid consent¹. In particular, if staff are obtaining consent from a senior available next of kin, staff should ensure that the senior available next of kin understands which organs and tissue will be removed and that they have consented to such removal. Such consent should generally be in writing.

¹The relevant NSW Health policy on consent is PD2005_406 Consent to Medical Treatment - Patient Information
2.1 Written Consent

Written consent may be obtained through either establishing evidence of a valid written consent of the deceased (such as the Australian Organ Donor Register) or by obtaining the written consent of the senior available next of kin of the deceased (Attachment 1).

In the case of a child in the care of the state, written consent may be obtained from the Principal Care Officer of the agency that has responsibility for the child (see 2.3).

2.2 Consent by other prescribed means

The Human Tissue Act 1983 allows consent for deceased organ and tissue donation to be obtained using audio or audio-visual recording (other prescribed means). If this form of consent is used, the following provisions must be met:

- The consent of the person/s being recorded to the making of the recording must be obtained; and
- The recording must comply with mandatory requirements for obtaining a valid consent to organ and tissue donation.

The following elements of the consent discussion must be recorded:

- The date and time of the recording;
- The name and designation of the health professional obtaining consent;
- The name of the person giving consent and their relationship to the deceased;
- A statement that the person giving consent is the most senior available next of kin;
- Information on the organs/tissues to which consent applies and their potential uses;
- Any other specific requirements of the consent such as use for research; and
- An offer for the family to ask questions.

The audio or audio-visual recording is the legal instrument of consent and a copy must be archived with the patient’s medical record. For example the recording may be copied to a compact disc (CD) and the CD archived with the medical record.

2.3 Consent for organ and tissue donation by children in the care of the State

A child or young person is in the care of the state if either the Minister or the Director-General of Family and Community Services has sole parental responsibility in respect of the child or young person.

The Principal Care Officer (PCO) of the designated agency which has full case management responsibility for the child or young person automatically becomes the person with responsibility for consent for organ and tissue donation for transplantation. The Act does not allow for organs and tissues to be retained for research or other medical scientific or therapeutic purposes in these cases.

Before deciding whether or not to give consent for the removal and donation of organ and tissue from the deceased child or young person’s body, the PCO must use reasonable efforts to contact persons who have been significant in the child’s or young person’s life and who the PCO considers to be appropriate to assist in the decision making process. This may include:

- Birth parents;
- Foster parents;
- Extended family;
- If the child/young person is Aboriginal or Torres Strait Islander, appropriate persons from the child’s or young person’s Aboriginal and/or Torres Strait Islander community; and
- Other persons considered relevant by the PCO.

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The PCO will determine whose approval is required and may determine that more than one person’s approval is necessary. The PCO should record the actions that they have taken and the details of any parties they contacted, or attempted to contact, as this information may be required by the Designated Officer prior to granting their authorisation.

A PCO must not give consent unless all relevant parties have been consulted and have given their approval to the organ and tissue donation.

Once the PCO has given written consent the Designated Officer may authorise removal of organ and tissue from a deceased child’s body. In order to authorise the Designated Officer must have access to the written consent of the PCO and be satisfied that the child or young person did not express objection during his or her lifetime about removal and donation of their organs and tissue after death.

Under section 25 of the *Human Tissue Act 1983*, the consent of the Coroner must also be obtained prior to the removal of organs and tissues from the deceased child or young person’s body.

It is acknowledged that the donation of organs and tissues from a child in the care of the state may be a relatively rare event. However, the complexity of the consent and authorisation process requires conversation between the PCO, the Coroner and the Designated Officer to facilitate a timely process and ensure that all legal authorisations are obtained.

The Designated Officer may use reasonable inquiries to check the status of a child or young person who is presented as a potential donor following their death. This is to confirm whether the child or young person was under the sole parental responsibility of the Minister or the Director-General of Family and Community Services.

### 2.4 Consent for organ and tissue donation from the authorised person/delegate of the senior available next of kin

In some cultures and communities it is usual for responsibilities relating to death to be undertaken by someone other than the person who would be legally defined as the senior available next of kin under the *Human Tissue Act 1983*.

Section 5A of the Act provides an option for the senior available next of kin to delegate their authority in writing to another person, who may then assume the functions of that level of next of kin. It is essential that this delegation is made with the consent of the senior available next of kin and that they understand what granting such an authority to another person will mean.

A form for delegation is attached (Attachment 2). This form should be attached to the document of consent and provided to the Designated Officer for authorisation.

### 2.5 Consent for organ/tissue donation: When family objection overrides a potential donor’s known consent

Respecting the most recent decision of the donor is a priority. The majority of families support donation where they know that their deceased family member wanted to be a donor.

The Act makes no provision for families to override prior patient consent for organ and tissue donation. However, for prudential and compassionate reasons family agreement is generally sought. There may be cases in which donation is considered inappropriate for clinical or other reasons, regardless of the donor’s decision. Each case should be considered on its merits. It is recognised that obtaining family support for organ/tissue donation requires complex and sensitive communication, regardless of whether the donor’s decisions are known.
If a deceased person had given their consent to the removal of tissue but a health practitioner determines that the removal of tissue should not proceed due to the objection of the deceased person’s family, then the relevant health practitioner must document the reasons for not proceeding. A form has been developed to assist requesting health professionals meet their obligations under this policy. The form (Attachment 3) should be completed and signed by the requesting clinician, and then signed by the Designated Officer.

3. DISCUSSION OF ORGAN AND TISSUE DONATION

The requesting health professional must contact the NSW OTDS so that staff can consult the relevant donor register to ascertain if the potential donor has registered a decision.

Organ donation should be raised in a timely manner and sensitively discussed with the senior available next of kin (or the broader family if requested by the senior available next of kin), including exploring and rectifying any misperceptions about the donation process and procedure. The requesting health professional should alert the Designated Officer so that they can determine whether or not they attend the family interview, consistent with current local practice and their existing discretionary authority.

The aim of the discussion is to attain a consensus amongst the senior available next of kin (or the family if requested) which supports the patient’s decision.

If the family or those close to the deceased person object to the donation when the potential donor has expressed a written or verbal consent to donate, the basis of these objections should be explored.

The senior available next of kin (or the family if requested) should be encouraged to accept the deceased person’s decision. The requesting health professional should emphasise that this is a discussion seeking their support for the decision of the donor and that proceeding with donation accords with that decision.  

If there is dissent amongst the family to proceeding with donation, the benefits of carrying out the donation should be weighed against the distress and resentment that may result if donation proceeds in the face of strong objection from some family members.

The decision not to proceed with organ/tissue donation in this context depends on the presence of strong and sustained family objection in spite of appropriate information provision, and time to reflect.

3.1.1 Documenting the decision not to proceed with donation

The decision not to proceed with donation will require the information to be documented as per the form Documenting Family Objection to Organ Donation Contrary To Known Wishes Of the Donor (Attachment 3).

3.1.2 Designated Officer role when family objection overrides potential donor consent

The Designated Officer’s role is to review the documentation and confirm that the reasons for family objection are documented and that the donation will not proceed.

The completed and signed form should be included in the patient’s medical record.

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2 UK Human Tissue Authority Code of Practice 2 – Donation of solid organs for transplantation, 2012
3.1.3 Tissue donation requests

There is no requirement for reasons for objection to be recorded in this format regarding tissue only donation.

3.2 Determining the most recent views of the deceased

Section 23 of the Act has been amended to allow a Designated Officer to consider the most recent views of the deceased when determining whether or not to authorise the removal of tissue where the deceased may previously have registered an objection to donation.

This provision recognises situations where a deceased person may have registered a “no” on a donation register, subsequently changed their decision, but failed to re-register their written consent to donation. In practice this allows a Designated Officer to consider information from relatives and friends that the deceased has subsequently changed their mind and has indicated that they would like to donate.

In keeping with their legislative responsibilities, the Designated Officer may make reasonable enquiries to determine the most recent views of the deceased. Inquiries may take the form of discussion with next of kin and those close to the deceased or consideration of other evidence of the deceased’s wishes, such as statements expressed through social media.

If the new information indicates that the deceased’s most recent views were not in objection to organ donation, then organ donation can proceed but only if a valid written consent to the donation is obtained from the senior available next of kin or their delegate and the Designated Officer authorises the removal of the tissue.

3.3 Substitute decision makers and the Human Tissue Act 1983

Only a senior available next of kin as defined by the Human Tissue Act 1983 can give consent to the removal of organ and tissue from a deceased person (see section 1.2.10).

A person who fulfils any of the following functions in relation to a deceased person is not able to give consent under the Human Tissue Act 1983 unless they are also the senior next of kin:
- Persons appointed as Guardians under the Guardianship Act 1997,
- Persons who hold a “Power of Attorney”,
- Persons nominated as a “person responsible” in a hospital or medical record, or
- Persons nominated as a “person to notify” in a hospital or medical record.

4. ORGAN AND TISSUE DONATION PROTOCOL

The NSW Organ and Tissue Donation Service (OTDS) coordinates organ and tissue donation in NSW and develops and maintains clinical and operational protocols for organ and tissue donation in NSW. Coordination of multi-organ and tissue donation at LHD/specialty network level is managed by specialist donor staff employed in selected hospitals. Coordination of tissue-only donation is facilitated by the tissue donor coordination team of the NSW Eye and Tissue Bank.

The OTDS provides education and training on organ and tissue donation for LHD and Specialty Network health professionals. Information on organ and tissue donation protocols and fact sheets are available from the NSW Organ and Tissue Donation Service on (02) 8566 1700 or via http://www.donatelifegov.au
4.1 Identification of potential multi-organ and tissue donors

Public and private hospitals must have systems in place to identify all potential organ and tissue donors and to provide opportunities for families to support the donation of organs and tissues for transplantation.

4.1.1 Multi-organ donation pathways

The GIVE tool, a nationally consistent clinical trigger checklist must be used in all public and private hospital emergency departments (EDs) and Intensive Care Units (ICUs) to identify patients who may be considered for multi-organ and tissue donation (see Attachment 4).

The GIVE tool identifies intubated and ventilated patients in ED or ICU with irrecoverable brain injury for whom end of life decisions are being made.

Further information on the GIVE tool is available at www.donatelife.gov.au

The GIVE tool requires appropriate referral protocols to be established between EDs and ICUs for the ongoing care of patients who may be considered for multi-organ and tissue donation. If a patient meets the GIVE criteria the treating team should notify the appropriate staff as per their local protocol.

All potential multi-organ and tissue donors should be referred to the NSW Organ and Tissue Donation Service for assessment of medical suitability. Enquiries regarding medical suitability can be made via a paging service on 02 9963 2801.

For further specific information regarding identification of donors in whom donation after cardiac (circulatory) death is being considered see GL2014_008 Organ Donation after Circulatory Death.

4.1.2 Tissue-only donation pathway

A potential donor of tissue for corneal, musculoskeletal and cardiac tissue (heart valve) transplantation is a deceased person for whom retrieval is possible within 24 hours after circulatory standstill.

In order to increase the level of potential donor identification all deaths (including Coroner’s cases) occurring within or declared on arrival at a hospital are to be notified as matter of urgency to the Lions NSW Eye Bank Coordinators, through the Sydney Eye Hospital on 9382 7288 (24 hours a day).

The minimum information must include:
- Name and date of birth of the deceased;
- Time and date of death; and
- Ward and hospital.

4.2 Referral to the local Donation Specialist Nurse and tissue donor coordinators

Donation Specialist Nurses are located in selected NSW hospitals. Their role includes management of the process for referring potential donors to the NSW OTDS.

Contact details for the local Donation Specialist Nurse should be available in wards and hospital units where potential multi-organ and/or tissue only donors are likely to be admitted.
On referral the Donation Specialist Nurse will require the following information:

- Name, address and date of birth of the deceased;
- Reason for hospital admission;
- Cause of death or reason for proposed withdrawal of cardio respiratory support;
- Current haemodynamics and ventilator settings;
- Past medical history; and
- Current blood results (biochemistry and haematology).

Tissue donor coordinators will also request information to undertake medical suitability assessment of tissue only donors.

4.3 Determination of the potential donors consent status and provision of this information to family

Authorised staff of the NSW OTDS must access all relevant registries to ascertain the potential organ and tissue donor’s consent status.

This information must be obtained prior to the family discussion so that the family can be advised of the donor’s decision. This information will also be available to the Designated Officer in determining whether to authorise the donation.

4.4 Discussion of organ and tissue donation with senior available next of kin and family

The approach to a family regarding organ and tissue donation must be handled with great care and sensitivity. A multidisciplinary team approach to managing end-of-life decisions should occur in accordance to the NSW Health GL2005_057 End-of-Life (EOL) Care & Decision-Making Guidelines.

The discussion with the family regarding potential organ and tissue donation should be separate from, and subsequent to the discussion related to brain death or the decision to withdraw life sustaining treatment.

The NSW OTDS should be contacted prior to the commencement of discussion with the family regarding organ and tissue donation. The donation specialist staff including a “designated requestor” (a specialist who is specifically trained for discussions with families regarding organ and tissue donation) will usually lead the approach the family for this discussion. The discussion may also be led by the treating medical team if specialist staff are not available.

During this discussion, information on the donation process will be given to the family. The following points should also be canvassed where relevant:

- The potential donor’s consent or decision in relation to donation must be provided where it is known.
- The duration of the organ and tissue donation process and the investigations required (i.e. blood samples for virology testing and tissue typing and purpose).
- That retrieval of organs may not proceed if the donor is deemed medically unsuitable, test results are abnormal, or there are no suitable transplant recipients.
- If death occurred under circumstances where it must be reported to the Coroner, Coronial permission must be sought and formal identification of the body for the Coroner is required by law.
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- As consent to the removal and use of organs and tissues from a deceased person must be authorised by a Designated Officer prior to the removal of the organ and tissue, the Designated Officer may wish to contact the family to satisfy themselves as to any specific issues raised in the discussion and that the consent accurately reflects the family’s understanding of the procedures.
- If organs and/or tissues are removed and are subsequently unable to be transplanted, they will be returned with the body of the donor (unless permission for research was granted) or disposed of as per the next of kin’s wishes.

4.5 Classification of the Multi-organ donor for billing purposes

Private patients must be converted to hospital patients at the point of diagnosis of brain death or for patients in whom DCD is being considered when consent to the donation has been agreed. Investigations subsequent to confirmation of brain death or following consent for DCD should not be charged to a private patient’s account. All relevant paperwork should be labelled or stamped “FOR ORGAN DONATION, NOT FOR BILLING”.

4.6 Certification of Death

The Human Tissue Act 1983 prescribes that a person has died when the following has occurred:
(a) Irreversible cessation of all function of a person’s brain (brain death); or
(b) Irreversible cessation of circulation of blood in a person’s body (commonly referred to as cardiac death).

4.6.1 Determination of Brain Death


Where brain death criteria are used, two (2) medical practitioners who have practiced medicine for at least five (5) years in the previous eight (8) years must certify that death has occurred.

One of the medical practitioners must be a Designated Specialist appointed by the governing body of the hospital.

Neither medical practitioner can be associated with the retrieval process nor responsible for the care of the intended recipient.

The form “Certification of Brain Death” must be completed (Attachment 5).

4.6.2 Determining death by circulatory (cardiac) criteria

Cardiac (circulatory) death must be certified by a medical practitioner in accordance with the usual procedure for assessment of extinction of life.

Chapter 5 “Donation After Cardiac Death” of The ANZICS Statement on Death and Organ Donation edition 3.1, 2010 (http://www.anzics.com.au/Downloads/ANZICS%20Statement%20on%20Death%20and%20Organ%20Donation%20Edition%203.2.pdf) recommends that death be determined when the following features are present:
- Immobility;
• Apnoea;
• Absent skin perfusion; and
• Absence of circulation as evidenced by absent arterial pulsatility for a minimum of two minutes, as measured by feeling the pulse, or preferably by monitoring intra arterial pressure.

When all of these criteria have been met, the patient is determined to be dead. The death certificate should be completed immediately following the examination. The death cannot be certified by a member of the organ retrieval team.

The form “Certification of Death Determined by Absence of Vital Signs Following Circulatory Death” must be completed. (Attachment 6)

A 5 minute stand down period is mandatory before donor surgery can proceed. The Donation Specialist Nurse must document the stand down period on the donation after cardiac (circulatory) death observation chart in the Australasian Transplant Coordinators’ Association Confidential Donor Referral Form. The Donation Specialist Nurse will notify the donation specialist coordinator at commencement of the stand down period. During the 5 minute stand down period the deceased can be transferred to theatres if this has not already been done.

Health facility staff should also act in accordance with Guideline GL2014_008 Organ Donation after Circulatory Death.

4.7 Coronal cases and organ and tissue donation

In cases where a report of death to the Coroner is necessary, any removal of organs and tissues requires the prior authorisation of the Coroner (in addition to the normal requirements to obtain consent of the deceased and/or family and authority of Designated Officer).

It is the responsibility of the Donation Specialist Nurse/Donation Specialist Medical or Tissue Donor Coordinator to ascertain from the treating team if the death is examinable by the Coroner. This information must be communicated to the NSW OTDS donation specialist coordinator or tissue donor coordinator who will liaise with the forensic pathologist and the Coroner. It is the responsibility of the Donation Specialist Coordinator or Tissue Donation Coordinator to seek consent for organ and Tissue Donation from the Coroner.

4.7.1 Coronal consent - Organ donation after cardiac (circulatory) death (DCD)

The Coroner does not have jurisdiction over a person’s body until death has been declared. Therefore in DCD cases, a conversation between the donation specialist coordinator and the on call Coroner ascertains if organ and tissue donation would impact in the Coronial investigation. If donation will impact then the process is ceased. If it is ascertained that it will not, the work up of the donor can continue. The Donation Specialist Coordinator will contact the Coroner just prior to extubation and then again immediately post the declaration of circulatory death and obtain authorisation. This authorisation must be obtained prior to the commencement of organ retrieval surgery.

4.8 Designated Officer’s authority

In accordance with the Act once consent to the removal of organs and tissues for the purposes of donation has been obtained, a Designated Officer must be contacted to authorise the removal in accordance with the consent.
Before issuing their written authority, the Designated Officer must be satisfied that the deceased person had not, when living, expressed an objection to organ or tissue donation. If the deceased had previously recorded a written objection on a register (or had previously indicated an objection to organ donation in any other way) but family or friends indicate that they had subsequently changed their decision, Section 23 (3)(a)of the Act provides the Designated Officer with the discretion to consider most recent views of the deceased with respect to organ donation. If, after undertaking such reasonable inquiries, the Designated Officer is satisfied that the most recent views of the deceased indicated that the deceased was in favour of organ donation, then notwithstanding any historical objections, the Designated Officer may authorise the removal of organs.

The Designated Officer has discretion as to whether they participate in the consent interview with the senior available next of kin, conduct their own separate interview, or discuss the consent with the Donation Specialist Nurse, Donation Specialist Coordinator or tissue donation coordinator.

The Donation Specialist Nurse/Donation Specialist Coordinator must provide the Designated Officer with the following information:

- Circumstances surrounding the admission;
- Evidence of the potential donor’s intention from the registries or more recent evidence of the deceased’s wishes regarding organ and tissue donation if relevant;
- The instrument of delegation of authority of the senior next of kin (if applicable);
- The written consent of either the deceased or the senior available next of kin;
- The Coronial consent and/or any restrictions placed by the Coroner on the donation if required;
- Clinical notes which document discussions with family; and
- Senior available next of kin contact details should the Designated Officer wish to discuss authorisation.

Once satisfied, the Designated Officer may authorise in writing removal of organ and tissue from that person’s body in accordance with the terms and conditions of the consent.

4.9 Completion of the Confidential Donor Referral Form (CDRF) (Organ donation cases only)

It is the responsibility of the Donation Specialist Nurse to collate information required by the Australasian Transplant Coordinators Association Confidential Donor Referral Form (CDRF) and relay the information to the donor specialist coordinator. In the absence of the donation specialist nurse, the donation specialist coordinator will attend/contact the referring hospital and undertake this process.

The CDRF serves as part of the record of the donation for the NSW OTDS. To comply with NSW Health requirements each page of the CDRF should include the donor’s three identifiers (i.e. medical record number, date of birth and donor number). All details and events must be documented including telephone calls and electronic communications.

4.10 Donor maintenance and care

Maintenance of a donor must be in accordance with chapter 6 Donor Management of the National Guidelines for Organ and Tissue Donation 4th edition, 2008 see http://www.atca.org.au/files/F.pdf and with reference to any guidelines developed or issued by the NSW OTDS.
As the condition of potential organ and tissue donors may become unstable and/or deteriorate the treating team managing the potential donor should alert the NSW OTDS Donation Specialist Nurse or medical staff of any specific physiological and metabolic changes occurring in the donor.

For potential donors for whom donation after cardiac (circulatory) death is being considered staff must be aware of GL2014_008 Organ Donation after Circulatory Death. In particular interventions specifically for the benefit of future organ recipients cannot be administered, for example the use of pre-mortem procedures or drugs to optimise organ function.

Continuation of eye care is paramount for eye donation.

4.11 Blood specimens

Blood specimens for serological testing, tissue typing, and arterial blood gases (for lung donation) are obtained as part of the organ and tissue donation process. The NSW OTDS will coordinate the collection and transport of specimens and provide specific guidance to LHD staff where a donation specialist nurse is not available to manage the process.

4.11.1 Blood typing and sub typing requirements

On referral of a potential donor, the Donation Specialist Nurse will need to obtain a record of the blood group from the hospital blood bank for tissue typing. If a blood group (ABO) has not been obtained during admission, the Donation Specialist Nurse will need to obtain a blood group from the hospital blood bank.

Potential donors who have an ABO of either A or AB must have sub-typing performed to facilitate appropriate matching of their organs with potential recipients. If the hospital caring for the potential donor is unable to perform this subtyping the Donation Specialist Coordinator will arrange for the testing to be performed by the ARCBS Red Cell Laboratory.

4.11.2 Blood sampling for tissue typing and serological testing

Multi-organ retrieval surgery cannot proceed until routine serology testing has been completed. The approximate turn around time for virology results is 3-4 hours. However, should prospective nucleic acid testing (NAT) be required, results will be available 8 hours from the time of the request. If prospective NAT is required organ retrieval surgery cannot proceed until results are available (see PD2013_029 Organ Donation and Transplantation - Managing Risks of Transmission of HIV, HCV and HBV).

Due to these timing limitations blood samples can be drawn for serological testing and tissue typing as soon as the medical suitability of the potential donor is established and the senior available next of kin has given consent (verbal consent is acceptable) for donation to proceed. If verbal consent is given this must be documented in the clinical notes prior to blood collection and the written consent completed as soon as possible.

4.11.3 Blood sample collections

The Donation Specialist Nurse and/or the bedside nurse are responsible for following the guidelines (found in the blood specimen boxes for organ and tissue donation) for the blood sample collection. If the facility does not have access to a blood specimen box for organ and tissue, staff should contact the NSW OTDS for advice.
4.12 Organisation of retrieval surgery

The Donation Specialist Nurse and the Donation Specialist Coordinator will liaise with the retrieval teams, hospital executive and administration and the treating team to arrange operating theatre time for the retrieval of organs and tissues.

The donor family should be offered the opportunity of viewing the deceased’s body after the retrieval surgery. The Donation Specialist Nurse and the donation specialist coordinator may facilitate the viewing if the family requests it or they may organise this in conjunction with appropriate hospital staff.

4.12.1 Tissue-only retrieval

In a tissue only donation, the Tissue Donor Coordinators facilitate the eye and/or tissue retrieval. Medical Officers or specifically authorised non-medical staff may perform the retrieval procedure. Eye only retrieval can occur in any location - for example, hospitals, mortuaries, nursing homes - using clean technique. Musculoskeletal and cardiovascular retrieval usually occurs in a mortuary using aseptic surgical technique.

4.12.2 Retrieval of Organ and tissues for Research

Organ and tissue may only be removed for research purposes where specific consent for research use was granted by the senior available next of kin or their delegate and with the specific permission of the forensic pathologist and Coroner (if the death was reportable to the Coroner).

In addition, organ and tissue can only be used for research purposes if the research has ethics approval.

Where organs are deemed unsuitable for transplantation but suitable for research, the retrieving surgeons or transplant centre must inform the Donation Specialist Coordinator.

4.12.3 Disposal of Non-utilised Allocated Organs

Where consent for research has not been granted by the senior available next of kin and procured allocated organs/tissues have been retrieved and subsequently deemed not suitable to transplant, the retrieving surgeon and/or tissue bank must notify the donor specialist or tissue bank coordinator.

The retrieving surgeon and/or transplant centre must either respectfully dispose, use for research or return organs to the body, depending on family wishes. The family’s wishes for this situation should be recorded when obtaining consent.

4.13 Donor family support

4.13.1 Counselling for families of donors

Hospitals managing donors should ensure appropriate ongoing bereavement support for donor families through the hospital’s social work or related services. In addition to support offered by an individual hospital, a donor family support program is provided by the NSW Organ and Tissue Donation Service. Bereavement care is also offered to tissue only donors through the NSW Eye and Tissue Bank.
4.14 Privacy Issues

Neither a medical practitioner who performs a transplant operation nor any employee of the hospital may disclose information which could lead to the identity of the donor or recipient of transplanted organ and tissue (whether living or deceased) becoming publicly known.

LIST OF ATTACHMENTS
10. Delegation of authority of the senior next of kin form.
11. Documenting family objection to organ/tissue donation contrary to the known wishes of the donor form.
12. GIVE Clinical Trigger Poster.
13. Certification of brain death form.
14. Certification of cardiac death form.
15. Implementation Checklist.
SECTION 6 GENERAL ADMINISTRATIVE MATTERS IN RELATION TO POST-MORTEM EXAMINATIONS

6.1 The Post-Mortem Examination

Once consent is obtained and authorised, all reasonable efforts should be made to minimise delays in proceeding with the post-mortem examination.

At the completion of the post-mortem examination, the next-of-kin should be contacted and provided with appropriate information about the outcome of the post-mortem and any associated investigations. If consent was given for retention of tissue, the next-of-kin should be advised where the tissue is stored and provided with the contact details of the person responsible for storage and use of the tissue.

The medical certificate stating the cause of death under Section 39 of the Birth Deaths and Marriages Registration Act 1995 should either be provided at this time or explicit arrangements agreed for its provision (such as to funeral directors at the time of collection of the body).

Requests for information regarding Coronal post-mortem examinations must be directed to, and authorised by, the Coroner.

6.2 Costs of Disposal of Retained Organs: Reuniting Organs With Bodies, Burial or Cremation

As of 1 January 2002, Public Health Organisations should have a policy in place to meet additional funeral costs associated with burial or cremation of organs and tissue retained at both coronial and non-coronal post-mortem examination, where the family requests this. These payments should be reasonable, equitable and accessible to families and apply in a prospective manner to post-mortems carried out from 1 January 2002.

The NSW Department of Health will continue to be the point of contact for requests for assistance relating to costs associated with post-mortems carried out prior to 1 January 2002.

Any additional funeral costs to re-unite body parts retained from post-mortem examination with the other remains of the deceased should be discussed with the next-of-kin prior to obtaining their consent for a non-coronal post-mortem examination, and families should be made aware that assistance with these costs is available.

Payment of costs associated with burial or cremation of body parts retained at coronial post-mortem examination for purposes associated only with the coronial investigation should be discussed with the Coroner.

SECTION 7 RECORDS OF STORAGE OF BODIES, BODY PARTS AND ORGANS

The following requirements do not apply to samples, blocks or slides of tissue, blood, bone, fluids etc taken at post-mortem examination. The retention of records in relation to tissue slides and blocks are covered by guidelines endorsed by the National Pathology Council of Australia which should be referred to.
7.1 Content of Records in Relation to Post-Mortem and Human Tissue - General Principles

Files of post-mortem examinations must contain clear, explicit, written notes signed and dated by the responsible pathologist, for the removal, reasons for removal, examination, testing and use of all organs and tissue removed for the purpose of post-mortem examination.

Records of tissue used for medical and scientific research must include signed and dated written records of the actual use and final disposal of all such tissue.

7.2 Requirement to Maintain Records and Minimum Retention Periods

Public Health Organisations are required to retain records for minimum periods as specified in the State Records General Disposal Authority for Public Health Services: Patient/Client Records, and this circular.

Private hospitals should also be aware of the provisions included in the Private Hospitals Regulation in respect of retention of patient/client records.

Copies of autopsy/post-mortem consent forms/reports/recordsregisters/diagrams and other representative images (see definition of records in section 1) are to be retained for a minimum of 20 years from the date of the disposal of tissue then destroyed in accordance with the requirements of the State Records General Disposal Authority for Public Health Services: Patient/Client Records. A post-mortem file is to be created and maintained separately. This file will include consent forms, reports etc. Copies of consent forms for post-mortems and reports are to be placed on the patient file (where applicable) with the retention periods applying as for patient files eg 15 years and 10 years.

An original or copy of an autopsy/post-mortem report should be maintained as part of the main (unit) patient record. Please note, where an integrated record is maintained, the record is to be retained for the longest retention period required for any part of the record.

Electronic records must be accessible for the length of the specified retention period. This means that some electronic records may need to be migrated over time and across systems to ensure continued accessibility. Electronic records must be protected to the extent that data cannot be amended without an audit trail of such amendments being available.

The Anatomy Act requires holders of Anatomy licences to maintain a register of bodies and human tissue. Each part of the register which contains particulars about a body or human tissue must be retained for at least 5 years from the date of the last entry made in the register. Please refer to paragraph 9.10 of this Circular for further information about this requirement.

7.3 Minimum Record or Register Requirements

All Public Health Organisations that manage stores of bodies, body parts or tissue retained from post-mortem examination, for any purpose, must maintain up-to-date secure and confidential registers that include a minimum of:

- full name of the deceased;
- date of birth;
- date of death;
- where the death occurred;
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- mother’s name if a child;
- a description of the tissue including:
  - the name of the tissue (e.g. heart);
  - the amount of tissue retained (whole, part);
  - the type and description of tissue retained (pathological, non pathological);
  - for limbs, the side of the person’s body the limb originates from;
  - what type of specimen the body part has been stored as (wet, waxed);
- whether the deceased was of Aboriginal or Torres Strait Islander descent;
- religion of the deceased (if known);
- how relevant autopsy reports may be accessed (laboratory number or medical record number);
- the cross referencing of tissues removed and retained from one body by all available identifiers - eg. Medical Record Number/Unit No.; post-mortem number; Pathology reference numbers; University record number etc.
- where the tissue is stored;
- use of the tissue and any conditions for which consent has been given.

7.4 Disposal of Tissue

Disposal of tissue removed for the purposes of the post-mortem examination or for other therapeutic, medical and scientific purposes must be carried out in accordance with the consent. The record or register should include:
- date of disposal;
- how the tissue was disposed of;
- if returned to family or the authorised delegate of the family, a form of signed receipt should be recorded and maintained with the record or register.

SECTION 8  HUMAN TISSUE ACT 1983 - OFFENCES AND ENFORCEMENT

8.1 Offences

The Human Tissue Act 1983 creates several offences, including the following:
- failing to obtain consent and/or authority to use, remove and retain tissue in accordance with the Act;
- authorising the removal of tissue, a post-mortem examination and the use of tissue removed post-mortem from a child who was in the care of the State immediately before his or her death;
- trading in human tissue; and
- without lawful excuse, neglecting or failing to comply with a requirement made by an inspector;
- furnishing any information or do any other thing in purported compliance with a requirement made by an inspector, knowing that it is false or misleading in a material respect; and
- hindering or obstructing an inspector in the exercise of any of his or her powers.

8.2 Prohibition on the Trade in Human Tissue

Section 32(1) of the Act provides that it is an offence to enter into a contract or arrangement under which any person agrees, for valuable consideration, to the sale or supply of tissue from a person either living or deceased, or to the post-mortem examination of any person after death.
Section 32 not only captures any contract or arrangement that might breach section 32(1) but also captures an offer to enter into such an arrangement.

8.3 Enforcement

The Director-General may appoint inspectors. An inspector may at any reasonable time enter and inspect any premises for the purpose of ascertaining whether or not a provision of the Act, or any regulation is being or has been complied with or contravened.

Inspectors Powers

While on premises an inspector has powers, including the power to one or more of the following:

- inspect all tissue and blood products kept on those premises, all containers that the inspector reasonably believes to contain or to have contained tissue or blood products, and all equipment kept on the premises that the inspector reasonably believes to be or to have been used for processing, packing or storing tissue or blood products;
- take and remove for analysis or testing a sample of any tissue or blood product kept on the premises, or anything the inspector reasonably believes to be tissue or blood products;
- inspect any records kept on those premises and require any person whom the inspector reasonably believes to have custody or control of those records to produce them for inspection;
- require any person on those premises to answer questions;
- take away and retain any records or other information, or any part of them, in order to make copies of them or to use them as evidence of an offence;
- seize and detain any tissue or blood product, or anything the inspector reasonably believes to be tissue or a blood product, any container in which any such tissue or blood product, or other thing, is kept, and any equipment;
- take such photographs, films, audio, video and other recordings, as the inspector considers necessary.

SECTION 9 ANATOMICAL EXAMINATIONS AND ANATOMY LICENCES - LEGAL REQUIREMENTS

9.1 General Introduction

Pursuant to the Anatomy Act 1977, the Director-General may grant licences to a person in charge of the “conduct of anatomical examinations” at any university, college, school or other educational institution. Licence holders are able to lawfully possess human bodies and tissue for the purposes of conducting anatomical examinations and are responsible for keeping a register of body parts and human tissue in their possession.

Pursuant to section 8 of the Anatomy Act 1977, if a person consents in writing, during his or her lifetime, to the anatomical examination of their body after death and he or she does not revoke his consent, the anatomical examination of his or her body can be authorised, subject to any terms and conditions specified in the consent.

This section covers the following topics:

- Anatomical examinations
- Delegation of functions of next-of-kin
- Anatomy licences
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- Authority for anatomical examination where the body of the deceased is at a hospital or forensic institution
- Authority for anatomical examination where the body of the deceased is not at a hospital or forensic institution
- Consent by Coroner
- An authority is not to be given in respect of child in care of the State
- Effect of authority
- Conditions of taking possession of body
- Duty to keep register
- Transfer of bodies
- Transfer of human tissue
- Disposal of bodies
- Permanent retention of tissue
- Bodies and tissue that were in the possession of a licence holder prior to the commencement of the amendments (1 November 2003)

Failure to comply with many of the requirements discussed below constitutes as an offence.

9.2 Anatomical Examinations

A new definition of “anatomical examination” has been included into the Anatomy Act to make it clear that such examination includes the use of the body for medical and scientific purposes. A reference to medical or scientific purposes includes educational purposes connected with medicine or science.

An anatomical examination does not include a post-mortem examination. An anatomy licence is not required in order to conduct post-mortem examinations.

9.3 Delegation of Functions of Next-of-Kin

The Anatomy Act addresses cultural sensitivities by allowing a next-of-kin of a deceased person to authorise another person to exercise his or her functions under the legislation. Any delegation of the functions of next-of-kin must be in writing.

The ability to delegate the functions of next-of-kin aims to recognise the kinship and other familial relationships that exist in cultural groups such as the Aboriginal and Torres Strait Islander cultures. For example, in the case of a death of an Aboriginal person or a Torres Strait Islander, the powers and duties of the senior next-of-kin would traditionally be exercisable by the designated culturally appropriate person of the family, extended family, clan or tribe to which the deceased person belonged.

9.4 Anatomy Licences

The Director-General may issue licences to persons to conduct anatomical examinations at a place specified in the licence.

Any person in charge of the conduct of anatomical examinations at any university, college, school, or other educational institution may apply for a licence.

The Director-General may impose terms and conditions on the licence and may revoke the licence at any time.
A licence issued and in force immediately before the commencement of the amendments made to the Human Tissue Act 1983 is still valid to authorise the conduct of anatomical examinations at the place specified in the licence as the place at which the study and practice of anatomy may be conducted, after the amendments commence.

9.5 Authority for Anatomical Examination Where the Body of the Deceased is at a Hospital or Forensic Institution

Authority for Anatomical examination Where Body of Deceased is at a Hospital or Forensic Institution and the deceased had given written consent in their lifetime for an anatomical examination.

If a Designated Officer for a hospital or forensic institution is satisfied, after making reasonable inquires about an adult deceased person whose body is at the hospital or forensic institution, that:
(a) the person, had, during their lifetime, given their consent in writing to the anatomical examination of their body after death; and
(b) that consent had not been revoked,
the Designated Officer may authorise the anatomical examination of that person’s body. The Designated Officer’s authorisation must be in writing.

Authority for Anatomical examination Where Body of Deceased is at a Hospital or Forensic Institution and the deceased had not given written consent in their lifetime for an anatomical examination.

If a deceased adult had not, during their life, given written consent to an anatomical examination of their body after death, or if the Designated Officer is not satisfied that this had occurred, or the deceased is a child, the Designated Officer should pursue the following enquires:
• establish that the deceased had not, during life, expressed an objection to an anatomical examination of their body after death, then ascertain that a senior available next-of-kin has given their consent in writing to the anatomical examination of the deceased; and
• ascertain that there is no senior available next-of-kin of the same or higher order in the hierarchy of “senior available next-of-kin” who objects to the removal of tissue from the person’s body.

The Designated Officer may then, in writing, authorise the anatomical examination of the deceased, in accordance with any terms or conditions placed on the consent by the deceased or the senior available next-of-kin.

Authority for Anatomical examination Where Body of Deceased is not at a Hospital or Forensic Institution and the deceased had given written consent in their lifetime for an anatomical examination.

If the body of a deceased person (other than a deceased child) is at a place other than a hospital or forensic institution, and:
(a) the person, had, during their lifetime, given their consent in writing to the anatomical examination of their body after death; and
(b) that consent had not been revoked,
the anatomical examination of that person’s body is authorised, in accordance with any terms or conditions placed on the consent.
Authority for Anatomical examination Where Body of Deceased is *not* at a Hospital or Forensic Institution and the deceased had *not given written consent* in their lifetime for an anatomical examination.

If the body of a deceased person is at a place other than a hospital or forensic institution, a senior available next-of-kin can authorise the anatomical examination of that person’s body, if:

- the deceased person had not expressed an objection to the anatomical examination of their body during their lifetime; and
- there is no senior available next-of-kin of the same or higher order in the hierarchy of “senior available next-of-kin” who objects to the removal of tissue from the person’s body.

### 9.6 Consent by Coroner

A Designated Officer for a hospital or forensic institution or a senior available next-of-kin cannot authorise the anatomical examination of the body of a person in respect of whose death a coroner has jurisdiction to hold an inquest under the *Coroners Act 2009* unless a Coroner has given consent to the examination.

Consent by a Coroner may be expressed to be subject to such conditions as are specified in the consent. Consent by a Coroner under this section may be given *orally* and, if so given, is to be confirmed in writing as soon as practicable.

### 9.7 An Authority is Not to be Given in Respect of Child in Care of the State

A person must not authorise the anatomical examination of the body of a deceased child if the child was, immediately before his or her death, in the care of the State.

### 9.8 Effect of Authority

An authority provided by a Designated Officer (if the body of a deceased was at a hospital or a forensic institution) or by a senior available next-of-kin (if the body of the deceased was not at a hospital or forensic institution) is sufficient authority for:

- a person who has lawful possession of a body to cause or permit the body to be used by a holder of a licence for anatomical examination in accordance with the authority; and
- for the holder of a licence, to conduct an anatomical examination of the body, at licenced premises, in accordance with the authority, subject to the terms and conditions of the licence.

### 9.9 Conditions of Taking Possession of Body

The holder of a licence cannot take possession of a body for anatomical examination, other than a body transferred from another licence holder, unless:

- the holder is permitted to use the body for anatomical examination pursuant an authority given by a Designated Officer or a senior available next-of-kin; and
- where section 53A of the *Coroners Act 2009* applies, the holder is satisfied that a document referred to in that section has been signed, issued, made or given in relation to the body.

Section 53A of the *Coroners Act* states that a person must not deliver or hand over human remains for anatomical or medical research from the State, or cause such remains to be so delivered, handed over or removed, unless a document authorising the disposal of the remains.
has been signed, issued or made or the disposal of the remains is otherwise authorised by the regulations. Licence holders accepting deliveries of bodies from the State Coroner must ensure that they also receive the relevant document authorising the release of the body.

9.10 Duty to keep register

The holder of a licence must keep a register of bodies in their possession. On taking possession of a body, the following minimum details must be entered in the register:
• the name and address of the person who had lawful possession of the body and who delivered the body into the holder’s possession;
• the date on which the holder took possession of the body; and
• the date, place and cause of death of the deceased and the sex, name, age and last place of abode of the deceased.

The holder of a licence must produce the register to an inspector, if requested to do so. The register must be retained for at least 5 years from the date of the most recent entry.

9.11 Transfer of bodies

The holder of a licence may transfer a body which is in the holder’s possession:
• to another holder of a licence; or
• with the approval of an inspector, to any person who is in charge of the conduct of anatomical examinations at any place outside New South Wales

for anatomical examination unless the holder has reason to believe that to do so would be contrary to the wishes of the deceased or the senior available next-of-kin of the deceased.

When a body is transferred, a copy of the particulars contained on the register relating to that body must also be transferred with the body. When a body is transferred, the licence holder must enter the following details on the register:
• the fact that the body was transferred;
• the date on which the body was transferred; and
• the name and address of the person to whom the body was transferred.

9.12 Transfer of human tissue

The Act formally made provision for the transfer of bodies between institutions licenced under the Act, but was silent regarding the transfer of tissue between licencees. The Anatomy Act now allows for the transfer of human tissue from a body that is in the possession of a licenced institution to another holder of a licence, an authorised officer of a hospital, or a person approved by the Director-General for use for medical or scientific purposes. Such transfer will not be permitted where it is contrary to the authority given by the deceased or the next-of-kin.

The holder of a licence may transfer human tissue from a body which is in the holder’s possession for anatomical examination:
• to another holder of a licence; or
• to an authorised officer of a hospital; or
• to an authorised officer of an interstate hospital; or
• to any other person approved in writing by the Director-General.

for use for medical or scientific purposes, unless the holder has reason to believe that to do so would be contrary to the wishes of the deceased or the senior available next-of-kin of the deceased.
The licence holder must ensure that arrangements are made for the return of the human tissue as soon as practicable, and by no later than the end of the period within which the tissue is required to be disposed of.

When human tissue is transferred, the licence holder must enter the following details on the register:
- the fact that the human tissue was transferred;
- the date on which the human tissue was transferred;
- the name and address of the person to whom the body was transferred and of the licenced premises, hospital or other place where the human tissue is to be retained; and
- details of the arrangements made with respect to the return of the human tissue.

9.13 Disposal of Bodies

The holder of a licence must dispose of any body which is in the holder’s possession for anatomical examination (including any human tissue from that body):
(a) within 4 years after the death of the deceased person, or
(b) in accordance with the terms of an authorisation granted by an inspector.

An inspector may, by instrument in writing, authorise:
- the retention of a body for anatomical examination for a period specified by the inspector, being a period that does not end more than 8 years after the death of the deceased person;
- the retention of human tissue from a body (whether for a specified period or otherwise).

When authorising the retention of a body or human tissue for a period over 4 years, an inspector must consider the purposes for which the retention of the body or tissue is sought and must ensure that the further retention complies with any terms and conditions placed on the original consent given by the deceased or the next-of-kin.

The holder of a licence must comply with any terms or conditions that are imposed by an inspector in granting an authorisation for the retention of a body or human tissue and must enter details of the authority in the register.

9.14 Permanent Retention of Tissue

Specific provision has been made in the *Anatomy Act* for the permanent retention of tissue where express written consent has been given by the deceased prior to death. Where no consent has been given and the wishes of the deceased in this respect are unknown, the senior available next-of-kin may consent. However, no consent is required for the retention of tissue in the form of tissue blocks and slides.

Permanent retention of human tissue can be expressly authorised:
- by the consent in writing of the deceased person given during his or her lifetime (except in the case of a deceased child); or
- by the consent in writing of the senior available next-of-kin of the deceased person;
- small samples of human tissue that are retained in the form of tissue slides or tissue blocks that enable microscopic examination of the tissue can be retained without specific authority.
9.15 Bodies and Tissue That Were in the Possession of A Licence Holder Prior to the Commencement of the Amendments (1 November 2003)

The new requirements relating to the disposal and retention of bodies and human tissue apply to a body that is in the possession of a holder of a licence for anatomical examination immediately before the commencement of those amendments, including any human tissue from that body.

Bodies that are not subject to an existing authority to retain them for more than 4 years should be disposed of within 4 years from the date of death of the deceased person.

Bodies that are subject to an existing authority allowing them to be retained for more than 4 years can be retained for a further 4 years from 1 November 2003, i.e. until 31 October 2007, regardless of the date of death of the deceased.
SECTION 10 FORMS AND APPENDICES.

Forms

Title

Request/Consent for Medical Treatment Form (Adult & Child)

Consent to Donation of Tissue By an Adult
(with Medical Practitioners Certificate) (Form A)

Donation of Regenerative Tissue by a Child
(with medical Practitioners Certificate) (Form B)

Consent and Authority for Removal of Tissue After Death

Consent for Non - Coronial Post-mortem Examination

Consent for the Use of Human Tissue following a Coronial Post-mortem Examination for Therapeutic, Medical or Scientific Purposes Excluding Organ Donation for Transplantation.

Authorisation to Delegate Responsibilities of the Next-of-Kin

Documenting family objection to organ/tissue donation contrary to the known wishes of the donor form

GIVE Clinical Trigger Poster

Certification of Brain Death Form

Certification of Cardiac Death Form

Donor Medical History and Behavioral Risk Assessment

Implementation Checklist

Appendices

Appendix 1 Information for the Next-of-Kin Regarding Consent for A Non-Coronial Post-Mortem

Appendix 2 Procedures for the return of tissue to the Patient/Next-of-kin
FIRST NAME

LAST NAME

ADDRESS

DATE

DIAGNOSIS

POSSIBLE RESULT

ADMISSION DATE

I, Dr. .................................................. have informed this parent/guardian * as detailed below including the nature, likely results, and material risks of the recommended procedure or treatment.

Interpreter present *

.................................................. (Signature of Interpreter)

.................................................. (Signature of Medical Practitioner)

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

I understand that I may withdraw my consent.

* I have been told that the procedure/treatment may be performed by another doctor.

I request and consent to the procedure/treatment described above for ........................................

While I consent to the above procedure/treatment, after discussing this matter with doctor, I refuse consent for my child to the following aspects of the recommended procedure or treatment:

* This text must be countersigned by your doctor if included

I note that the Children (Care and Protection) Act 1987 provides that such treatment may be provided notwithstanding my objection if it is necessary to prevent death or serious injury to my child.

I also consent to anaesthetics, medicines or other treatments which could be related to this procedure/treatment:

........................................ (Signature of Patient or Guardian) / J.20........ (Post name of patient or guardian)

........................................ (Address) * Delete where applicable
**REQUEST/CONSENT FOR MEDICAL PROCEDURE TREATMENT**

(For patients 14 years and above - not for Guardianship Act purposes)

**PROVISION OF INFORMATION TO PATIENT**

To be completed by Medical Practitioner

I, Dr. [full name of medical practitioner] have informed this patient as detailed below including the nature, likely results, and material risks of the recommended procedure or treatment.

Interpreter present *

[Signature of Interpreter]

[Signature of Medical Practitioner]

**PATIENT CONSENT**

To be completed by Patient

Dr. [full name of medical practitioner] and I have discussed my present condition and the various ways in which it might be treated. The doctor has recommended:

[Insert name of procedure or treatment]

The doctor has told me that:

- the procedure/treatment carries some risks and that complications may occur;
- an anaesthetic, medicines, or blood transfusion may be needed, and these may have some risks;
- additional procedures or treatments may be needed if the doctor finds something unexpected;
- the procedure/treatment may not give the expected result even though the procedure/treatment is carried out with due professional care.

I understand the nature of the procedure and that undergoing the procedure/treatment carries risks.

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

I understand that I may withdraw my consent.

* I have been told that the procedure/treatment may be performed by another doctor.

I request and consent to the procedure/treatment described above for me.

**REFUSAL**

While I consent to the above procedure/treatment, after discussing this matter with doctor, I refuse consent to the following aspects of the recommended procedure or treatment:

[Insert refusal]

This part must be countersigned by your doctor if refused.

**ACKNOWLEDGEMENT**

I also consent to anaesthetics, medicines or other treatments which could be related to this procedure/treatment.

I consent/do not consent* to a blood transfusion if needed.

[Signature of Patient] [Date] [Print Name of Patient]

[Signature of Medical Practitioner]

[Address]

* Delete where applicable
FORM A

HUMAN TISSUE ACT 1983
DONATION OF TISSUE BY AN ADULT

Name of Donor

Aged

Address of Donor

DONOR'S CONSENT

I, ____________________________

(name of donor)

of ____________________________

(address of donor)

being an adult of sound mind, freely consent to the removal of

__________________________

(type of tissue)

being *regenerative/*non-regenerative tissue, from my body:

* for transplantation to the body of another living person.

* in the case of regenerative tissue, for use for other therapeutic purposes or for medical purposes or scientific purposes.

Dr ____________________________

(name of certifying doctor)

has explained to me to my satisfaction the nature and effect of the removal of the tissue.

Signature of donor ____________________________

Date ____________________________

* Delete if not applicable
MEDICAL PRACTITIONER’S CERTIFICATE

I, __________________________________________________________________________
(name of medical practitioner)

of __________________________________________________________________________
(address of medical practitioner)

being a medical practitioner registered in New South Wales, hereby certify that:

(a) the above consent was given in my presence;

(b) I explained to the abovenamed donor, before the consent was given, the nature and effect of the removal from his/her body of the tissue specified in the consent;

(c) I am satisfied that, at the time the consent was given:

(i) the donor was not a child;

(ii) the donor was of sound mind; and

(iii) the consent was freely given.

Signature of medical practitioner ________________________________

Date ________________________________
FORM B

HUMAN TISSUE ACT 1983

DONATION OF REGENERATIVE TISSUE BY A CHILD

Name of Donor ______________________________________ Age ______

Address of Donor ______________________________________________________

PARENT’S CONSENT

I, __________________________________________________________

(name of mother or father)

of ______________________________________________________________

(address of mother or father)

being the *mother/*father of the abovenamed child, consent to the removal of:

___________________________________________________________

type of tissue

being regenerative tissue, from the body of my abovenamed child for the purpose of transplanting

the tissue to the body of:

___________________________________________________________

(name of recipient)

who is the ______________________________________________________ of the donor.

(brother/sister/mother/father)

Dr ___________________________________________________________

(name of certifying doctor)

has explained to me to my satisfaction the nature and effect of the removal of the tissue and the

intended effect of the transplantation.

Signature of parent ___________________________________________

Date _________________________________________________________

* Delete if not applicable
MEDICAL PRACTITIONER’S CERTIFICATE

I, ________________________________
(name of medical practitioner)

of ________________________________
(address of medical practitioner)

being a medical practitioner registered in New South Wales, hereby certify that:

(a) the above consent was given in my presence;

(b) I explained to the abovenamed parent(s) and to the child, before the consent was given, the nature and effect of the removal the child’s body of the tissue specified in the consent and the intended effect of the proposed transplantation;

(c) I am satisfied that, at the time the consent was given:

   (i) the parent(s) and the child were each of sound mind;

   (ii) the parent(s) and the child each understood the nature and effect of the removal of the tissue and the intended effect of its proposed transplantation;

   (iii) the consent was freely given; and

   (iv) the child was in agreement with the proposed removal and transplantation of the tissue.

Signature of medical practitioner ________________________________

Date ________________________________
26. TISSUE/ORGAN

Consent and Authority For Removal Of Tissue After Death

This form is to be completed for removal of tissue after death for the purpose of transplantation to the body of a living person and/or for therapeutic or medical or scientific purpose(s).

Consent (Circle either A, B or C)
A. Consent of Deceased (Attach written consent of the deceased or a copy of the consent document and proceed to the Authorisation by Designated Officer).
   Or
B. Consent of Senior Available Next-of-kin /Delegate (Attach written authorisation of delegate if applicable)
   Or
C. Consent by audio or audio-visual recording (Complete the following information and proceed to the authorisation by the Designated Officer).
   Audio Recording Device No. Date Time
   ___________ ___________
   Address

If applicable;
1. [ ] I have no reason to believe that the deceased has expressed an objection to the removal of Blood vessels, lymphoid tissue, section of spleen and blood for tissue typing, blood for disease screening, cross matching and transplantation purposes. (Routinely retrieved)
2. [ ] Heart/Cardiovascular tissue (heart valves)
3. [ ] Lungs
4. [ ] Liver
5. [ ] Pancreas/Pancreas islets
6. [ ] Kidneys
7. [ ] Musculoskeletal tissue (bones from upper and lower limbs, including the pelvis, tibendas and ligaments from knees and ankles)
8. [ ] Section of spleen for research
9. [ ] Other (please specify)

From his/her body after death for the purpose of [*delete if not applicable]
*Transplantation to the body of a living person.
*Use for other therapeutic purposes or medical purposes or scientific purposes.
2. [ ] I have no reason to believe that an equal or more senior next-of-kin to the deceased has an objection to the removal of the above mentioned tissue for such purposes.
3. [ ] I understand that support interventions will continue until the removal of tissue and that procedures to preserve organ function will be undertaken as appropriate.
4. [ ] Any issue removed and not utilised in accordance with point 1, (subject to Coronial approval as applicable), is to be [*delete if not applicable]
   *Reunited with the body
   *Disposed of respectfully in accordance with hospital procedures

Name (Print) of senior available next-of-kin:

Signature:

Relationship to the deceased:

Date:

Officer requesting consent:

I have explained the nature, purpose and likely consequences of organ and tissue donation to the senior available next-of-kin signing this document.

Name (Print): Signature:

Designation:

Date:

Healthcare Interpreter (if applicable):

Signature:

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

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26. TISSUE/ORGAN

<table>
<thead>
<tr>
<th>FAMILY NAME</th>
<th>M/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>GIVEN NAME</td>
<td></td>
</tr>
<tr>
<td>DATE OF BIRTH</td>
<td>/ /</td>
</tr>
<tr>
<td>M/O</td>
<td></td>
</tr>
</tbody>
</table>

Facility:

Consent And Authority For The Removal Of Tissue After Death

Location / Ward

COMPLETE ALL DETAILS OR ATTACH PATIENT LABEL HERE

Removal of tissue cannot be authorised without written consent of the deceased or the consent of a senior available next-of-kin. If the deceased did not provide written consent during their lifetime and no next-of-kin is available to consent either in writing or by audio or audio visual means, the designated officer cannot authorise the removal of tissue.

1. (Name of Designated Officer)

   Hereby state that, having made such enquiries as are reasonable in the circumstances, I am satisfied that:
   1. the above named deceased person had during his/her lifetime, consented in writing to the removal after death of tissue from his/her body for the purpose(s) set out below and that he/she had not revoked the consent (attach deceased's written consent document);
   Or
   2. Hereby state that the above named deceased had not during his/her lifetime, expressed an objection to the removal of tissue from his/her body after his/her death, or, if he/she had expressed such an objection, based on the most recent views expressed by him/her, he/she no longer had an objection to the removal of tissue from his/her body.
   And
   3. That the senior available next of kin or their delegate has provided written consent, or an audio or audio visual consent, to the removal after death of tissue from the deceased's body for the purpose(s) set out below.
   And
   4. Where applicable that the consent of the Coroner to the removal and use of tissue after death has been given subject to the following conditions:

   [specify Coroner's conditions on removal and use of tissue if applicable]

2. Hereby authorise the removal of the following tissue from the body of the above named deceased (*delete if not applicable):

   Blood vessels, lymphoid tissue, section of the spleen and blood for tissue typing, Blood for disease screening, cross matching and transplantation purposes.
   - [ ] Heart/Cardiovascular tissue (heart valves)
   - [ ] Lungs
   - [ ] Liver
   - [ ] Pancreas/Pancreas islets
   - [ ] Kidneys
   - [ ] Eyes
   - [ ] Musculoskeletal tissue (bones from the upper and lower limbs, including the pelvis, tendons and ligaments from the knees and ankles)
   - [ ] Section of spleen for research
   - [ ] Other (please specify) __________________________

From his/her body after death for the purpose of (*delete if not applicable):

   * Transplantation to the body of a living person;
   * Use for other therapeutic purposes or medical purposes or scientific purposes.

Signature: __________________________ Date: / /

Designated Officer: [Designated officer]

Definitions

Designated Officer: A Designated Officer means:

- In a relation to a hospital, a person appointed under ss 1 of (1) (a) of the Human Tissue Act 1983, to be a Designated Officer for a hospital, or
- In relation to a forensic institution, a person appointed under ss 1 of (1) (a) of the Human Tissue Act 1983, to be a Designated Officer for the forensic institution, or
- In relation to a private hospital within the meaning of the Private Hospitals and Day Procedure Centre Act 1996 a person appointed by a governing body (defined by the Act as the licensed hospital) Hospital

Hierarchy of Next of Kin: Next of kin of a deceased adult means, in the following order of seniority

1. a person who was a spouse or de facto (including same sex partner) of the deceased immediately before the person's death;
2. where the deceased person has no spouse or the spouse is not available, a son or daughter of the deceased person, who has attained the age of 18 years;
3. where no person referred to in 1. or 2. is not available, a parent of the deceased person;
4. where no person referred to in 1. 2. or 3. is available, a brother or sister of the deceased person, who has attained the age of 18 years.

Next of kin of a deceased child means, in the following order of seniority:

1. a parent of the child;
2. where a parent to the child is not available, a brother or sister of the child, who has attained the age of 18 years;
3. where no person referred to in point 1. 2. is available, a person who is guardian of the child immediately before the child's death.

This space for information, notations, initial dates, etc.

173(24/01/13)
FORM 5

Consent for non-coronial post-mortem examination

This consent applies to post-mortem examination following any non-coronial death, including examination of stillborn babies and foetuses less than 20 weeks gestation.

Note: Copies of this form must be retained as part of the post-mortem record; placed in the deceased person’s notes; and given to the senior next-of-kin who signed it.

Person obtaining consent:

Full name: ____________________  Surname   ____________________  First name ____________________

Person’s Position: ____________________________________________________

Contact: Phone ____________________  Pager ____________________

Full name of deceased:   Surname  _______________  First name  _______________

MRN _________________  DOB ___/___/___  Date of Death ___/___/___

A. WHERE DECEASED HAS GIVEN CONSENT FOR A POST-MORTEM EXAMINATION DURING THEIR LIFETIME

Attach evidence of the consent of deceased.

B. WHERE CONSENT IS BEING OBTAINED FROM SENIOR AVAILABLE NEXT-OF-KIN

Full name of senior available next-of-kin: Surname:____________   First name _________ of (address):__________________________________________   Post code: __________

Relationship of senior available next-of-kin to deceased: ___________________________

Optional: Is the deceased an Aboriginal person or Torres Strait Islander? [tick if applicable] 

C. WHERE CONSENT IS BEING OBTAINED FROM A DELEGATE OF THE SENIOR NEXT-OF-KIN

Attach written authorisation of delegate (APPENDIX C)

1. I consent to the following being carried out on the above named deceased: [tick where applicable]

   ☐ a full post-mortem examination of the deceased
   OR
   ☐ a limited post-mortem examination of the deceased

   The following organs, body parts or body cavities are not to be removed or opened:

2. I also consent to: [tick where applicable]

   ☐ The retention of organs and other body parts for diagnostic testing.
   The following organs or body parts are not to be retained:

   ☐ The retention of __________________________ (specify organs or body parts) for __________________________ (specify research study)

   ☐ The retention of organs and other body parts for scientific, therapeutic, and medical purposes (see information sheet overleaf).
The following organs or body parts are **not** to be retained

1. I wish any organs and other body parts to be: [tick where applicable]
   - Returned to the body prior to burial;
   - Returned to me or a person nominated by me (if practicable),

Name of nominated person ____________ Relationship with nominated person ____________

   OR

- Disposed of in a lawful manner by the hospital.

I also request the following:

Please send a copy of the post-mortem report to:_________________________

Address:________________________________________________________

Please ensure the body is ready for the funeral: Date:___/____/______ Time _________

4. 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.

5. The nature of the post-mortem examination and the way that tissue from the deceased’s body will be dealt with has been explained to me. I have had the opportunity to ask questions. I am satisfied with the explanation and the answers to my questions.

---

**Signature of the senior available next-of-kin or authorised delegate** ________________

**Signature of doctor** ____________________________ Date: ___/___/______

Interpreter present: [ ] yes [ ] no Interpreter’s signature ______________________________

Authority by a Designated Officer of the hospital for post-mortem examination and the use of tissue for medical, therapeutic and scientific purposes (*Human Tissue Act 1983*).

I, ____________________________ hereby authorise: [tick where applicable]

- 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.

---

**Signature of Designated Officer** __________________ Date: ___/___/______

**Designated Officers**

A Designated Officer must not act in any case in which he/she has a personal interest or clinical involvement. Designated Officers may be determined by the Area Health Service board and might include: Staff and Visiting Medical Officers; Surgeons and Anaesthetists; Chief Resident Medical Officer; Medical Administrators; Director of Nursing; Deputy Director of Nursing; Senior Nurse Managers; Administration manager.
Consent for Use of Human Tissues following a Coronal Post-mortem Examination for Therapeutic, Medical or Scientific Purposes Excluding Organ Donation for Transplantation

This consent applies to retention of tissues from coronal post-mortem examinations following any coronial death.

Note: Copies of this form must be retained as part of the post-mortem record; placed in the deceased person’s notes; and given to the next-of-kin who signed it.

Person obtaining consent:
Full name: __________________  Surname __________________  First name __________________
Person’s Position: ______________________________________________________
Contact: Phone __________________  Pager      _________________
Full name of deceased: Surname __________________  First name __________________
MRN _________________ DOB ___/___/______  Date of Death ___/___/______

A. WHERE DECEASED HAS GIVEN CONSENT FOR USE OF TISSUES FOR THERAPEUTIC, MEDICAL, OR SCIENTIFIC PURPOSES DURING THEIR LIFETIME
Attach evidence of the consent of deceased.

B. WHERE CONSENT IS BEING OBTAINED FROM SENIOR AVAILABLE NEXT-OF-KIN
Full name of senior available next-of-kin: Surname:_____________First name ___________
of (address):__________________________________________ Post code: ___________
Relationship of senior available next-of-kin to deceased:__________________________
Optional: Is the deceased an Aboriginal person or Torres Strait Islander? [tick if applicable]  

C. WHERE CONSENT IS BEING OBTAINED FROM A DELEGATE OF THE SENIOR NEXT-OF-KIN
Attach written authorisation of delegate (APPENDIX C)

1. I consent to: [tick where applicable]
   □ The retention of __________________________(specify organs or body parts) for  
   ______________________________________(specify research study)
   □ The retention of organs and other body parts for scientific, therapeutic, and medical purposes
   (see information sheet overleaf).
   The following organs or body parts are not to be retained
2. I wish any organs and other body parts to be: [tick where applicable]
   - Returned to me or a person nominated by me (if practicable);
     Name of nominated person __________ Relationship with nominated person __________
   - Disposed of in a lawful manner by the public health organisation.

3. I have no reason to believe that the deceased had expressed any objection to use of the organs from the post-mortem examination.

4. The way that organs from the deceased’s body will be dealt with has been explained to me. I have had the opportunity to ask questions. I am satisfied with the explanation and the answers to my questions.

Signature of the senior available next-of-kin or authorised delegate

Signature of person obtaining consent __________ Date: ____/____/____

Interpreter present: ☐ yes ☐ no Interpreter’s signature __________

D. CORONERS CONSENT

The Coroner’s consent is required for the use of tissue removed for the purposes of the post-mortem for other therapeutic, medical or scientific purposes. This consent may be given verbally but must be confirmed in writing as soon as practicable.

Name of coroner from whom consent was obtained ______________

Time and date obtained ______________________

Person by whom obtained ______________________

Any conditions upon consent __________________________________

Authority by a Designated Officer in the Area administering to the relevant facility/department of forensic medicine for the use of tissue for medical, therapeutic and scientific purposes (Human Tissue Act 1983).

I, ______________________ hereby authorise:

[full name of Designated Officer]

use of tissue removed for the purposes of the post-mortem examination for other scientific, therapeutic, and medical purposes, as set out in the above consent.

Signature of Designated Officer __________ Date: ____/____/____

Designated Officers

A Designated Officer must not act in any case in which he/she has a personal interest or clinical involvement. Designated Officers may be determined by the Area Health Service board and might include: Staff and Visiting Medical Officers; Surgeons and Anaesthetists; Chief Resident Medical Officer; Medical Administrators; Director of Nursing; Deputy Director of Nursing; Senior Nurse Managers; Administration manager.
ss5A 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 ss5A of the Human Tissue Act 1983.

Print name of authorised person (Delegate): __________________________

Signature: __________________________ Date: ___/___/___
This form is to be completed by the requesting clinician indicating the reasons for family objection to organ donation proceeding contrary to the known decision of the donor. Once completed, the form should be signed by the Designated Officer and a copy placed in the patient’s medical record.

The decision to not proceed with organ/tissue donation in this context depends on the presence of strong and sustained family objection in spite of appropriate information provision and time to reflect.

Details of information provided to the family (e.g. seeking family support for known donor wishes, addressing misperceptions):

___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________

Family members or other close to the patient participated in the discussion:
Full name of Senior Available Next-of-Kin:
Surname __________________________________First name ___________
Relationship of Senior Available Next-of-Kin to deceased: ____________________________
Other significant family members or individuals close to the patient who were involved in the discussion___________________________________________________________________________
_____________________________________________________________________

Details of objections or reasons raised by the Senior Available Next-of-Kin or family:
☐ Verbal withdrawal of consent by patient;
☐ Family believed that religious considerations make donation inappropriate;
☐ Family believed that cultural considerations make donation inappropriate;
☐ Family believed patient would not want to donate;
☐ Family had an aversion to the idea of organ donation;
☐ Family did not accept that death was imminent or had occurred;
☐ Family dissatisfied with patient care;
☐ Family not prepared to wait for time required to organise donation;
☐ Family felt that the patient had “suffered” or been through enough;
☐ Family did not want the patient to be cut up;
☐ Family felt that organs should only go to specific recipients or certain types of people; or
☐ Other (including where no reason is disclosed)
(describe)___________________________________________________________________________
______________________________________________
Were there any extenuating family or patient circumstances considered relevant to the decision to not proceed with donation?

☐ No
☐ Yes

If so, describe

_________________________________________________________________

_________________________________________________________________

Requesting clinician

Full name: Surname ______________________ First name _______________

Person’s Position: ________________________________________________

Signature of requesting clinician________________ Date: ____/_____/______

Designated Officer

I confirm that the donation will not proceed because of these objections. I have reviewed the above documentation and confirm that reasons for family objection are cited.

Full name: Surname ______________________ First name _______________

Signature of Designated Officer __________________ Date: ____/_____/______
Have you given your patient the opportunity to G.I.V.E?

GIVE

GCS ≤5  Intubated  Ventilated  End of life care

www.donatelife.gov.au
For the purposes of the law of NSW, a person has died when there has occurred (a) irreversible cessation of all function of the person’s brain. (s 33 Human Tissue Act 1983) A designated officer shall not give an authority to remove tissue from a deceased person for its use for transplantation unless each of 2 medical practitioners has certified in writing that the following has occurred.

Known cause of irreversible loss of brain function

There is acute brain pathology consistent with the irreversible loss of brain function.

Doctor A: Specify condition

Doctor B: Specify condition

Period of continuous observation of apparent loss of neurological function

There has been at least a 4 hour period of observation (24 hours for hypoxic-ischaemic anoxia and hypotension and mechanical ventilation during which the patient has unresponsive coma, with pupils non-reactive to light, absent oculo-radiculal reflex and no spontaneous breathing efforts.

This period began at (Date and time)

Determination of brain death by clinical examination

Preconditions

1. Hypothermia is not present - temperature is > 35°C Specify Temperature:

2. Blood pressure is adequate (eg MAP>60 in an adult)

3. Sedative drug effects are excluded

4. There is no severe electrolyte, metabolic or endocrine disturbance

5. Neuromuscular function is intact

6. It is possible to examine the brain-stem reflexes (including at least one ear and one eye)

7. It is possible to perform apnoea testing

Clinical Testing

1. There is no motor response in the cranial nerve distribution to noxious stimulation of the face, trunk and four limbs and there is no response in the trunk or limbs to noxious stimulation within the cranial nerve distribution.

2. There are no pupillary responses to light

3. There are no corneal reflexes

4. There is no gag (pharyngeal) reflex

5. There is no cough (tracheal) reflex

6. There are no vestibulo-ocular reflexes on ice-cold calorics testing

7. Breathing is absent (Despite arterial PCO2 > 60mmHg (8kPa) and arterial pH < 7.30)

8. Specify PCO2 in mmHg or kPa (from one) and pH at end of apnoea

Determination of brain death when clinical examination cannot be done:

1. There is no intracranial blood flow

2. (Specify, as appropriate) This has been demonstrated by either intra-arterial angiography or other suitably reliable method

We have determined, according to the above procedures, that irreversible cessation of all function of the person’s brain has occurred:

Doctor A (Name): __________________________

Status: __________________________

Signature: __________________________

Date and time of assessment: __________________________

Doctor B (Name): __________________________

Status: __________________________

Signature: __________________________

Date and time of assessment: __________________________
Organ donation - certification of death determined by absence of vital signs following circulatory death.

For the purposes of the law of NSW, a person has died when there has occurred: (b) irreversible cessation of circulation of blood in the person’s body. (§ 33 Human Tissue Act 1983).

For the purposes of organ donation after cardiac (circulatory) death (DCD) death will be determined to have occurred when the attending Intensivist, or other designated doctor determines that there is irreversible cessation of circulation of blood in the person’s body and certifies that A and B have occurred and all of the features in C are present.*

A. Intensive therapies (including endotracheal tube, ventilatory support, inotropic support) were withdrawn at _________ hrs (24 hour clock) on __/__/_____

B. I have determined by the absence of vital signs that death has occurred.

C. All of the following features were present: (please mark with X)

☐ Immobility
☐ Apnoea
☐ Absent Skin Perfusion
☐ Absence of pulsatility on the arterial line of at least 2 minutes duration

Death occurred at _________ hrs (24 hour clock) on __/__/_____

Doctor (print name): ________________________________
Status: _________________________________________
Signature: _______________________________________

*(based on criteria developed by the Australian New Zealand Intensive Care Society: The ANZICS Statement On Death And Organ Donation edition 3.1 2010).
# DONOR MEDICAL HISTORY and BEHAVIOURAL RISK ASSESSMENT QUESTIONNAIRE

**Source of Information**

| Interview with NOK | | |
| Interview with other | | |
| Medical Notes | | |
| Attending Doctor | | |
| GP | | |
| Coroner's Police | | |
| Other | | |

**Person Conducting interview and completing form**

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Contact</th>
</tr>
</thead>
</table>

**Person/Persons interviewed**

**Relationship to potential donor**

**Place of Interview / telephone**

**Date / Time of interview**

The interviewer should comment and elaborate on all questions answered "yes".

**Has your relative had any of the following:**

1. History of heart disease? (including family history)
2. History of high blood pressure?
3. History of diabetes? Has treatment been with oral medication or insulin?
4. History of asthma or any lung disease or been treated for tuberculosis (TB) or atypical pneumonia?
5. History of kidney disease?
6. Had any history of liver disease? jaundice? Any contact with persons diagnosed with hepatitis in past 12 months?
7. A history of any eye disease, infection, cataracts, corneal disease, or operations involving the eyes?
8. A history of arthritis or joint disease? Eg. osteomyelitis, osteoporosis, Paget's Disease, rheumatoid arthritis, connective tissue disease such as systemic lupus erythematosus?

**Has your relative:**

9. Been hospitalised in the past 2 years?
10. Had any serious illnesses or operation performed in the past?
11. Taken any medications on a regular basis?
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Ever been exposed to toxic substances, i.e. lead,</td>
<td></td>
</tr>
<tr>
<td>pesticides or other?</td>
<td></td>
</tr>
<tr>
<td>13. In the past 3 years, travelled outside Australia? Taken any</td>
<td></td>
</tr>
<tr>
<td>anti-malarial drugs? Had malaria/typhus?</td>
<td></td>
</tr>
<tr>
<td>14. Did your relative live in or visit England, Scotland, Wales,</td>
<td></td>
</tr>
<tr>
<td>Northern Ireland, Channel Islands or Isle of Man for a total period of</td>
<td></td>
</tr>
<tr>
<td>5 months or more, between 1/1/1980 to 3/12/96 inclusive?</td>
<td></td>
</tr>
<tr>
<td>17. Ever received an organ or tissue transplant?</td>
<td></td>
</tr>
<tr>
<td>18. In the past 12 months, had a tattoo, body piercing,</td>
<td></td>
</tr>
<tr>
<td>acupuncture or accidental needlestick?</td>
<td></td>
</tr>
<tr>
<td>18. Ever had cancer or received drugs or radiotherapy for cancer?</td>
<td></td>
</tr>
<tr>
<td>19. Been vaccinated or immunised in the past 12 months for any reason?</td>
<td></td>
</tr>
<tr>
<td>20. Ever been given human pituitary derived growth/fertility hormone?</td>
<td></td>
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<tr>
<td>21. Ever suffered any type of dementia or brain disease such as:</td>
<td></td>
</tr>
<tr>
<td>Alzheimer’s, seizures, memory loss, history of brain tumour or</td>
<td></td>
</tr>
<tr>
<td>meningitis? Any family history of Creutzfeldt-Jacob disease (CJD)?</td>
<td></td>
</tr>
<tr>
<td>22. A history of long term infections, unexplained fever or</td>
<td></td>
</tr>
<tr>
<td>weight loss?</td>
<td></td>
</tr>
<tr>
<td>23. Ever used non prescribed drugs?:</td>
<td></td>
</tr>
<tr>
<td>* IV drugs (heroin, steroids)</td>
<td></td>
</tr>
<tr>
<td>* Other illegal drugs</td>
<td></td>
</tr>
<tr>
<td>* Inhalants</td>
<td></td>
</tr>
<tr>
<td>24. Been in prison in the past 12 months?</td>
<td></td>
</tr>
<tr>
<td>25. Had a sexual relationship in the past 12 months with a person who:</td>
<td></td>
</tr>
<tr>
<td>* had known or suspected Hepatitis or HIV?</td>
<td></td>
</tr>
<tr>
<td>* had multiple sexual partners?</td>
<td></td>
</tr>
<tr>
<td>* is a sex worker?</td>
<td></td>
</tr>
<tr>
<td>* is of the same gender (male only)</td>
<td></td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
</tbody>
</table>

"I, to the best of my knowledge, have taken all reasonable steps to ensure that the history obtained regarding the potential donor is current and accurate.

Signature: [Signature]  Date: [Date]  Time: [Time]

Updated: 8 February, 2001

173(24/01/13)
HUMAN TISSUE - REQUIREMENTS OF THE HUMAN TISSUE ACT 1983 IN RELATION TO RESEARCH & USE OF TISSUE (GL2006_021)


Status

This Guideline updates and replaces Guideline GL2005_046 to take into account amendments to the Human Tissue Act which came into effect in January 2006.

Format of this Guideline

1. This Guideline provides guidance for:
   - HRECs when reviewing research proposals involving human tissue;
   - researchers to determine the requirements of the law and the manner in which HRECs should review research proposals involving human tissue; and
   - persons in charge of laboratories that store and use human tissue samples.

2. Reference to paragraphs of the National Statement on Ethical Conduct in Research Involving Humans (the “National Statement”) is as follows: NS 2.1 refers to paragraph 2.1 of the National Statement.

3. “HREC” refers to NSW Health Human Research Ethics Committees.

Background

4. In 2003, there were amendments to the Human Tissue Act 1983 which affect the way HRECs assess applications for research involving human tissue.

5. The amendments relate to the legal requirement for consent to the use of human tissue for research purposes.

6. The amendments are not retrospective. That means there are different consent requirements for tissue removed before and after the commencement of the amendments. The amendments commenced on 1 November 2003.

7. Additional amendments to the Human Tissue Act commenced on 1 January 2006 relating to the use of small samples of human tissue for service delivery, quality assurance, and laboratory accreditation activities.

A. USE OF HUMAN TISSUE FOR RESEARCH

The requirements of the Human Tissue Act 1983 in relation to tissue removed prior to 1 November 2003

8. The following is an outline of the consent requirements of the Human Tissue Act in relation to human tissue which is proposed to be used for research.

9. Tissue removed for the purposes of a post-mortem examination prior to 1 November 2003 does not require any consents for it to be lawfully used for research. However, the National Statement indicates that consent should usually be obtained (NS 15.4), unless it is suitable to waive consent under NS 15.8. The law allows consent to be waived in accordance with the NS.
10. Tissue removed from a deceased person prior to 1 November 2003 other than for the purposes of a post-mortem examination can only be used with the oral or written consent of the deceased person given whilst alive, or their next-of-kin. The written authorisation of a designated officer of a hospital is also required. **The law does not allow consent to be waived even if the requirements of NS 15.8 are met. The law overrides the ability in the NS to waive consent.**

11. Where the tissue was removed prior to 1 November 2003 from a living person in the course of a medical, dental or surgical procedure, the law does not require any consents for its use for research. However, NS 15.4 indicates that consent should usually be obtained, unless it is suitable to waive consent under NS 15.8. **The law allows consent to be waived in accordance with the NS.**

12. Where tissue is removed from a person prior to 1 November 2003 for the purposes of research, the common law requires the person’s consent to the removal, otherwise the removal would be a battery. **The law does not allow consent to be waived.**

**The requirements of the Human Tissue Act 1983 in relation to tissue removed after 1 November 2003.**

Tissue blocks and tissue slides

13. Where tissue is removed after 1 November 2003 and is held in a tissue block or tissue slide, the law allows the tissue to be used for research without any consent being obtained. However, NS 15.4 indicates that consent should usually be obtained unless the requirements of NS 15.8 are met. **The law allows consent to be waived in accordance with the NS.**

Tissue other than tissue blocks and tissue slides

14. Where the tissue was removed from a deceased body (either for the purposes of a post-mortem examination or otherwise), and is not a tissue block or tissue slide, written consent to the use of the tissue for research (from the deceased person before death or their next-of-kin) is required. The written authorisation of a designated officer of the hospital is also required. **The law does not allow consent to be waived even if the requirements of NS 15.8 are met. The law overrides the ability in the NS to waive consent.**

15. Where the tissue was removed from a living person after 1 November 2003 as part of a medical dental or surgical procedure, and the person is still alive, written consent for use of the tissue for research must be obtained from that person (or their parent or guardian if they are a child) either before or after the removal. **The law does not allow consent to be waived even if the requirements of NS 15.8 are met. The law overrides the ability in the NS to waive consent.**

16. Where the tissue was removed from a living person after 1 November 2003 as part of a medical dental or surgical procedure, and the person is now deceased, written consent for the use of the tissue for research must have been obtained from the person whilst alive (or their parent or guardian if they were a child) or from their next-of-kin after their death. **The law does not allow consent to be waived even if the requirements of NS 15.8 are met. The law overrides the ability in the NS to waive consent.**

17. Where tissue is removed from a person after 1 November 2003 for the purposes of research, the common law requires the person’s consent to the removal, otherwise the removal would be a battery. **The law does not allow consent to be waived.**
18. In no circumstances is tissue to be removed from the body of a deceased child who is or was a ward of the state for research purposes, either with or without consent from any person.

How specific must consent be?

19. The Human Tissue Act allows consent to be general. A person may consent to the use of their tissue for research at large, and this will be sufficient at law for the tissue to be used for any research project. However, if the person consenting limits their consent, then the tissue may not be used outside the scope of the limited consent. For example, if the person consents to the use of their brain tissue for “research into Parkinson’s Disease”, it cannot be used for research which is not related to Parkinson’s Disease.

20. NS 15.5 states that consent should be specific to the purpose for which the tissue is to be used, unless the requirement for consent is waived in accordance with NS 15.6 and 15.8. Therefore, where the NS requires consent, it may be stricter than the requirements of law. The more specific requirements of the National Statement should be applied, if the requirements of the law are general.

What should an HREC do when assessing research applications involving use of human tissue?

21. HRECs must have regard for the law AND the requirements of the National Statement when assessing research protocols involving human tissue.

22. The requirements of the law override the provisions of the National Statement (NS preamble). Therefore, if the law requires consent, the HREC may not waive the requirement for consent even if the HREC considers the requirements of NS 15.8, which allow waiver in some circumstances, are met.

23. HRECs must not approve research protocols which contemplate an unlawful use of human tissue.

24. HRECs should examine the research protocol to determine whether the proposed use of tissue is lawful. If the proposed use is lawful, then the HREC should apply the National Statement in determining whether to give ethical approval (except that it may not waive consent if consent is required by law).

25. If it is clear from a research proposal that the researcher intends to use tissue without obtaining consent in circumstances where the law requires consent, the HREC should reject the proposal because it involves unlawful conduct. The HREC should explain the reason for rejection to the researcher.

26. Where it is unclear whether the use of tissue proposed in the research protocol is lawful, the HREC should require the researcher to give an explanation of the use of the tissue. The researcher should be given a copy of this circular in order to explain the requirements of the law.

27. If the protocol is returned stating that tissue samples will be identified according to the requirements of the law, and with undertakings by the researcher to comply with the law, and the HREC is satisfied that this is reasonable, the HREC may give approval (after ethical review) but should make its approval conditional upon adherence to the law.

28. The conditions included in the letter of approval should be specific, not general. Relevant conditions from those listed below should be used in the approval letter.
29. For tissue removed prior to 1 November 2003, from a deceased body, the researcher must ensure that the tissue was removed either:
   • for the purposes of a post-mortem examination; OR
   • with the consent of deceased person’s next-of-kin and with the authorisation of a designated officer of a hospital.

30. For tissue removed prior to 1 November 2003 from a living person, the research must ensure that the tissue was removed either:
   • in the course of a medical, dental or surgical procedure; OR
   • for the purposes of research with consent.

31. For tissue removed after 1 November 2003, from a deceased body (either for the purposes of a post-mortem examination or otherwise) and is not in the form of a tissue block or slide, the researcher must ensure that consent was obtained by the next-of-kin AND authorisation given to the removal and use by the hospital designated officer. Consent is mandatory under NSW law.

32. For tissue removed after 1 November 2003, from a living person as part of a medical dental or surgical procedure, the tissue is not in the form of a tissue block or slide, and the person is still alive, the researchers must ensure that consent for use of the tissue for research has been obtained (either before or after the removal). Consent is mandatory under NSW law.

33. Where the tissue was removed after 1 November 2003, from a living person as part of a medical dental or surgical procedure, the tissue is not in the form of a tissue block or slide, and the person is now deceased, the researchers must ensure that consent for the use of the tissue has been obtained from the next-of-kin. Consent is mandatory under NSW law.

34. Where the tissue was removed from a living person after 1 November 2003 specifically for research purposes, the researchers must ensure that consent for the removal and use of the tissue was obtained from the person. Consent is mandatory under NSW law.

B. USE OF HUMAN TISSUE FOR SERVICE DELIVERY, QUALITY ASSURANCE AND ACCREDITATION ACTIVITIES

35. Additional amendments to the Human Tissue Act to facilitate the use of tissue samples for the purpose of carrying out analyses or tests commenced on 1 January 2006.

36. These changes allow small tissue samples which have been lawfully removed from living or deceased persons to be used without consent for the purposes of carrying out analyses or tests:
   • that are part of a program (including any quality assurance program, quality control program, audit or evaluation) to ensure, or improve, the quality of services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products; or
   • that are necessary for the delivery of services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products or for the accreditation under any Act of a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products.
KIDNEY DONATION - LIVING (INCLUDING DIRECTED AND NON-DIRECTED DONATION) (PD2015_041)


PURPOSE

This Policy Directive states the NSW Ministry of Health’s policy in relation to both living directed and non-directed kidney donation. In NSW, kidney transplantation procedures include use of both organs sourced from deceased donors and kidneys donated by living people. ‘Directed’ donation, where the donor agrees to donate their kidney for transplantation to an identified recipient, usually a spouse or partner, family member, or close friend has occurred in NSW for many years. ‘Non-directed’ donation refers to where the donor donates to any suitable ‘stranger’ on the waiting list. Non-directed kidney donation was established in NSW in 2004.

MANDATORY REQUIREMENTS

Health professionals involved in the assessment, management and follow-up of individuals undergoing living kidney donation and their recipients must read and understand the standards and conditions for living kidney donation in NSW as outlined in the attached procedures (Attachment 1).

Local Health District (LHD), Specialty Health Network (SHN) and licensed private health facility’s policies on living kidney donation must refer to and be consistent with this policy.

The NSW Transplant Advisory Committee (TAC) must comply with the governance and oversight requirements as in Attachment 1.

IMPLEMENTATION

Chief Executives of LHD and Specialty Health Networks SHN and licensed private health facilities are responsible for ensuring that:

• Relevant staff are made aware of these procedures

• Local protocols to support living kidney donation consistent with the attached procedures are documented.

Directors of Renal Medicine and Renal Transplantation are responsible for ensuring that:

• Staff involved in the assessment and management of living kidney donors are aware of the attached procedures.

Staff responsible for procedures related to the assessment and management of living kidney donors must:

• Ensure that the assessment and management of living kidney donors meets the conditions and requirements outlined in the attached procedures.

This Policy Directive should be read in conjunction with the following NSW Ministry of Health policies:

• PD2005_406 Consent to Medical Treatment - Patient Information;

• PD2010_060 Kidney Transplantation - Participation in the Australian Paired Kidney Exchange Program; and

• PD2011_026 Organ Transplantation from Deceased Donors: Eligibility and Allocation Protocols.
Living Kidney Donation (Including Directed and Non-Directed Donation) Procedures

1 BACKGROUND

1.1 About this document

This Policy Directive applies to all public health organisations and licensed private health facilities that are involved in the donation of a single kidney by an adult living person for transplantation into another person.

There are three general categories of living kidney donors:

- Genetically related donor (generally parent, son, daughter, sibling, aunt, uncle, nephew, niece, cousin)
- Emotionally related donor (such as a spouse, friend or carer with whom the recipient has a genuine close relationship)
- Non-directed donor, also known as the “good Samaritan” donor or the “altruistic stranger” donor. Such a donor wishes to donate a kidney to an unspecified but suitably matched person on the deceased donor waiting list.

1.2 Legal and legislative framework

1.2.1 The Human Tissue Act 1983 (the Act) covers donation of regenerative and non regenerative tissue by adults and children. Section 7 of the Act allows living adults to donate non-regenerative tissue (including kidneys) if certain requirements are met.

The donation of non-regenerative tissue for the purposes of transplantation (including kidneys) by a child, as defined in the Act, is prohibited.

Section 9 of the Act states that a medical practitioner, other than the medical practitioner who will perform the surgery to remove the tissue, is required to certify that:

- The donor’s written consent was given in his or her presence
- The donor had explained to him or her, before the consent was given, the nature and effect of the removal of the organ from the donor’s body
- At the time the consent was given the medical practitioner must be satisfied that the
  o Donor was not a child
  o Donor was of competent mind
  o Consent was freely given.

1.2.2 Prohibition on the Sale of Organs - Under s 32(1) of the Act any agreements which entail supply of an organ or tissue

In exchange for the payment of ‘valuable consideration’ to the donor are prohibited in NSW. Valuable consideration is not restricted to financial consideration. The prohibition also includes an arrangement or the offer to enter into an arrangement or contract to agree to supply tissue in exchange for anything of value to the donor. This includes (but is not limited to):

- The sale of organs and tissue
- Donation of a kidney in exchange for another person (for example, the donor’s relative or friend) receiving priority on the waiting list for a deceased donation.

‘Paired kidney exchange’ is exempt from this prohibition provided Ministerial approval is obtained on a case-by-case basis, in accordance with the Act.

254(01/10/15)
26. TISSUE/ORGAN

Staff of public health organisations must not participate in any arrangements that are known to be in contravention of the Act.

2 GENERAL POINTS

Donation of a single kidney by genetically or emotionally related donors is a well-established practice in NSW and is recognised as being ethically acceptable both here and overseas. Non-directed kidney donations from living donors are also permissible provided all the requirements of this Policy Directive are met.

All kidney donations should be undertaken in sites recognised as established centres for performing renal transplantation.

Donors may be admitted as public patients and the costs associated with their management will be covered under the normal arrangements. A donor may incur some costs as a private patient in a public hospital. Other expenses including costs of a general practitioner referral are to be met by the donor.

Directed and non-directed donors may be considered for travel and accommodation support under applicable programs, for example the Isolated Patient Transport and Accommodation Assistance Scheme (IPTAAS).

Directed and non-directed donors qualifying for assistance under the Australian Government’s Leave for Living Donors Support Scheme or other Government income support services are not in breach of the Act.

There is no ‘right’ to be a kidney donor. A public health organisation has the discretionary capacity not to accept a willing donor if it is considered not to be in the donor’s or recipients best interest, although a second opinion may be sought by the potential kidney donor.

Living kidney donation is a process including (but not limited to) donor assessment, anaesthesia and surgery. If a donor dies at any point in this process of directed living kidney donation, then directed donation of that kidney may still proceed. In this circumstance, organs other than the directed kidney may also be donated, provided the consent of the senior available next of kin is given for their procurement, in accordance with the Act. Allocation of the organs will be made via the Transplantation Society Australia New Zealand (TSANZ) deceased donor protocols.

3 GUIDING PRINCIPLES FOR LIVING KIDNEY DONATION

3.1 In any living donation, the interests of the donor and the recipient are of equal importance.
3.2 The donor has an altruistic desire to assist the recipient generally.
3.3 Directed deceased donation, where an individual stipulates that at their death, any of their organs or tissue is exclusively intended for transplantation to a particular recipient, is not permissible.
3.4 ‘Conditional’ organ donation is not permissible i.e. where a donor nominates, or excludes certain categories of recipient, for example based on conditions of age, sex, cultural or racial group, religious belief, sexual orientation or criminal status. This applies to living and deceased donation.
3.5 The donor must have capacity for informed consent and be of sound mind.
3.6 Donor consent is voluntary and non-coerced. The potential donor is under no obligation to proceed with donation once donor assessment has begun.
3.7 The competent donor provides consent. Substitute consent to living kidney donation is not permissible.
3.8 The donor is 18 years of age or older. Children are explicitly excluded as donors of kidney tissue under the requirements of this policy.

3.9 There is a 24-hour ‘cooling off’ period for directed donations in which donation must not proceed following donor consent. For non-directed donations, a period of 3 months is required in the assessment process related to timeframes for sequential psychological assessment (see 6.5.1).

3.10 The donor may withdraw at any time before surgery i.e. prior to the time of administration of sedative without the need to give a reason.

3.11 It is reasonably expected that the donor will not suffer significant psychological and/or emotional harm by the donation process.

3.12 In the first instance, the donor determines the acceptability of the potential risks or harms to him or herself, providing there is understanding of risks and no contraindications. However, the donor surgeon has a duty of care to the donor and a decision to proceed with donation can only be made with the surgeon’s agreement.

4 LEGAL REQUIREMENTS

4.1 Certification by a Medical Practitioner
The statutory requirements for donation of kidneys by living adults are as follows:

- The donor must give written consent.
- Pursuant to the Act, a medical practitioner, other than the medical practitioner who will perform the surgery to remove the tissue, must certify that:
  - The donor’s written consent was given in his or her presence
  - The donor had explained to him or her, before the consent was given, the nature and effect of the removal of the organ from the donor’s body.
  - At the time the consent was given the medical practitioner was satisfied that the:
    - Donor was not a child
    - Donor was of competent mind
    - Consent was freely given.
- The kidney in directed donation must not be removed until 24 hours has passed from the time the consent was given.

4.2 Consent to Surgery for the Removal of the Kidney

4.2.1 The above certification is not the written consent for the donor nephrectomy. The surgeon who will remove the tissue must obtain written consent for the surgery to remove the kidney, in accordance with the Department’s consent policy and the additional requirements set out in sections 4.1 and section 5.1 of this policy directive.

4.2.2 The surgeon who removes the kidney has an independent legal obligation to ensure that the donor has given a valid consent and has been informed of risks and alternatives (see section 5 below), regardless of whether the medical practitioner who referred the donor to the surgeon also discussed these issues with the donor. The surgeon who removes the kidney cannot rely on the consent and information provided to the donor by the other medical practitioner in order to discharge his or her own duty of care. Certification under the Act by a medical practitioner who does not perform the surgery does not impact in any way upon the duty of the surgeon to inform the patient of material risks and alternatives.

4.2.3 The removal of the kidney is prohibited if the donor revokes their consent. The donor may revoke their consent at any time prior to the preoperative sedative for removal of the kidney.
5 REQUIREMENTS FOR ALL LIVING KIDNEY DONATIONS (directed and non-directed)

In relation to all living kidney donations, local protocols must be developed which cover the following matters.

5.1 Information for donors

5.1.1 Written material should be made available to recipients and families about kidney transplantation, including the possibility of living donor transplantation. It must then up to an interested potential donor to indicate their willingness to begin an assessment process. Such information should include:

- Reason for using a live donor as opposed to deceased donation
- A full description of the procedure
- Implications of the procedure for the donor, such as preparation for surgery by drugs or diet, hospital admission.
- Risks to the donor inherent in the procedure including:
  - Surgical risks
  - Immediate complications as a result of the procedure including risk of kidney failure
  - Risk of death
  - Long terms risks.
- The process of recovery for the donor, including:
  - Physical rehabilitation and length of expected recovery time
  - Level of probable pain or discomfort after procedure
  - Inhibition of normal activity
  - Time off work required (and related financial impact such as access to life insurance etc.).
- The likely outcomes for the recipient (including possibility of failure of the donation, possible complications, prospects of success).
- Possible changes to the donor/recipient relationship (including possible feelings of ‘ownership’ towards the recipient by the donor, the donor feeling the need or right to make demands upon the recipient, and that the donor may be the object of feelings of gratitude by the recipient).
- That the donor may choose not to proceed with donation at any time before surgery and that it is not a foregone conclusion that donation will occur once donor assessment has begun.

5.1.2 Attention should be paid to ensuring adequate understanding in the donor and recipient, consistent with informed consent standards, and may require interpreter assistance in some cases.

- Standard information for living kidney donors is available at:

5.2 Assessment of donor’s psychosocial (mental) health

5.2.1 Assessment of directed and non-directed donors’ psychological health and psycho-social circumstances shall be undertaken during the assessment process (see 6.4 for non-directed donors). This may, in some circumstances, require assessment by a suitably qualified mental health professional. The decision to proceed with donation should take account of the following aspects of the donor’s psychological health and psychosocial circumstances:
26. TISSUE/ORGAN

- Competence of the donor to consent
- Understanding of the risks and benefits of the procedure
- Motivations of the donor
- Relationship with the recipient and associated family (directed donation) and attitude to donation by those close to a potential non-directed donor
- Any undue pressure, or any coercion, threats or inducements potentially affecting the donor’s decision
- Any mental illness, personality disorder or substance abuse potentially affecting the donor’s decision to donate or potential postoperative outcome
- The donor’s understanding and acceptance of the requirement for anonymity (non-directed donation)
- The donor’s understanding of the principle that no financial or other benefits are to be sought from the recipient, the public health organisation or any other person as a result of the donation
- Support mechanisms for the donor during and after the procedure.

5.2.2 All potential donors must be able to decline donation for any or no reason. In particular, directed donors must be able to decline without disclosure of the reason for donation not proceeding to the recipient, their family or others close to the recipient.

5.2.3 A potential directed donor may be deemed ‘unsuitable’ for donation according to reasons applicable in one or more of the following broad categories:
- Medical or surgical reasons
- Infection
- Biological incompatibility, for example tissue matching
- Psychosocial reasons, including situations in which the prospective donor decides to decline surgery.

5.3 Assessment of donor’s medical suitability

5.3.1 A living directed donor’s medical suitability for donation will be assessed by a suitably qualified renal physician, independent of the recipient’s transplant team, in accordance with relevant selection criteria issued by the TAC and in accordance with good medical practice.

5.3.2 A living non-directed donor’s medical suitability for donation will be assessed by a suitably qualified renal physician formally associated with a NSW renal transplant service, but independent of the recipient’s transplant team, in accordance with relevant selection criteria issued by the TAC, and in accordance with good medical practice.

5.3.3 Directed and non-directed donors should have the same criteria for physical risk assessment applied and, where either type of donor does not meet those criteria, donation should not proceed.

5.4 Information for recipients

In addition to all information routinely provided prior to kidney transplantation relevant to the surgical procedure, the recipient must be provided with information regarding the following matters prior to giving consent for receipt of a donation from a living person:
- Feelings the recipient may encounter if the donation fails
- Possible changes in donor-recipient relationships (for directed donations)
- Possible feelings of ownership towards the recipient by the donor and the possibility of demands made by the donor
- Possible debt of gratitude or feelings of obligation felt by the recipient towards the donor.
26. TISSUE/ORGAN

- Possible psychological consequences if donation has harmful effect on donor
- The right of the donor to withdraw at any time, without the provision of a reason for doing so, and the possible cancellation of the procedure.

5.5 Recipient’s consent

5.5.1 It is the recipient’s voluntary and non-coerced choice whether or not to accept a donation from a living directed or non-directed donor. Any decision not to accept such a donation shall not prejudice the recipient’s place on the cadaveric waiting list.

5.5.2 The potential recipient is under no obligation to proceed with accepting the donation once donor assessment has begun.

5.5.3 A recipient’s consent to the procedure must be obtained in writing in accordance with the Ministry’s policy on consent.

6 ADDITIONAL REQUIREMENTS FOR NON-DIRECTED KIDNEY DONATIONS ONLY

All the requirements set out above must be met, and in addition, the following matters are to be addressed.

6.1 Institutional Discretion

6.1.1 It is a matter for each public health organisation to determine whether or not it will assist in assessing potential non-directed donors or undertake donor nephrectomy in the non-directed donation setting.

6.1.2 It is at the discretion of each transplant unit to determine whether or not it will receive kidneys from non-directed donors.

6.1.3 If a physician, surgeon or unit does not support non-directed kidney donation then the potential donor should be referred to a unit that does support the practice.

6.2 Anonymity

6.2.1 All reasonable steps are to be taken by the TAC, the transplant team and relevant medical and clinical staff to preserve the donor’s and the recipient’s anonymity through the donation and transplantation process.

6.2.2 Health professionals’ involvement in exchange of correspondence between the non-directed donor and recipient may only proceed according to TAC Standard Operating Procedure (SOP). This SOP is in line with the provisions in s37 of the Act.

6.3 Donors must approach/be referred to the public health organisation

6.3.1 To be accepted as a non-directed donor, the donor must have raised the issue of donation with their primary health care provider or public health organisation of their own accord, and not in response to any invitation by the public health organisation, a recipient, or a recipient organisation.

6.3.2 All potential donors should obtain a referral from their general practitioner to a relevant renal physician formally associated with a NSW renal transplant service. Persons who contact a public health organisation about wishing to be a donor should be provided with preliminary information and advised to seek advice and referral from their general practitioner. The same renal physician should not manage the donor and recipient.

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6.3.3 Public health organisations shall not advertise for, or otherwise encourage individuals, to become non-directed donors.

6.3.4 Public health organisations shall not encourage potential recipients, recipient organisations, or other health care providers to advertise for non-directed donors.

6.4 Assessment of the non-directed donor’s mental health

6.4.1 The potential donor should be assessed by a suitably qualified mental health professional (such as liaison psychiatrist with advice from a psychologist as appropriate) on at least two occasions, with at least three months interval between the first assessment and the second assessment, to allow the potential donor time to consider all information provided to him or her regarding the donation (see also 5.2.1).

6.4.2 Proceeding with kidney donation in the non-directed donor is contingent on that person being willing to undergo such psychological assessment.

6.4.3 A suitably qualified mental health professional should provide a written opinion concerning aspects of the donor’s psychosocial circumstances, in conjunction with the requirements of 5.2.1, ascertaining whether or not the following pre-conditions for non-directed donation are met:

- The potential donor is competent to make such a decision
- The motivation/s of the donor are substantially altruistic
- No significant psychological harms are likely to be associated with the non-directed kidney donation.

6.4.4 A person shall not be accepted as a non-directed donor if the above opinion indicates that it is not in their best interests.

6.5 Final decision is discretionary

6.5.1 In the first instance, the donor determines the acceptability of the potential risks or harms to him or herself, providing there is understanding of risks and no contraindications. However, the donor surgeon has a duty of care to the donor and a decision to proceed with donation can only be made with the surgeon’s agreement (see 2.6).

6.5.2 The non-directed donor may not demand or place limitations on a recipient’s eligibility to receive their donated kidney (see 3.4).

6.6 Recipient selection/allocation

6.6.1 Allocation of the donor kidney will be discussed with the potential donor at the outset of assessment for suitability. This will include that the non-directed donor kidney may be allocated into the Australian Paired Kidney Exchange (AKX) program or to a single NSW recipient (see 6.6.2 and 6.6.3). The non-directed donor does not have discretionary decision-making about which allocation route is used. If they are unwilling to have the kidney allocated by either route they become ineligible to be a non-directed donor.

6.6.2 At the discretion of TAC all suitable living non-directed donor’s will in the first instance, be referred to the AKX program to participate in a minimum of two exchange ‘runs’. If the donor is matched, allocation of the non-directed donor kidney to the AKX potentially gives rise to multiple transplants.

6.6.3 If there is no match through the AKX program the living non-directed donor will then be allocated to a single recipient via the National Organ Matching Scheme.

6.6.4 The TAC must approve the recipient selection in writing.

6.6.5 Living donation should proceed such that ischaemic time affecting the donated kidney is minimised. Excluding AKX program arrangements, potential donors, or on occasion recipients, may need to travel to a centre for surgery other than where they are assessed. Donor and recipient teams should negotiate the most appropriate location of donor and recipient surgeries through TAC.
6.7 Recipient choice

6.7.1 It is advisable at the initial point of assessment for transplantation that the transplant recipient is asked by the treating unit whether they would potentially accept a donation from a non-directed donor. If the patient would be prepared to do so, they should be informed about whether that unit could accommodate such an option.

6.7.2 At the time of allocation of a non-directed donated kidney, the potential recipient should be informed that transplantation of such a kidney is proposed in their particular case.

7 OVERSIGHT OF LIVING KIDNEY DONATION IN NSW

7.1 Oversight by TAC

All directed and non-directed kidney donations are to be overseen by the TAC that operates under the auspices of NSW Health. The purpose of such oversight is to:

- Monitor the operation of this policy
- Allow for assessment and development of recommendations in relation to ongoing review of this policy
- Ensure transparency in the assessment and allocation procedure
- Facilitate negotiations about location of donor and recipient surgery (see 8.6)
- Provide a review mechanism in the event of cases where living kidney donation is contested, including in particular non-directed kidney donation.

The TAC will notify the public health organisation whether or not a non-directed donation may proceed.

7.2 Ongoing Monitoring

Both directed and non-directed donors should be informed of the need for ongoing future contact with the health care institution for the purposes of:

- Ongoing monitoring of individual donors’ clinical outcomes, including psychological outcomes after donation
- Health assessment and potential participation in research in relation to non-directed donation and transplantation. All future health assessments of donors and participation in research must be voluntary with consent obtained at the relevant time.

7.3 Reporting requirements

Transplant Units (including licensed private health facilities) that undertake living directed and non-directed kidney transplantation must provide TAC with an annual report on donation activity in their unit using the template at Attachment 1.

7.4 Follow-up

Public health organisations shall keep appropriate records regarding non-directed donors and recipients to allow for ethically approved research into future outcomes to be facilitated.
## ATTACHMENT 1: LIVING DONOR KIDNEY TRANSPLANTATION REPORT

<table>
<thead>
<tr>
<th>Name of Hospital</th>
<th>Calendar year</th>
<th>Number</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Description</th>
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<tbody>
<tr>
<td>Living related kidney transplants performed</td>
<td></td>
</tr>
<tr>
<td>Living non-related kidney transplants performed</td>
<td></td>
</tr>
<tr>
<td>Total living kidney transplants performed</td>
<td></td>
</tr>
<tr>
<td>Living non-directed (altruistic) donor nephrectomies</td>
<td></td>
</tr>
<tr>
<td>Country of usual residence of donor</td>
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<td>AUST/NZ</td>
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</tr>
<tr>
<td>Other (please specify country)</td>
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</tr>
</tbody>
</table>

Completed annual reports (calendar year) must be sent to the Chair, NSW Transplant Advisory Committee (via the TAC secretariat) by 1 February of the following year.
ORGAN DONATION AFTER CIRCULATORY DEATH (GL2014_008)

GL2014_008 rescinds GL2011_005.

PURPOSE

The Guideline describes the necessary requirements for health facilities to undertake organ donation after circulatory (formerly cardiac) death (DCD) in NSW. This approach to organ donation entails retrieval of organs after the patient’s death where death is certified according to the irreversible cessation of circulation of blood in the body (rather than according to neurological criteria). The Guideline outlines the applicable setting for DCD in NSW, donor referral criteria, patient management (including decision making and consent processes), criteria for the declaration of death, care of the patient and family (before and after the patient’s death), the phases of organ retrieval and subsequent organ allocation.

This Guideline should be read in conjunction with:

PD2013_001 Deceased Organ and Tissue Donation - Consent and Other Procedural Requirements
PD2013_002 Designated Officer Policy and Procedures
PD2005_406 Consent to Medical Treatment – Patient Information
GL2005_057 End of Life Care and Decision Making – Guidelines
PD2010_054 Coroner’s Cases and the Coroners Act 2009

KEY PRINCIPLES

DCD provides further donation opportunities for people who wish to be organ donors after their death and is a potential means of increasing the availability of deceased donor organs in NSW within current accepted ethical and legal requirements.

Quality end of life care for a potential organ donor, as with any individual whose cardio-respiratory support is being withdrawn, is the priority and must not be compromised by the donation process.

Once donation has been agreed upon and consented to, efforts should be made to ensure optimal outcomes for the donation. This includes ensuring that the family are fully informed regarding donation processes and that warm ischemic time for the donor organs is minimised.

USE OF THE GUIDELINE

Chief Executives of Local Health Districts (LHD) and Speciality Health Networks (SHN) are responsible for ensuring that:

- Relevant staff are made aware of these guidelines.
- Local protocols to support DCD consistent with this Guideline are documented.

The NSW Organ and Tissue Donation Service (NSW OTDS) is responsible for:

- Ensuring that organ and tissue donation and retrieval protocols in NSW are consistent with this guideline.
- Facilitating education and training on DCD for LHD/SHN staff as required.

Intensivists/Treating Clinicians/Donation Specialists in LHD/SHNs should:

- Familiarise themselves with the donor referral criteria and management of potential DCD donors as outlined in these guidelines (section 2, 3 and 4).
Clinicians certifying death for the purposes of DCD:
- Must do so according to the criteria outlined in the attached procedures and using the prescribed State form (section 2.3.7 and Appendix 1).

Designated Officers in hospital facilities:
- Must ensure that authorisation is provided for the removal of tissue after death for its use for donation and transplantation (sections 2.3.4 and 2.3.7).

Transplant Units who accept DCD organs for transplantation:
- Should familiarise themselves with the general principles of allocation of DCD organs (section 5).

ORGAN TRANSPLANTATION FROM DECEASED DONORS: ELIGIBILITY AND ALLOCATION PROTOCOLS (PD2011_026)

PURPOSE

This policy provides the framework for implementation in New South Wales (NSW) of the Transplantation Society of Australia and New Zealand Organ Transplantation from Deceased Donors: A Consensus Statement On Eligibility Criteria And Allocation Protocols (the Consensus Statement). Consensus Statement Protocols relate to patient referral, assessment and listing and allocation of deceased donor organs.


Guidelines for implementation of Consensus Statement Protocols and compliance with the audit requirements prescribed in the Consensus Statement are at Attachment 1.

Procedures for the review of eligibility assessment processes are at Attachment 2.

MANDATORY REQUIREMENTS

Consensus Statement Protocols must be used by recognised Transplant Units for assessment of patients for eligibility for deceased donor organ transplantation.

Tissue typing for transplantation will only be conducted if it is authorised by a recognised Transplant Unit.

IMPLEMENTATION

Roles and responsibilities of the NSW Department of Health:
• Provide advice and assistance for the implementation of this policy.
• Monitor and evaluate the health system implementation of the Consensus Statement Protocols and Guidelines.

Roles and responsibilities of Chief Executives:
• Ensure that personnel involved in the management of patients requiring listing for transplantation are aware of the requirements of this policy directive.
• Assign responsibility, personnel and resources to implement the Consensus Statement Protocols and Guidelines within their Local Health Network.

Roles and responsibilities of health service executives responsible for clinical operations and governance:
• Ensure successful implementation of the Consensus Statement Protocols and the Guidelines.
• Monitor and evaluate the implementation of the Consensus Statement Protocols and the Guidelines across their services
• Ensure the Guidelines are incorporated into the local orientation program for relevant clinical staff.
Roles and responsibilities of recognised Transplant Units:

- Implementation of and adherence to the Consensus Statement Protocols for assessment, review, referral and pre-transplantation management of patients.

- Ensure that assessments and decisions regarding eligibility for transplantation are documented in a format that allows for an audit of records to determine compliance with the requirements of this policy.

- Ensure that records include demographic data (e.g. age; gender; post-code; identification of Aboriginal or Torres Strait Islander origin [as per PD2012_042 Aboriginal and Torres Strait Islander Origin - Recording of Information of Patients And Clients] and data regarding the renal unit from which the patient was referred for transplant.

- Conduct an annual audit of implementation of the Consensus Statement Protocols eligibility and allocation criteria.

- Submit a report of the audit to the relevant TSANZ Standing Committee and the NSW Transplant Advisory Committee which includes data on:
  - the number of documented patient assessments undertaken by the Transplant Unit using the TSANZ organ specific eligibility criteria;
  - the number of patients documented as eligible for acceptance onto the NSW transplantation waiting list;
  - the number of patients documented as ineligible for acceptance to NSW transplantation waiting list;
  - the number of referrals to another recognised Transplant Unit of patients seeking a second opinion; and
  - the number of patients who request a review of the eligibility assessment process after a second assessment found them to be ineligible for transplantation.

Roles and responsibilities of referring clinicians:

- Referring clinicians are responsible for ensuring their practices are consistent with the Consensus Statement Protocols and the Guidelines, including the options for review of the assessment process for patients deemed ineligible for transplant.
Guidelines for the implementation of the Consensus Statement on Organ Transplantation from Deceased Donors: Eligibility Criteria and Allocation Protocols

Background

Organ transplantation is a highly effective treatment for advanced organ failure. Currently the number of patients who may benefit from transplantation is higher than the number of organs donated from deceased donors each year in Australia. This limitation requires that robust criteria and protocols are developed and applied to both the listing of patients for transplantation and to the allocation of deceased donor organs to patients on the waiting list.

The Transplantation Society of Australia and New Zealand has recently published *Organ Transplantation from Deceased Donors: A Consensus Statement On Eligibility Criteria And Allocation Protocols* (the Consensus Statement Protocols). This document provides guidance to clinicians and the public on nationally consistent eligibility and allocation criteria.

These Guidelines support implementation of the Consensus Statement Protocols and compliance with audit requirements.

Management of patients assessed as eligible for listing for transplantation

Transplant Units should consider all options for pre-transplantation management to occur at the local level. Patient safety is paramount, therefore management at the local level will be dependent on case complexity; and the availability of appropriate local resources, including specialist staff and technological capacity.

Clear lines of responsibility should be identified for the Transplant Unit and the referring clinician. Correspondence to referring physicians regarding a listed patient should include investigations considered essential and desirable; the time frame within which the results of investigations are required; and other guidance for ongoing care. If appropriate, other specialist resources which may be available to the referring clinician should be identified by the Transplant Unit.

The agreed care plan should include a review date in addition to a clinical summary of the patient.

A communication mechanism should be developed between the patient, the referring physician and the Transplant Unit; and the name, email and telephone number of the Transplantation Case Manager should be provided.

To minimise travel-related burden, the Transplant Unit team should consider the use of technology such as video conferencing where possible for the review of patients from rural and regional settings.

Listed patients may be removed from the transplant list if their condition improves or deteriorates to the point where they no longer meet the eligibility criteria for transplantation.

Management of patients assessed as ineligible for listing for transplantation

Patients who are assessed as ineligible for transplantation have the right to know the reasons for the clinical decision.
The patient should be informed of the decision by the Transplant Unit and documentation should be provided to the referring physician which includes the reasons for ineligibility; options for seeking a second opinion and a review of the assessment process following second opinion that the patient is ineligible for transplantation; and guidance for ongoing care.

Transplant Units should develop standardised documents for providing information to ineligible patients and their referring physicians.

Kidney Patients assessed as ineligible for deceased donor organ transplant may be considered for live donor transplantation in accordance with the provisions of PD2014_031 Kidney Donation - Living (including Directed and Non-Directed Donation).

If a patient who is seeking eligibility for the NSW Kidney Required List requests a second opinion, then the referring physician should offer the option of referral to another appropriate NSW Renal Transplant Unit. Where the patient lives in a NSW border area, referral to a Transplant Unit in an adjacent State or Territory may present the best option.

For all other solid organs, NSW Transplant Units should establish formal referral networks with interstate Transplant Units for patients seeking a second opinion.

To avoid unnecessary expense and duplication of effort, relevant test results should be provided to the Transplant Unit from which the second opinion is sought.

**Mechanisms for review of eligibility assessment processes**

The NSW Transplant Advisory Committee (TAC) will convene the Transplantation Eligibility Review Panel (TERP) on a case by case basis to review assessment processes for patients who are assessed as ineligible for listing for transplant. The terms of reference and membership for the TERP are set out in Attachment 2.

**Compliance Audit**

Transplant Units are required to undertake an annual audit of records and report the outcomes to the relevant TSANZ Standing Committee and the NSW Transplant Advisory Committee.

To facilitate the conduct of the audit and preparation of the report, Transplant Units should ensure that records for each patient include sufficient detail regarding application of the organ specific eligibility criteria; correspondence to the referring physician regarding the outcome of the assessment process; the date of acceptance to the waiting list; and the date of entry to waiting list.

Adequate records should also be maintained regarding patient and referring physician requests for second opinions and a review of the assessment process where 2 transplant units have assessed the patient as ineligible for transplantation.

**Auditing of Allocation Criteria**

The NSW Organ and Tissue Donation Service conducts an audit of the allocation of kidneys every 6 months. This audit is reported to the Renal Transplant Advisory Committee and the NSW Transplant Advisory Committee.
All solid organ Transplant Units should also conduct an annual audit of records of allocation and provide a report to the relevant TSANZ Standing Committee and the NSW Transplant Advisory Committee. The audit report should include the number of solid organs allocated and consistency with the Consensus Statement organ specific allocation criteria.
The Transplantation Eligibility Review Panel

The Transplantation Eligibility Review Panel (TERP) will operate under the auspice of the NSW Transplant Advisory Committee.

The role of the TERP is to review the process for assessment of eligibility for listing for transplant for patients who, on the basis of a second opinion, have been assessed as ineligible.

The TERP has no role in reviewing patient eligibility for listing.

**Terms of Reference:**

1. To determine whether the TSANZ Consensus Statement general and organ specific criteria were applied in determining a patient’s eligibility for listing for transplant.
2. To determine whether all relevant factors to assessment of a patient’s eligibility for listing for transplant were considered.
3. To determine whether the assessment process was appropriately documented.
4. To report on reviews of the processes applied to determine eligibility to NSW Health and to the TSANZ Council."

The Panel will be convened as required.

**Membership of the Transplantation Eligibility Review Panel**

**The Chair:**
The Chair of the NSW Transplant Advisory Committee (or their delegate) will chair TERP.

**Subject Matter Experts**
The TAC will establish a list of subject matter experts in each of the organ specific transplantation fields who agree to be called upon by the Chair when required. Subject matter experts may be recruited from other jurisdictions.

The TAC will ensure that there are sufficient subject matter experts available to ensure that it is possible to convene a Panel which has members who are independent of the transplant units which assessed the patient who has requested the review.

**Convening a Panel**
The Chair will convene a Panel on a case by case basis. A Panel will have a minimum of 3 and a maximum of 5 members and should include a person with expertise in the organ-specific discipline to which the case relates and a person with expertise in assessing procedural matters such as a Patient Representative or a Health Service Manager.

**Conflict of interest**
All members of the Panel, including the Chair, must be recruited from Transplant Units which have not been involved in assessment of the patient who has requested the review.

**Secretariat services:**
The Chair of TAC will determine secretariat arrangements on a case by case basis.

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Process:

- An application for review by TERP will only be accepted in relation to a patient who has been assessed as ineligible for transplantation by 2 Transplant Units.

- Applications for review must be made in writing by the patient and their referring physician to the Chair of the NSW TAC.

- The Chair of the TAC must ensure that a Panel is convened as soon as possible and no later than 4 weeks of receiving a written application. In recognition that in certain cases a delay may have particularly detrimental consequences for a patient consideration should be given to an expedited review process.

- Applications for review must include a report regarding the referral of the patient for assessment for transplantation; and written consent from the patient for release of all relevant documentation and records to the TERP by the Transplant Units which assessed the patient.

- Where TERP finds that the assessment process for an individual patient is either not appropriately documented; and/or did not include application of the eligibility criteria set out in the Consensus Statement; and/or did not include consideration of all relevant factors; and/or included consideration of irrelevant factors, it may recommend that the patient be reassessed.

- The outcome of the review and the reasons for the decision of the panel will be conveyed in writing by the Chair to the patient, their referring physician; the Transplant Units which assessed the patient; and the TAC and reported within a month. This correspondence will be conveyed within 4 weeks of the conclusion of the review for non-urgent cases.

- The patient may choose to be reassessed by a Transplant Unit which was not involved in either of the previous assessments.

- The Chair of TAC will include a summary of TERP reviews of the process of assessment of eligibility and the outcomes in the TAC annual report to the NSW Department of Health; and to the TSANZ Council.
ORGAN DONATION AND TRANSPLANTATION - MANAGING RISKS OF TRANSMISSION OF HIV, HCV AND HBV (PD2013_029)

PD2013_029 rescinds PD2010_002.

PURPOSE

The objectives of this policy directive are to provide a process by which clinicians can identify organ donors who are at increased risk of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV) infection (referred to hereafter as “increased risk donors”), conduct appropriate and timely diagnostic testing and consult where necessary to identify circumstances where an organ that may transmit infection may be transplanted and also circumstances where transplantation may be relatively contraindicated because of infection risk.

The policy directive also gives guidance with respect to informed consent from recipients with respect to HIV, HBV or HCV risk from solid organ transplantation.

MANDATORY REQUIREMENTS

All organ donors in NSW must be assessed for evidence of risk or risk behaviour for blood borne virus infection (BBV) prior to retrieval of organs and tissues for transplantation according to the criteria outlined in the following document.

All organ donors in NSW must have the following serological testing prior to retrieval and transplantation of organs.

- Antibody to Human Immunodeficiency Virus, Type 1 (anti-HIV-1 Ab);
- Antibody to Human Immunodeficiency Virus, Type 2 (anti-HIV-2 Ab);
- Hepatitis B surface antigen (HBsAg);
- Hepatitis B core antibody (anti HBc Ab);
- Antibody to Hepatitis C (anti-HCV Ab)

Donors with evidence of risk, potential risk behaviour, or where there is no medical history available must also have the results of Nucleic Acid Testing (NAT) returned prior to transplantation of organs. (Note that some donors with no evidence of risk have been diagnosed with infection, although nearly all have been identified on antibody testing.)

There is a requirement in law to inform potential recipients of all material risks that acceptance or non acceptance of a particular organ might cause. Transplant physicians are responsible for ensuring that recipients give a valid consent to accepting a particular organ immediately prior to transplantation.

Post transplant infection surveillance must be undertaken by Transplant Units within NSW, and all unanticipated transplant associated infections reported immediately to the NSW Organ and Tissue Donation Service in order to facilitate testing and review of other patients receiving organs from the same donor.

Laboratories will also notify positive test results of scheduled medical conditions to the local Public Health Unit as appropriate.

All facilities involved in the assessment and/or transplantation of deceased donor organs must have appropriately documented procedures consistent with the following guide.

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3 Note that the combined HIV antibody/antigen test is acceptable.
26. TISSUE/ORGAN

IMPLEMENTATION

Chief Executives of LHDs are responsible for ensuring that:
• All staff are made aware of their obligations in relation to this Policy Directive.
• Documented procedures are in place to support the Policy Directive. All procedures must be consistent with the steps outlined in this guide.

The State Medical Director of the Organ and Tissue Donation Service (OTDS) is responsible for:
• Ensuring that written procedures for the assessment and testing of deceased donors for BBV are available for all relevant personnel. All procedures must be consistent with the steps outlined in this guide.

DonateLife Network staff based in NSW health facilities:
• Are required to assess donor risk and arrange for appropriate testing for BBV and other infections prior to organ retrieval. Appropriate documentation of all steps outlined in the attached guide is required.

On call Medical Consultant for the OTDS:
• Will make the decision to proceed to retrieval of organs. Advice of the on call consultant of the donor testing laboratory or their delegate is available to the on call Medical Consultant to assist in this decision making.

Transplantation Physicians:
• Are responsible for accepting organs for transplantation in consultation with the recipient. Potential recipients must give a valid consent to acceptance of any organ which may be potentially infected prior to transplantation consistent with the steps outlined in this guide.

Transplantation Unit Directors:
• Are responsible for ensuring that post transplant infection surveillance is undertaken consistent with the steps outlined in this guide.
• Must ensure that unanticipated transplant associated infections are reported appropriately according to the attached procedures. This also includes immediate notification to the OTDS.

1. BACKGROUND

1.1 About this document

Organ transplantation is associated with a risk of transmission of some infectious diseases including HIV, HBV and HCV and other blood borne viruses (BBV). It is an absolute necessity to reduce the risk of transmission of these infections. However, it is not possible to completely eliminate this risk, and it is important to balance this risk against the life-saving, and life-enhancing benefits of organ transplantation.

Some transplants need to be performed urgently in order to save specific patients’ lives, and there is a need to optimally use this scare resource. For example, where organ transplantation is life saving, a higher risk of infectious disease transmission may be acceptable to the recipient. Conversely, where transplantation aims to improve the quality of the recipient’s life, a greater margin of safety may be appropriate. However, the patient must have the opportunity to consent to such risk at a time when their underlying condition does not adversely affect their ability to make decisions.
This policy directive seeks to:

- Assist in identification of organ donors in NSW who are at increased risk of HIV, HBV or HCV infection through appropriate and timely diagnostic testing and consultation;
- Assist in decisions to allocate NSW donor organs infected by HIV, HBV or HCV; and
- Provide advice in relation to consent requirements for potential recipients and surveillance of transplant-associated BBV infections.

The policy directive does not apply to:

- Living donors;
- Tissue transplantation, blood or blood products, haemopoietic stem cells, reproductive organs, autografts or xenografts;
- Infections caused by other pathogens (including health care-associated infections);
- Risks of transmission of cancer; or
- Assessment or testing of solid organ donors from other States and Territories.

1. **ASSESSMENT OF POTENTIAL DONORS FOR BLOOD BORNE VIRUS**

All donor notifications should be made to Donation Specialist Nurses through their paging service (Telephone 9963 2801).

The Donation Specialist Nurse must review all potential donors’ available medical records to identify evidence of an infectious disease or documentation of established risk behaviours associated with BBV. This includes a standard questionnaire relating to risk of BBV completed with a next of kin and/or other person who has an established relationship with the donor (e.g. the donor’s general practitioner). This must be in accordance with the Australian Transplant Coordinator Association (ATCA) and Transplantation Society of Australia and New Zealand (TSANZ) Confidential Organ Donation Referral Form.  

The Donation Specialist Nurse is responsible for communicating all relevant information that has been collected in the donor assessment and testing process to the medical consultant of the NSW Organ and Tissue Donation Service (OTDS).

See Attachment 1 Blood Borne Virus testing – summary flowchart page.

2.1 **Testing**

In NSW HIV infection is currently an *absolute contraindication* for organ donation. Testing for HBV and/or HCV co-infection is therefore not warranted where the donor is known to be HIV positive either on serology or NAT assay.

As pathology testing (especially nucleic acid testing - NAT) can be a rate-limiting step in the assessment of a donor’s suitability, appropriate specimens should be sent to the laboratory at the earliest opportunity. Where appropriate, this includes sending specimens for testing before organ retrieval has been confirmed.

All potential organ donors must have serology testing for BBV as follows:

- Antibody to Human Immunodeficiency Virus, Type 1 (anti-HIV-1 Ab);
- Antibody to Human Immunodeficiency Virus, Type 2 (anti-HIV-2 Ab);
- Antigen testing for Human Immunodeficiency Virus, usually as part of the combined
- Hepatitis B surface antigen (HBsAg);
Hepatitis B core antibody (anti-HBcAb);
Hepatitis B surface antibody (HBsAb);
Antibody to Hepatitis C (anti-HCV Ab); and
Human T-cell Lymphototropic Virus I/II (at the clinician’s discretion)

Other diagnostic tests, for example Cytomegalovirus IgG antibody, Epstein-Barr Virus IgG antibody, and syphilis antibody (TPHA) may also be indicated.

Nucleic Acid Testing (NAT) for BBV

NAT allows detection of HBV, HCV or HIV, whereas routine serology detects antibody response, which may persist for life after infection. NAT assays are especially useful in recent infection where serology may be negative (in the serological window period), in the presence of high amounts of virus. NAT also assists with assessment of discordant serological assays.

For deceased organ donors at increased risk of having BBV (Increased risk donors), urgent (often after hours) testing may be performed with the aim of providing a NAT result before organ retrieval.

A blood sample for NAT is routinely taken on all donors in NSW, however when this is performed during normal working hours the result is usually not known until after transplantation.

A negative NAT assay does not completely eliminate the possibility of recent infection. NAT assays also have periods when they are negative following acute infection (i.e. NAT “window” periods). In practice, the risk of infection from screened donors has been extremely low in this NAT window period. The current NAT window periods for inability to detect virus are approximately as follows:
- HBV: 21 days
- HIV: 9 days
- HCV: 7 days

For deceased donors assessed to be at increased risk of BBV, testing must be performed prospectively so that the NAT result is available at the time of organ allocation. In all other cases, the test is performed after organ transplantation, if the timing of the request does not align with the laboratory schedule for running NAT. Every effort should be made to transport specimens to the laboratory by the recommended time, in order to facilitate timely availability of results. Communication with the laboratory during this time is essential in optimizing outcomes for the organ transplant process.

Further information about NAT for HIV, HBV and HCV is available via the Australian Society for HIV Medicine web site [http://testingportal.ashm.org.au](http://testingportal.ashm.org.au)

Specimen sampling (serology and NAT)
- For donors declared dead by brain death criteria, all blood samples should only be drawn after brain death has been confirmed.
- For potential donation after cardiac death (DCD) donors, it is acceptable to test blood that is drawn in the pre-mortem period.
- Where the donor is a neonate (less than 28 days of age), testing should also be performed on a maternal blood specimen.
- Where the specimen may have unusual characteristics, including donors who have had massive blood and/or blood product transfusion, it is essential to indicate the underlying condition on any request form accompanying the specimens.
26. **TISSUE/ORGAN**

- If the donor has received greater than 50% of blood volume in blood product transfusion the sample is unsuitable for serology and NAT testing. A pre-transfusion sample should be provided to the laboratory.
- The Donation Specialist Nurse should liaise with the hospital staff as to proper sampling, labeling and transport.
- The Donation Specialist Nurse should liaise with the laboratory regarding the increased risk donor clinical condition, and to determine when NAT result is expected. This information should be communicated to the medical consultant of the OTDS and relevant transplant units as required.

2. **DECIDING TO PROCEED WITH ORGAN DONATION**

The on-call medical consultant of the OTDS is responsible for the decision as to the medical suitability of the potential donor and proceeding with organ retrieval. This will be in consultation with the transplant team, and where appropriate with the on-call OTDS laboratory consultant.

Where there are risk factors or any positive diagnostic serology or NAT assays, the on-call medical consultant for the donor agency or the transplant clinician should consult with the on-call infectious disease consultant of the SEALS donor testing laboratory and/or Chair of the NSW Health Blood Borne Virus Panel, or delegate.


The Transplant Unit retains the discretion to accept, or decline the offer of an organ from an infected or potentially infected donor. It is important the retrieval team is aware of the infectious status of the donor.

3.1 **Donors who are regarded as non-infectious for donation purposes**

These include individuals for whom:
- No risk behavior or risk factors have been identified and serology is negative; **OR**
- Risk behavior occurred (reliably reported) more than six months ago and serology is negative; **OR**
- Risk behaviour occurred (reliably reported) between two and six months ago and both serology and NAT are negative; **AND**
- There is no clinical evidence of active infection.

In these cases, organ procurement can proceed and organs can be allocated according to usual protocols if all other donor criteria are satisfied. The caveat still applies that false negative (“window period”) serology and NAT assays can occur in these circumstances. However, the above donors represent as practically as possible, donors who are not infected with HIV, HBV and HCV.

3.2 **Donors with identified BBV risk factors (increased risk donors)**

- Decisions about the suitability of organ retrieval from these donors may require both serology and NAT.
- Newly-acquired infections may not be detected by NAT if the acute infection occurred within the NAT assay window periods (see above).
• Depending on laboratory timetables for NAT, it may be necessary for the NSW OTDS to request urgent out-of-hours testing of specimens from potential organ donors. Urgent testing produces a result within 8 hours of specimen receipt.

These donors may proceed to organ procurement if there are recipients for whom risk of infection is substantially outweighed by the urgency for transplantation, in accordance with current TSANZ allocation protocol available at http://www.tsanz.com.au/downloads/201123June-TSANZConsensusStatementVs1.1.pdf

3.3 Donors who are known to be infectious

• For a donor already known to be infected with HBV and/or HCV, the donor agency should be notified and the specimen should be sent directly for NAT assay for HIV, HCV and HBV to confirm the known infection/s, and to test for the other BBVs. It will be possible in future to genotype the HCV infection, to allow directed donation to recipients with appropriate genotypes.
• The Hepatitis C Register should be consulted for potential consenting recipients for a Hepatitis C positive organ.

Potential organ donors who have positive serology, NAT or clinical evidence of active HBV or HCV infection may proceed to organ donation if there are recipients for whom risk of infection is substantially outweighed by the urgency for transplantation or where recipients have pre-existing infection and have expressly consented to receiving such an organ.


If a deceased donor is diagnosed with HIV the State Medical Director of the NSW OTDS should refer the case to the sexual health service in the local health district where the donor resided for contact tracing. Sexual health service contact details are on the NSW Health website at: http://www.health.nsw.gov.au/sexualhealth/Pages/sexual-health-clinics.aspx

If a deceased donor is diagnosed with hepatitis B or hepatitis C the State Medical Director of the NSW OTDS should notify the case to the public health unit in the local health district where the donor resided. Public health unit contact details are on the NSW Health website at: http://www.health.nsw.gov.au/Infectious/Pages/phus.aspx

3. ASSESSMENT OF POTENTIAL RECIPIENTS ON THE TRANSPLANT WAITING LIST

The HIV, HCV and HBV status of potential recipients placed on a transplantation waiting list must be determined as this affects decisions about organ allocation of both infected and uninfected organs. All recipients on the waiting list should be offered immunisation according to national recommendations for solid organ transplant recipients (see the current edition of the Australian Immunisation Handbook available at www.immunise.health.gov.au)

It may be necessary to periodically retest negative potential recipients to ascertain their current infection status depending on the length of time on the waiting list and any ongoing risk behaviour.
Immediately prior to transplantation, a sample of serum should be collected from the recipient and stored according to National Pathology Accreditation Advisory Council guidelines Requirements for the Retention of Laboratory Records and Diagnostic Material (Fifth Edition 2009).

4. RECIPIENT CONSENT

There is a legal requirement for the transplant unit to inform a potential recipient of the risks and consequences of accepting versus not accepting an organ. In order for consent to be valid there should be disclosure to the recipient of all material risks to which the patient may attach significance that may be associated with accepting a particular organ. See PD2005_406 Consent to Medical Treatment – Patient Information http://www.health.nsw.gov.au/policies/PD/2005/PD2005_406.html

In many circumstances, decisions about transplantation are made quickly and this may make it difficult for a potential recipient to carefully evaluate the risks and benefits. To provide potential recipients with reasonable time to consider these matters, the possibility of accepting a potentially infectious organ should be discussed with the recipient at entry onto the waiting list for transplantation and periodically thereafter.

Regardless of the results of the donor screening and testing process, the transplant team should ensure that the potential transplant recipient understands that:

- No pathology test that is performed on a donor is entirely capable of reducing risk of transmission to nil, although all efforts are taken to reduce risk of BBV transmission, effectively resulting in extremely low risk,
- There is a small chance that screening of the donor has not identified a serious infectious disease;
- Tests are not performed for all known infectious diseases; and
- There are rare instances where transplantation results in the transmission of infections that have not been described before.

At the time of transplantation where transmission of an infectious disease from a donor is thought to be possible, the transplant team should discuss the risks and benefits with the potential recipient presenting case-specific information. Information should include:

- That the infection that may be transmitted and the likely risk of transmission;
- The potential severity of infection;
- The ease of treating the infection should it occur;
- Whether all testing of the donor has been completed;
- The risk of significant morbidity or mortality without transplantation at this time; and
- The benefit of accepting this organ at this time.

The consent form completed at the time of transplant must expressly include recipient’s acceptance of a potentially infectious organ.

5. SURVEILLANCE OF BBV INFECTION IN TRANSPLANT RECIPIENTS

The transplant unit should determine whether transmission of blood borne viruses may have occurred by performing serological testing of the recipient, as clinically indicated.

All transplant-associated infections including evidence that transmission of infection from donor to recipient may have occurred must be reported by the transplant unit to:
26. TISSUE/ORGAN

• Incident Information Management System (IIMS) in accordance with Policy Directive PD2014_004 Incident Management Policy.
• OTDS; and
• Local public health unit.

6. DOCUMENTATION

Documentation related to donor assessment (e.g. ATCA Confidential Donor Referral Form), recipient consent, and offer and allocation processes should address risk of transmission of Blood Borne Virus.

Investigations that have been performed but for which no report has been issued should be noted.

Organs for transplantation should be accompanied by a de-identified summary of the donor’s relevant medical records that documents risk factors or clinical evidence of infection.

16. LIST OF ATTACHMENTS

1. Blood Borne Virus testing - summary flowchart
2. Implementation Checklist
Attachment 1: Blood Borne Virus testing – summary flowchart

Risk assessment using ATCA/TSANZ Referral Form

No risk factors

Risk factors

Most recent exposure more than 6 months ago

Most recent exposure less than 2 months ago

Most recent exposure between 2 and 6 months ago

Serology

Positive serology*

Urgent NAT and serology

Negative serology and negative NAT (if result known)

Donor unlikely to be infectious

Urgent NAT and serology

Positive serology and /or positive NAT

* Hep B surface antibody detection with negative hep B core antibody and no hep B surface or e-antigen indicates prior vaccination and is not considered positive serology

Donor rejected

Infectious donor

Donor Rejected

HIV infection

HBV or HCV infection

Donor Rejected

Proceed with organ retrieval according to current TSANZ guidelines for organ allocation in HBV/HCV donors

May still consider organ retrieval but requires further discussion between relevant consultants

NAT ‘Windows’
- HBV: 21 days
- HIV: 9 days
- HCV: 7 days

Donor unlikely to be infectious

Infectious donor

Proceed with organ retrieval
Attachment 2: Implementation checklist

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KIDNEY TRANSPLANTATION - PARTICIPATION IN THE AUSTRALIAN PAIRED KIDNEY EXCHANGE PROGRAM (PD2017_030)

PD2017_030 replaced PD2010_060

PURPOSE

The Australian Paired Kidney Exchange (AKX) Programme is a national live kidney donor program which aims to increase opportunities for live kidney donor transplantation by identifying matches for incompatible donor-recipient pairs.

The AKX Programme provides national protocols and standards to guide clinicians and health facilities in undertaking paired kidney exchange by living donors and recipients.

MANDATORY REQUIREMENTS


Facilities must ensure flexibility in surgical scheduling in order to prioritise the optimisation of paired kidney transplant operations. Arrangements must be made to accommodate simultaneous donor operations ensuring optimal and fair exchanges of organs as part of the AKX Program.

IMPLEMENTATION

Chief Executives of Local Health Districts, Specialty Networks and licensed private health facilities must ensure that this policy directive is brought to the attention of participating clinical staff and health facilities.

Directors of Renal Medicine and Renal Transplantation must ensure that local protocols, including for assessment and management of living kidney donors and donor-recipients, are aligned with the AKX Programme and are consistent with the AKX User Manual.

Staff responsible for procedures related to the assessment and management of living kidney donors must ensure compliance with this and related policy directives.
Kidney Transplantation - Participation in the Australian Paired Kidney Exchange Programme - Procedures

1 BACKGROUND

1.1 About this document

This Policy Directive deals with the Australian Paired Kidney Exchange (AKX) Programme. The AKX Programme is a national live kidney donor program which aims to increase opportunities for live kidney donor transplantation by identifying matches for incompatible donor-recipient pairs.

The AKX Programme operates under the auspice of the Australian Organ and Tissue Authority. The Transplant Society of Australia and New Zealand's Renal Transplant Advisory Committee provides clinical advice to the AKX Programme.

The AKX Programme provides national protocols and standards to guide clinicians and health facilities in the practice of paired kidney exchange by living donors and recipients.

1.2 Legal and legislative framework

1.2.1 Approvals under the NSW Human Tissue Act 1983

In accordance with the NSW Human Tissue Act 1983, approval of the Minister for Health (or their delegate, for instance the Chief Health Officer) must be obtained for paired kidney exchanges.

Section 32 of the Human Tissue Act 1983 prohibits the entering into of a contract or arrangement that may result in the sale or supply of tissue from one person to another for “valuable consideration”. Valuable consideration may include the exchange of kidneys between incompatible donor-recipient pairs.

Section 32 (4) of the Human Tissue Act 1983 allows for the Minister (or their delegate) to approve entering into such a contract or arrangement by reason of special circumstance.

To facilitate this approval process, donor-recipient pairs must indicate evidence of their willingness and consent to participate and to donate/receive an exchanged kidney to/from someone else.

Approvals are organised through the AKX National Coordination Centre upon receipt of donor and recipient Agreement to Participate in AKX Forms.

1.2.2 Corresponding Policy Directives

This Policy Directive should be read in conjunction with:

- PD2005_406 Consent to Medical Treatment – Patient Information
- PD 2015_041 Kidney Donation - Living (Including Directed and Non-Directed Donation)
- PD2016_001 Donation, Use and Retention of Tissue from Living Persons

2 THE AKX USER MANUAL

The AKX User Manual is the agreed procedural guideline for the provision of paired kidney exchange in Australia. The AKX User Manual is available at:


302(06/09/17)
The AKX User Manual outlines the roles and responsibilities of NSW facilities and of clinical and administrative staff including renal specialists, transplant nephrologists, transplant coordinators, transplant surgeons and Australian Red Cross Blood Service tissue typing staff.

NSW Health staff must comply with the requirements and processes outlined within the AKX User Manual including the procedures for assessing, consenting and registering donors and donor-recipient pairs into the AKX Programme, and the use of specified forms.

3 PARTICIPATION IN THE AKX PROGRAMME

3.1 Informed consent

Informed consent for participation in the AKX Programme must be obtained from each participating donor and donor-recipient pair in accordance with the protocols in the AKX User Manual.

Valid, informed consent for participation in paired kidney exchange is contingent on donor-recipient pairs’ receipt and consideration of information on the nature, implications, foreseeable risks and benefits of their participation in this donation process.

Participant donor-recipient pairs must sign a written consent instrument - the relevant donor or recipient Agreement to Participate in AKX form.

Participants must also accept a number of pre-conditions with regard to the exchange including anonymity of donor-recipient pairs, the lack of an enforceable contract to the exchange and mandatory pre-donation counselling.

3.2 Non-directed (altruistic) donors

Non-directed (altruistic) living kidney donation is permitted in NSW.

Non-directed living kidney donors in NSW will be registered in the AKX Programme for potential matching and kidney allocation for a specified number of AKX match “runs” in the National Organ Matching Service (NOMS).

Assessment and management of non-directed living kidney donors must first meet the requirements outlined in PD 2015_041, Kidney Donation - Living (Including Directed and Non-Directed Donation).

3.3 Responsibilities of Clinical Staff and Facilities

3.3.1 Access to the AKX Registry

NSW transplant units participating in the AKX Programme must have at least one health professional designated as an authorised Medical Message Exchange (MMEx) user in order to access and facilitate use of the AKX Registry.

Authorisation is granted by the AKX National Coordination Centre. Contact information for the AKX National Coordination Centre is available within the AKX User Manual.

3.3.2 Patient management and scheduling

Local protocols must support the enrolment of living kidney donors and recipients in the AKX Programme and must be consistent with protocols outlined in the AKX User Manual.

Facilities must ensure flexibility in surgical scheduling to accommodate synchronized donor operations, ensuring optimal and fair exchanges of organs as part of the AKX Program.

Staff involved in the assessment and management of living kidney donors and donor-recipients must be aware of the AKX procedures.
PURPOSE

This document provides the framework for the registration of patients who are hepatitis C (HCV) antibody positive and RNA positive (Ab positive/RNA positive), and are awaiting renal transplantation, who consent to receive kidneys from HCV Ab positive and hepatitis B core antibody negative (HBVcAb negative) organ donors. The register will be known as the NSW Kidney Transplant Program Hepatitis C Register (‘the Register’).

The NSW Register will be part of a national register of HCV Ab positive/RNA positive potential kidney transplant recipients within the National Organ Matching System (NOMS) Kidney Required List.

MANDATORY REQUIREMENTS

The NOMS Kidney Required List is to have a field added to the waiting list criteria to indicate whether the patient is on the Register. Potential recipients listed on the Register will be matched using the national kidney matching algorithm but will also remain on the general kidney allocation waiting list.

The decision to list and transplant a HCV positive potential recipient requires the following strategies to be put in place to minimise any risk of inappropriate allocation or transplantation:

- Transplant Units are to assess and select potential recipients who are HCV Ab positive/RNA positive who would be suitable to receive a kidney from a HCV Ab positive donor.
- Transplant Units must inform a potential recipient of the potential risks of both acceptance and non-acceptance of a HCV Ab positive kidney including disclosure of all material risks. This is to include providing the potential recipient with a copy of the Potential Recipient Information Sheet (Attachment 1).
- Transplant Units must afford the potential recipient reasonable time to make a decision regarding the possibility of being listed on the Register. The option of being listed on the Register should ideally be given to the potential recipient at the time of entering onto the Kidney Required List or as soon as their HCV Ab positive/RNA positive status is confirmed.
- Transplant Units are to retain a signed copy of the Potential Recipient Information Sheet as part of the medical record once the potential recipient has decided on whether to enter the Register or not. A copy must also be provided to the potential recipient.
- The potential recipient must also sign the Agreement to Enter the NSW Kidney Transplant Program Hepatitis C Register (Attachment 2). The Transplant Unit is to forward this form together with the Medical Request to Place a Potential Recipient on the NSW Kidney Transplant Program Hepatitis C Register (Attachment 3) to NOMS at the Australian Red Cross Blood Service (ARCBS). NOMS will only list a potential recipient on the Register once both forms have been received.
- Listing on the Register requires dual entry and authorisation by two (2) NOMS users.

4 Potential donors only need to be tested for HCV antibodies as all potential recipients are HCV Ab positive and RNA positive. Potential donors maybe HCV RNA positive or negative.
• Listing on the Register is valid for twelve (12) months from the date of consent. NOMS will automatically identify potential recipients whose Agreement to Enter the NSW Kidney Transplant Program Hepatitis C Register has lapsed. Transplant Units will be notified by email when a potential recipient’s Agreement has lapsed and will be informed that the potential recipient will be removed from the Register unless a new Agreement is completed and forwarded to NOMS.

• Transplant Unit Directors or their Authorised Representatives are to ensure that potential recipients on the Register have a HCV PCR test performed 6 monthly and to forward the result to both NOMS and the tissue typing laboratory at ARCBS. The tissue typing laboratory is to be notified immediately in writing if the potential recipient’s HCV PCR test returns a negative result.

IMPLEMENTATION

From the date on which this Policy Directive is issued:

• Area Health Services must ensure Transplant Units have established procedures to ensure that hepatitis C positive potential kidney transplant recipients are assessed for their eligibility for listing on the Register, offered appropriate information regarding the Register, sign the appropriate documentation if they consent to listing on the Register and have their hepatitis C RNA status monitored.

• NOMS must ensure that it has established procedures and processes to establish and maintain the Register in NSW, including issuing reminders to Transplant Units when a hepatitis C positive potential recipient’s Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register has lapsed.

• The State Medical Director, NSW Organ and Tissue Donation Service (NSW OTDS) is responsible for ensuring that hospital-based organ donation staff understand the need to notify confirmed HCV Ab positive/HBVc Ab negative deceased persons as potential organ donors.

Roles and responsibilities of the NSW Department of Health

• Maintain a collaborative relationship with Area Health Services, the Australian Red Cross Blood Service (ARCBS) Tissue Typing Laboratory and National Organ Matching Service (NOMS).

Roles and responsibilities of Chief Executives

• Ensure Transplant Units implement procedures for identifying HCV Ab positive/RNA positive potential recipients, assessing their suitability for listing on the Register and listing them on the Register.

Roles and responsibilities of Transplant Units

• Develop and implement procedures for identifying HCV Ab positive/RNA positive potential recipients, assessing their suitability for listing on the Register and listing them on the Register.

• Ensure that the potential recipient renews their Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register annually and that the updated form is sent to NOMS.

• Notify NOMS in writing should the potential recipient revise their decision to be listed within the 12 month cycle.

• Confirm the hepatitis C status of the potential recipient at the time of offer of an organ for transplantation.

• Collect immediately prior to transplantation a sample of serum for storage from the potential recipient.
Ensure the consent form at the time of transplant reflects the potential recipient’s acceptance of the organ from a HCV Ab positive donor. All forms annexed to this Policy Directive can be obtained from SALMAT by Electronic Print On Demand (ePOD).

Roles and responsibilities of the NSW Organ and Tissue Donation Service

- Work collaboratively with health services to identify HCV Ab positive/HBVc Ab negative potential organ donors.

Kidney transplantation is a highly effective treatment for advanced renal disease and relies on the donation of organs from living or deceased donors. Currently, the number of patients who may benefit from transplantation is far greater than the number of kidneys donated, and the availability of donor organs is the limiting factor in applying organ transplantation as a therapy.

In order to manage equitable access to donated kidneys the Transplantation Society of Australia and New Zealand (TSANZ) has developed eligibility criteria for patients to be listed for organ transplantation and protocols for the allocation of organs to patients once listed. Decisions to allocate kidneys take into account the following ethically relevant criteria:

- relative urgency of need;
- medical factors which affect likelihood of success (e.g., tissue matching);
- relative severity of illness and disability;
- relative length of time on the waiting list;
- likelihood that the recipient will (be able to) comply with the necessary ongoing treatment after transplantation.

There is evidence that recipients of kidneys and other transplants with chronic hepatitis C infection have significantly worse long-term outcomes following transplantation than non-infected recipients. However, it is also recognised that individuals with chronic hepatitis C infection with end-stage renal disease may benefit from transplantation for reasons of medical urgency - for example, where transplantation may be life-saving. In recognition of such situations, the Renal Transplant Advisory Committee of TSANZ developed a Hepatitis C Register to allow transparent and equitable allocation of kidneys from hepatitis C antibody positive (HCV Ab positive) and hepatitis B core antibody negative (HBVc Ab negative) donors to hepatitis C Ab positive and RNA positive (HCV RNA positive) potential recipients who consent to be considered for such kidneys.

This Guideline provides the framework for establishment of the NSW component of the TSANZ National Hepatitis C Register - the NSW Kidney Transplant Program Hepatitis C Register (the Register).

This Guideline must be read in conjunction with PD2013_029 Organ donation and transplantation - managing risks of transmission of HIV, HCV and HBV.

The NSW Kidney Transplant Program Hepatitis C Register

The Register is housed within the National Organ Matching Service (NOMS) database.

NOMS will match deceased HCV Ab positive, hepatitis B c Ab negative kidney donors with HCV Ab positive/RNA positive potential recipients. The Kidney Required List will have a field for the Register added. Potential recipients listed on the Register will be matched using the national algorithm.
Potential recipients who accept listing on the Register will remain on the Kidney Required List.

**Listing of potential recipients on the NSW Kidney Transplant Program Hepatitis C Register**

The decision to list and transplant HCV Ab positive/RNA positive potential recipients requires that strategies are in place to minimise any risk of inappropriate allocation or transplantation. These strategies include:

- NOMS will only update the Register on receipt of the signed *Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register* (Attachment 2) and the *Medical request to place potential recipient on the NSW Kidney Transplant Program Hepatitis C Register* (Attachment 3).
- Listing on the Register will require dual entry and authorisation by 2 NOMS users.
- NOMS will automatically identify a potential recipient whose annual *Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register* has lapsed. This will prompt an email to notify the relevant Transplant Unit that the potential recipient will be removed from the Register unless the *Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register* is updated.
- NOMS requires that Transplant Unit Directors or their authorised representatives ensure that a HCV PCR test is performed every 6 months and that the tissue typing laboratory at ARCBS is notified immediately if the potential recipient’s HCV PCR test result is negative.

**Transplantation Unit Responsibilities**

It is the responsibility of individual Transplant Units to assess and select potential recipients who would be suitable to receive a kidney for transplantation from a HCV Ab positive donor.

**Potential Recipient Inclusion/Exclusion Criteria**

Transplant Units must exclude those potential recipients who are:

- currently being treated for HCV; or
- who are HCV RNA negative.

All other suitable potential recipients for inclusion on the Register must:

- be reviewed by a NSW Renal Transplant Unit and accepted and listed for transplantation as per the TSANZ protocol; and
- discuss with their Transplant Unit the possibility of accepting an organ for transplantation from a HCV Ab positive donor.

**Informed consent of potential recipients**

There is a requirement in law for the Transplant Unit to inform a potential recipient of the risks and consequences of both acceptance and non-acceptance of a particular organ, including disclosure of all material risks.

Transplant Units must afford potential recipients reasonable time to make a decision regarding the possibility of listing on the Register and to receive a potential offer of a kidney from a HCV Ab positive donor. This option should ideally be given to the potential recipient at entry onto the waiting list or as soon as their HCV Ab positive/RNA positive test result is confirmed.
The potential recipient should be provided with the Potential recipient information sheet (Attachment1) and given the opportunity to consider the decision.

The Potential recipient information sheet provides an opportunity for the potential recipient to acknowledge and document that they have received, read and understood the information provided and have had an opportunity to ask questions. The potential recipient should initial each criterion.

The signed Potential recipient information sheet must be retained as part of the medical record. A copy must also be given to the potential recipient.

Transplant Unit responsibilities re listing of potential recipients on the NSW Kidney Transplant Program Hepatitis C Register

If a potential recipient agrees to be listed on the Register it is the responsibility of the Transplant Unit Director (or delegate) to ensure that:

- the potential recipient has signed the Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register (Attachment 2). A copy must be given to the potential recipient.
- they have signed the Medical request to place potential recipient on the NSW Kidney Transplant Program Hepatitis C Register (Attachment 3).
- the potential recipient’s HCV RNA status has been ascertained prior to nominating them for listing.
- the local tissue typing laboratory has been provided with a copy of the Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register, the Medical request to place potential recipient on the NSW Kidney Transplant Program Hepatitis C Register and a copy of the results of the potential recipient’s HCV PCR test.

Maintenance of a potential recipient’s listing on the NSW Kidney Transplant Program Hepatitis C Register

The Transplant Unit must monitor the potential recipient’s HCV status every 6 months by PCR testing. The results of repeat PCR testing must be provided to the tissue typing laboratory or the potential recipient’s listing on the Register will be discontinued.

The tissue typing laboratory must be notified in writing if the potential recipient’s HCV PCR test returns a negative result. In the event of a negative HCV RNA test result the potential recipient will be removed from the Register.

The Transplant Unit must ensure that the potential recipient renews their Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register annually and that the updated form is sent to NOMS. NOMS will remove the listing from the Register if an updated Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register is not received.

To ensure that the relevant documentation and test results are maintained in the Register, NOMS will circulate listings on the Register to each Transplant Unit Director with the date of entry to list. The relevant dates for repeat HCV PCR testing and renewal of the potential recipient’s Agreement to enter the NSW Kidney Transplant Program Hepatitis C Register will also be provided.

Should the potential recipient revise their decision to accept listing on the Register within the 12 month cycle, the Transplant Unit Director (or delegate) must notify NOMS in writing of that decision.

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Responsibilities of Transplant Units at time of offer for transplantation

The HCV status of the potential recipient at the time of offer of organ for transplantation should be confirmed by the Transplant Unit (based on the PCR result within the last 6 months). If the patient’s PCR test result or HCV status cannot be confirmed, then the offer should not be made and the kidney should be reallocated.

Immediately prior to transplantation, a sample of serum should be collected from the potential recipient and stored according to National Pathology Accreditation Advisory Council guidelines.

The consent form at the time of transplant must reflect the potential recipient’s acceptance of the organ from a HCV Ab positive donor. In addition to the usual risks of transplantation, the transplant team should also ensure that the potential recipient understands that:
- no pathology test which is performed on a donor is entirely accurate;
- there is a small chance that screening of the donor has not identified another potential infectious agent;
- tests are not performed for all known infectious diseases; and
- there are rare instances where transplantation results in the transmission of infections that have not been described before;
- the donor may have a different genotype of HCV to the recipient and the implication of this.

Surveillance of infections in transplant recipients

The Transplant Unit should determine whether any unanticipated transmission of a blood borne virus has occurred by performing serological testing of the recipient at least two months post-transplant. Unexpected seroconversion post-transplant may indicate infection as a consequence of transplantation. Where this occurs, the recipient’s stored serological sample that was collected immediately prior to the transplant should be tested in order to determine whether transplantation played a role in transmission.

All unanticipated transplant-associated infections should be reported to the:
- Incident Information Management System (IIMS) in accordance with PD2014_004 Incident Management Policy.
- NSW OTDS State Medical Director
- local Public Health Unit

Hepatitis C antibody positive donors

The NSW OTDS State Medical Director (SMD) is responsible for ensuring that hospital-based organ and tissue donation staff notify the NSW OTDS of potential HCV Ab positive/ HBV cAb negative deceased donors.

The NSW SMD must also ensure that appropriate screening algorithms and protocols are in place to assist staff in determining clinical suitability of such potential donors. These protocols and algorithms must include assessment and screening of the potential donor for other blood borne viruses or co-infections which may potentially impact on the recipient.

Assessment and screening should be undertaken according to the requirements of PD2013_029 Organ Donation and Transplantation - managing risks of transmission of HIV, HCV and HBV.
26. TISSUE/ORGAN

The Chair of the NSW Transplant Advisory Committee (TAC) will monitor and report on transplant program outcomes for recipients of organs from HCV Ab positive donors through the RTAC; and report and advise the NSW Chief Health Officer as required of the need to revise this policy.

CONDUCT OF ANATOMICAL EXAMINATIONS AND ANATOMY LICENSING IN NSW (PD2011_052)

PURPOSE

The activity of conducting anatomical examinations is governed by the Anatomy Act 1977 and regulated by NSW Health.

This document outlines the procedures for the licensing, inspection and regulation of Anatomy facilities conducting anatomical examinations, and provides clear directives to licence holders of acceptable activities and government regulations under the provisions of the licence.

Failure to comply with requirements of the Anatomy Act 1977 may constitute an offence.

MANDATORY REQUIREMENTS

Anatomy Licences

• The licence is issued to an individual or the holder of an identified position for a specific facility location.
• Anatomy licences are issued by the Director-General, NSW Department of Health, or their delegate, for a 2 year period subject to satisfactory annual inspections. The Director-General may revoke the licence at any time. Once a licence has been granted the NSW Department of Health must be notified in writing of any change to the designated licence holder of an institution.
• Licence holders are required to submit an application to the Director-General, NSW Department of Health, to reapply for their anatomy licence prior to the expiration of their current licence.
• A person wishing to conduct an anatomical workshop or training session as a one-off event is required to apply to the NSW Department of Health for a licence for the specified time period.

License Applications and Inspections

• All applications must be received in writing. An inspection of the proposed facility and subsequent report will be undertaken as part of the licence application process.
• Inspections are conducted by the local Public Health Unit Director or their delegate.
• Licensed facilities will be inspected annually. An inspector can also inspect a licensed premise at any time. The holder of a licence must comply with any terms or conditions included on the licence.

Registers

• All licence holders are required to keep a register of all bodies and/or human tissue in their possession. The register must also be used to contain information relating to the transfer of bodies and/or human tissue from or to another licence holder.
• The licence holder must produce the register to an inspector as requested.
• The register must be retained for at least 5 years from the date of the most recent entry.

Conditions on taking possession of a human body for anatomical examination

• Written consent must be obtained for a body to be used for anatomical examination. Consent is either that of the individual written during their lifetime or received from the senior available next-of-kin after an individual’s death.

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• If the body of the deceased is at a hospital or forensic institution, a Designated Officer must authorise the use of the body prior to the body being transferred to the licence holder.
• A Designated Officer or a senior next-of-kin cannot authorise the anatomical examination of the body of a person whose death has been reported under the Coroners Act 2009, unless a Coroner has consented to the examination.
• A person must not authorise the anatomical examination of the body of a deceased child if the child was, immediately before death, in the care of the State.

Acquisition and retention of donated bodies and human tissue
• Bodies and human tissue specimens can be acquired by a licence holder as either a transfer from another licensed institution (including international institutions) or from a specific body donation program. Minimum standards must be met for information to be included in the donation program information package.
• A transfer of a body or human tissue to another licence holder outside NSW is permitted only with prior approval of a NSW inspector. A licence holder may transfer a body in their possession to another licence holder within NSW without prior approval.
• A body can be retained for a maximum of 4 years. Upon application an inspector may authorise the retention of a body for an additional 4 year period. Generally bodies must be appropriately disposed of within 8 years from the date of death of the deceased.
• Specific provision has been made in the Anatomy Act for the permanent retention of tissue (anatomical specimens) where written consent has been given by the deceased prior to death. Where no consent has been given and the wishes of the deceased in this respect are unknown, the senior available next-of-kin may consent to permanent retention of tissue.

IMPLEMENTATION
• Applicants for licences: must ensure that the application includes information as detailed in the attached procedure and that it is accompanied by additional documentation where required.
• Licence holders: must ensure that they meet all legislative requirements of the Anatomy Act 1977 and relevant provisions of the Human Tissue Act 1983, the Coroners Act 2009 and the Public Health (Disposal of Bodies) Regulation 2010 or any subsequent regulation made under the Public Health Act. Licence holders must satisfy all terms and conditions set by the licence.
• Public Health Unit anatomy inspectors: must undertake inspections as required by this policy or as directed by the Director-General or delegate. Guidelines for facility inspections and the inspection of registers of bodies and human tissue are in the attached procedures.
• Designated Officers in health facilities and forensic institutions: must authorise the release of a body from a hospital or forensic institution for anatomical examination. A body must not be released from a hospital to an authorised licence holder until a Designated Officer has authorised its release. (See following procedures.)

1. BACKGROUND

1.1 About this document

The practice of anatomical examination in NSW is the dissection of a dead human body for the purposes of medical, scientific and educational training and research. This activity is predominately undertaken in university anatomy departments or medical schools for the teaching and training of students and staff and in associated facilities for conducting research.
The anatomical training and research undertaken in facilities would either form part of a university degree or be a specialised training workshop for medical and health professionals.

This document outlines the procedures for the licensing, inspection and regulation of anatomy facilities conducting anatomical examinations, and provides clear directives to licence holders of acceptable activities under the provisions of the licence.

Included in these procedures are guidelines for:
1. Application for a Licence (Attachment 1).
2. Inspection of facilities (including the Inspection Checklist at Attachment 2).
3. Suggested pro-forma for a register of donated bodies and dissections (Attachment 3).
4. Minimum Information to be included in body donor programs.

1.2 Key definitions

**Anatomical examination** of a body includes use of the body for medical or scientific purposes. However, an anatomical examination does not include a post-mortem examination. Medical or scientific purposes include educational purposes connected with medicine or science. *(NSW Anatomy Act 1977 Part 1 Section 4)*

**Anatomical waste** in this document means a discarded biologic product, such as blood or other bodily fluid, fat, skin or other small amounts of human tissue removed from a cadaver that is undergoing preparation or dissection for anatomical examination. This waste material may be disposed of as clinical waste according to relevant requirements.

**Body** in this document means a dead human body. *(NSW Anatomy Act 1977 Part 1 Section 4)*

**Designated Officer** means a person appointed to be a Designated Officer for the hospital, or a forensic institution. *(NSW Human Tissue Act 1983 Part 1 Section 5)*

**Dispose** means dispose of the body by burial, cremation or other lawful means. *(NSW Anatomy Act 1977 Part 1 Section 4)*

**Human tissue** means an organ or part of a body. *(NSW Anatomy Act 1977 Part 1 Section 4)*

**Senior available next-of-kin** means the most senior next-of-kin in the hierarchy of next-of-kin within the Anatomy Act 1977.

1.3 Legal and legislative framework

**Anatomy Act 1977**

The Anatomy Act 1977 regulates the conduct of anatomical examinations in NSW, including the issue of licences, the appointment of inspectors, the conditions of taking possession of bodies or human tissue, the requirements for keeping registers of bodies and human tissue and for the disposal of bodies. In addition the Act outlines general offences. Failure to comply with the requirements of the Anatomy Act 1977 may constitute an offence.

**Human Tissue Act 1983 - Designated Officers**

Designated Officers are appointed in accordance with Section 5 of the Human Tissue Act 1983 by the governing body of a hospital or forensic institution. Section 8 of the Anatomy Act 1977
states that a Designated Officer of a hospital or forensic institution may, by instrument in writing, authorise the anatomical examination of a body of a person in accordance with the consent given by either the deceased or their senior available next-of-kin.

**Coroners Act 2009 - Coronial Consent**

Section 56 of the *Coroners Act 2009* states that a Coroner has a right to take possession of and retain the remains of a deceased person whenever the coroner has jurisdiction to hold an inquiry concerning the death of the person. This right of the Coroner has priority over any other right to possession such as a potential donation to a school of anatomy.

Once an order for disposal of the remains has been issued by the Coroner, a licence holder may proceed with the potential donation. A copy of the Coronial order for disposal of the remains should be retained with the consent paperwork.

**Public Health (Disposal of Bodies) Regulation 2002 - List A and B diseases**

Anatomy license holders wanting to use donated bodies and human tissue must determine that the body or tissue is not infected with a List B disease as outlined in section 3 (1) of the *Public Health (Disposal of Bodies) Regulation 2002* regarding List A and List B diseases.

2. ANATOMY LICENCES

2.1 General Information

A person in charge of the conduct of anatomical examinations at a university, college, or other tertiary educational institution can apply for a licence to lawfully possess human bodies and tissue for examination purposes at a location specified in the licence.

An anatomy licence is issued in accordance with the *Anatomy Act 1977*. A licence may be issued with additional terms and conditions.

Anatomy licences are issued by the Director-General, NSW Department of Health, or their delegate, for up to a 2 year period subject to satisfactory annual inspections. Re-application is required at the completion of the licence period. The Director-General may revoke the licence at any time.

2.1.1 Applying for an Anatomy Licence

Written applications for an anatomy licence must be submitted to the Director-General, NSW Department of Health. The information required in an application is outlined at attachment 1. Additional information can be included in the written application if desired.

2.1.2 Application inspections

An inspection of the proposed facility specified in the application, will be undertaken as part of the licence application process.

The inspection involves audit of the physical environment of the facility and a review of the policies and procedures of the facility and the register of specimens. The relevant local anatomy inspector conducts the inspection.
On receipt of a written application, NSW Department of Health will advise the inspector to contact the applicant to arrange an inspection. On completion, the inspection report is forwarded to NSW Department of Health with recommendations.

Depending on the report outcomes a licence may be issued with standard and additional conditions.

Applicants can refer to the anatomy licence inspection guidelines [see attachment 2] to gain a comprehensive overview of the inspection process.

2.1.3 One-off licences

A person wishing to conduct an anatomical workshop or training session as a one-off event is required to apply to NSW Department of Health for a licence for the specified time period of the event. The person must, in writing, address each criteria listed in attachment 1 with the exception of providing an ethics committee statement. Bona fide documentation of the event, such as a course program or workshop brochure, must be included with the licence application.

2.1.4 Reapplying for licences

Licence holders wishing to renew a licence are required to submit an application to the Director-General, NSW Department of Health prior to the expiration of their current licence. The written application needs to address the criteria listed in attachment 1. Licence holders should ensure that they submit their application 3 months prior to their current licence expiring.

2.1.5 Re-issue of licence to reflect changes to a licence holder

The Director-General, NSW Department of Health, must be notified in writing of any change to the designated licence holder of an institution. A re-issue of a licence can be requested at any time to accurately reflect changes to staff or duties within the anatomical facility.

A re-issue of a licence should be considered when the current licence holder will be absent from their regular duties for a period of time greater than 3 months.

3. INSPECTIONS

The local anatomy inspector conducts inspections for each local anatomy facility. The facility will be notified of the inspection and must fully cooperate with the inspection. An inspector can inspect any licensed premise at any time.

The inspection audits the physical environment of the facility and reviews the policy and procedure protocols of the facility and the register of specimens. After each inspection a report is sent to the facility that may include recommendations to ensure compliance with licence conditions or the requirements of the Anatomy Act 1977. The anatomy inspector will continue monitoring the facility to follow up on the progress of any recommendations.

The inspection is to consist of:

- ensuring the designated holder of the licence is still applicable
- ensuring compliance with any standard and additional licence conditions
- reviewing the register to ensure it conforms with the requirements of the Anatomy Act 1977 and
- reviewing the anatomy laboratory facility to ensure it conforms to required standards.
NSW Department of Health has developed Anatomy Licence Inspection Guidelines to assist inspectors in undertaking the application audit and assessment (Attachment 2).

3.1 Annual inspections

The anatomy inspector is required to establish an annual schedule for inspection of anatomy facilities within his/her jurisdiction and advise those institutions accordingly.

4. ANATOMY REGISTER

All anatomy licence holders are required to keep a register of all bodies, including human tissue, in their possession. The register must also contain particular information relating to the transfer of bodies and human tissue and the disposal of bodies. An example of a register is attached (Attachment 3). Registers may be in electronic or hard copy format.

The licence holder must produce the register to an inspector as requested. If the register is kept in electronic format it must be accessible to the Inspector during an inspection and able to be printed for signature.

The register must be retained for at least 5 years from the date of the most recent entry.

4.1 Taking possession of a body/tissue

On taking possession of a body, the following information must be entered onto the register:
- the name and address of the person who had lawful possession of the body and who delivered the body into the licence holder’s possession;
- the date on which the licence holder took possession of the body; and
- the name, age, sex and last place of abode of the deceased and the date, place and cause of death of the deceased.

4.2 Transfer of a body

When a body is transferred either within or outside NSW, a copy of the particulars contained on the register must also be transferred with the body. The following information must be entered onto the register:
- notification and date of the transfer; and
- the name, address/contact details of person receiving the body.

4.3 Transfer of human tissue

When human tissue is transferred either within or outside NSW, the following information must be entered onto the register:
- notification and date of the transfer;
- the name, address/contact details of the person to whom the tissue was transferred;
- the location where the tissue is to be retained; and
- details of the arrangements regarding the return of the human tissue.

5. DONATION OF BODIES FOR ANATOMICAL EXAMINATION

5.1 General Information

Authorisation for a body to be used for anatomical examination is predicated on the attainment of consent. Consent can be given either via a pre-registered body donation to a licensed
anatomical facility by a deceased person in their lifetime, or after death by the senior next-of-kin of the deceased.

5.1.1 Written consent: hospital or forensic institution

A Designated Officer may authorise the anatomical examination of an deceased adult’s body at a hospital or forensic institution if they are satisfied, that the person (during their lifetime) had given their written consent to the anatomical examination of their body after death and that consent had not been revoked. The Designated Officer’s authorisation must be in writing. The anatomy facility should ensure that a copy of the Designated Officer’s written authority is received at the time the body is transferred to their program. Attachment 2 provides an example of a Designated Officers Authority for donation of a body for anatomical examination.

5.1.2 No written consent: hospital or forensic institution

If there is no pre-written consent by the deceased to the anatomical examination of their body after death, or the deceased is a child, the Designated Officer may authorise the anatomical examination, providing it is:
- established that the deceased had not during their lifetime expressed an objection to an anatomical examination of their body after death;
- ascertained that a senior available next-of-kin has given their consent in writing to the anatomical examination of the deceased; and
- ascertained that there is no senior available next-of-kin of the same or higher order in the hierarchy of senior available next-of-kin who objects to the removal of tissue from the person’s body.

The Designated Officer may authorise, in writing, the anatomical examination of the deceased in accordance with any terms or conditions placed on the consent by the deceased or the senior available next-of-kin.

5.1.3 Written consent: not at hospital or forensic institution

If the body of a deceased adult is at a place other than a hospital or forensic institution, and the person had (during their lifetime) given their consent in writing to the anatomical examination of their body after death and that consent had not been revoked, the anatomical examination of that person’s body is authorised, in accordance with any terms or conditions placed on the consent.

5.1.4 No written consent: not at hospital or forensic institution

If the body of a deceased person is at a place other than the hospital or forensic institution, the senior available next-of-kin can consent to the anatomical examination of that person’s body even if consent was not given in writing during the deceased person’s lifetime. The senior available next-of-kin should establish that the deceased had not expressed an objection to the anatomical examination of their body during their lifetime and there is no objection from any other next-of-kin (See 8A(4)(b) Anatomy Act 1977).

5.1.5 Coroner consent

The Designated Officer or the senior available next-of-kin cannot authorise the anatomical examination of the body of a person in respect of whose death a coroner has jurisdiction to hold an inquest under the Coroners Act 2009 unless a Coroner has given consent to the examination.
The Coroner may set specific conditions to his/her consent. Consent by a Coroner may be given orally and, if so, is to be confirmed in writing as soon as practicable.

5.1.6 Effect of authority

The authority of a Designated Officer or a senior available next-of-kin is sufficient for:

- a person who has lawful possession of a body to cause or permit the body to be used by a licence holder for anatomical examination; and
- for the licence holder to conduct an anatomical examination of the body, at licensed premises, in accordance with the authority, subject to the terms and conditions of the consent.

5.1.7 Children in the care of the State

A person must not authorise the anatomical examination of the body of a deceased child if the child was, immediately before death, a child in the care of the State.

5.2 Taking possession of a body

Licence holders can only take possession of a body for anatomical examination (other than a body transferred from another licence holder) when they have the written authority of a Designated Officer or a senior available next-of-kin.

Licence holders accepting deliveries of bodies from the Coroner must ensure that they also receive the relevant documentation authorising the release of the body.

5.3 Human tissue acquisition

Human tissue can be acquired as either a transfer from another licensed institution or facility (including international institutions) or by a specific body donor or specimen donation program.

Tissue acquisition in NSW is covered by the Anatomy Act 1977. Applicants who source tissue from interstate or international institutions are responsible for obtaining statements from the supplying institution that demonstrate that the acquired tissue complies with the consent and other provisions of the Act. It is incumbent upon the facility to ensure that any agreements with interstate/international suppliers of imported tissue clarify the requirements of the original consent regarding the disposal of the tissue. If the tissue is for local disposal the supplier should ensure that it is accompanied by the appropriate documentation to allow disposal in NSW.

If an applicant wants to use body specimens from international institutions they must also ascertain that the body specimen meets the requirements of the Public Health (Disposal of Bodies Regulation2002) with regard to List B diseases.

5.4 Transfer of Human bodies or Human Tissues

5.4.1 Transfer of a Body

A licence holder may transfer a body in their possession to another licence holder within NSW without prior approval of an inspector. A transfer to any person in charge of the conduct of anatomical examinations at any place outside NSW is permitted with prior approval of an inspector.

Transfer of a body is not permitted if the licence holder has reason to believe that the transfer would be contrary to the wishes of the deceased or the senior available next-of-kin.
If the body is to be disposed of by the receiving institution it is a requirement that all relevant paperwork (including cremation certificates and medical referee’s permit) accompany the body.

5.4.2 Transfer of human tissue

The Anatomy Act 1977 allows for the transfer of human tissue from one licence holder to another, or to an authorised officer of a NSW hospital, or to a person approved, in writing, by the Director-General within NSW without prior approval of an inspector for use for medical or scientific purposes.

Transfer of tissue will not be permitted if the licence holder has reason to believe that the transfer would be contrary to the wishes of the deceased or the senior available next-of-kin.

The licence holder must ensure that arrangements are made for the return of the human tissue as soon as practicable, and by no later than the end of the period within which the tissue is required to be disposed.

6.  RETENTION OF BODIES OR TISSUE FOR ANATOMICAL EXAMINATION

6.1 Extension to retain bodies and human tissue

A licence holder must dispose of a body in their possession within 4 years of the date of death of the deceased.

A licence holder wishing to apply for an extension to retain bodies or human tissue in their possession can do so by writing to the local anatomy inspector. A request for an extension must include the relevant donor details.

An inspector may authorise the retention of a body or tissues for a maximum of an additional 4 year period. All bodies and tissues from those bodies must be disposed of within 8 years from the date of death of the deceased.

An inspector may not give such an extension if it would be inconsistent with the terms of the original consent of the deceased or next-of-kin.

Further authorisation is not required for the retention of tissue slides or tissue blocks or museum pathology specimens in sealed containers.

In granting authorisation, an inspector should consider:
- any conditions placed by the deceased or senior available next-of-kin qualifying their original consent that would prevent extension;
- the purposes for which extended retention of the body or human tissue is sought;
- justification for why the body or human tissue had not been utilised in the four year period; and
- the condition of the body or human tissue.

The holder of a licence must comply with any terms or conditions that are imposed by an inspector in granting an authorisation for the retention of a body or human tissue and must enter details of the authority in the register.

6.2 Permanent retention of human tissue

Specific provision has been made in the Anatomy Act for the permanent retention of tissue where written consent has been given by the deceased prior to death.
Where no consent has been given and the wishes of the deceased in this respect are unknown, the senior available next-of-kin may consent to permanent retention of tissues.

No consent is required for the permanent retention of small samples of tissue in the form of tissue blocks and slides.

7. DISPOSAL OF BODIES OR TISSUE

7.1 General Requirements for disposal of bodies

The licence holder is required to dispose of a body in their possession for anatomical examination (including any human tissue from that body) within 4 years after the death of the deceased person, or in accordance with the terms of an authorisation or extension granted by an inspector.

A licence holder, where practicable, should dispose of a body in accordance with the wishes of the deceased or, the wishes of the senior available next-of-kin.

7.1.1 Register

The licence holder, following the disposal of a body, must enter onto the register the:
- notification and date of the body’s disposal; and
- the name, address/contact details of the person who disposed of the body.

7.1.2 Disposal of permanently retained tissues

There are many circumstances that necessitate disposal of human tissue separately from the rest of the body from which the tissue originated. These circumstances include where the institution has consent to the permanent retention of tissue that is no longer in a usable state. Decisions on the usable state of such tissues should be taken on a case-by-case basis by anatomy facilities and referred to the local anatomy inspector. If the specimens are to be disposed of the institution should ensure that records detailing the method and reason for disposal are maintained.

Depending on the original consent documentation options for disposal may include:
- contact with next-of-kin to arrange collection of the tissues usually by a funeral director of their choice to make their own arrangements for cremation or burial; or
- appropriate disposal of the tissues by the institution. Dignified treatment and separate disposal are the minimum considerations involved in disposing of human tissue. Arrangements for respectful and sensitive disposal should be made at local level.

These practices should be explained to donors through the donation program information.

7.13. Requirements for the disposal of anatomical waste tissue

Anatomical waste should be managed in accordance with the requirements of PD2005_132 Waste Management Guidelines for Healthcare Facilities.

These practices should be explained to donors through the donation program information.
8.BODY DONATION PROGRAMS

It is strongly recommended that body donation programs are overseen by a suitable human ethics committee. Cadaveric material is most commonly sourced from the willed-body donation programs of the schools of anatomy at universities within NSW and interstate. A person may decide in their lifetime to donate their body, after death, to a facility for the purpose of medical training and research. Prospective donors are provided with information about the donation program to which they are considering committing their body once they are deceased. The institution will arrange for prospective donors to complete a consent form to document this decision.

8.1 Written consent

The standard of consent for a body donation program in NSW is written consent. All body donation programs should provide clear consent forms for potential donors that include options for potential donors to specify terms and conditions to their consent [See 8.2].

A body donation program can refuse to accept a body from a deceased person who gave written consent to donate their body. The reasons for non-acceptance of a body should be outlined in the information about the body donation program and a statement as to the possibility of non-acceptance by the institution should be included on the consent form signed by potential donors.

8.1.1 No written consent by the deceased

Generally, programs will not accept body donations from the next-of-kin in the absence of a signed and witnessed consent of the deceased made in their lifetime. There is however, no legislative impediment to consent to body donation from an appropriate next-of-kin, as long as the non-objection of the deceased and other next-of-kin is established. Institutions should provide appropriate forms for next-of-kin consent.

8.2 Consent forms

Donor consent forms developed by body donation programs will vary in content depending on the opportunities offered to the prospective donor to authorise specific activities and place terms and conditions on the use of their body as discussed above.

Consent forms at a minimum should therefore allow the prospective donor to:

- consent or not consent to the use of their body for certain activities, such as sponsored research, educational research; training students or other activities;
- consent or not consent to the transfer of their body to other organisations;
- consent or not consent to the permanent retention of human tissue and allow for authorisation if specific organs are to be retained, including for museum displays; and
- consent or not consent to the release of their prior medical history and/or records to the licence holder or their delegate for the purposes of determining medical suitability of the donation or for research purposes.

In addition the form should contain:

- a statement for the Designated Officer to authorise the donation (for donations from hospital and or forensic institutions);
- a statement as to the reasons why a facility may choose not accept a prospective body donation at the time of death; and
- a statement outlining the screening tests that the donor program may chose to undertake on a donated body and the reason for those tests.
Licence holders should review the range of activities contemplated within their licence and ensure that these activities are reflected in the consent options.

8.2.1 Revocation of consent

A person can change their consent to donation during their lifetime. Body donation programs should include the option of a form for the revocation of consent within their body donation program information.

8.3 Donor information

Information re: body donation programs should provide detail for prospective donors which explain the potential uses of donated bodies and the terms and conditions that a facility may place on the acceptance and use of the donation. It is recommended that the relevant institutional ethics committee or other appropriate governance body review the donor program and its information and materials prior to their publication.

- **Uses of donated bodies/body parts/tissues:** Donor information should contain an explanation of how bodies can have different uses, such as for teaching, research and training, and provide some detail of the meaning of ‘anatomical examination’ to outline the intended use of a body. Examples of this include where a facility wishes to use the body/tissues from the body for public display in anatomy museums or where other activities such as forensic experimentation may be conducted.

- **Retention:** Donor program materials should include information regarding the length of time a body can be retained, from the date of death, for medical use. Programs should provide an option for permanent retention on their consent forms.

- **Disposal of bodies and tissues and anatomical wastes:** Information on the options for disposal of bodies or tissues should be outlined for prospective donors. This should include information that small amounts of tissue such as body fluids, fat, skin etc may be disposed of as anatomical waste through appropriate clinical waste guidelines. Information should also be provided on the permanent retention of tissue slides and tissue blocks.

- **Public Display:** The fundamental principle of the Anatomy Act is the requirement that consent is obtained for the donation, storage and use of relevant material which has come from a human body for certain purposes. It is mandatory that donor consent forms include an option for the potential donor to authorise the use of their body or tissue for particular activities which may be considered by the facility including public display.

- **Use of Images:** The making and displaying of images (including photographs, films and electronic images) requires that facilities put systems in place to ensure suitable practices are carried out. Where licensable activities are concerned this includes ensuring that the dignity of deceased people is maintained at all times. Therefore, facilities need to put in place procedures and systems to prevent the inappropriate use of images of deceased persons or body parts.

- **Transfer of body:** Donor programs should advise prospective donors that their body, body parts or tissues, may be transferred to other organisations for use. It should be specified that transfer can occur both within and outside Australia, and allow donors the opportunity to consent to this use.
8.4 Occupational health and safety and screening of donated bodies or human tissue.

It is recommended that licence holders take steps to ensure that donated bodies or tissue specimens are appropriately screened for blood borne viruses and other pathogens prior to their acceptance of the body/tissue. This may include the use of donor screening tools and/or medical and social history questionnaires and/or the use of specific cadaveric screening tests.

8.4.1 Notification mechanisms

(See: IB2013_010 Notification of infectious Diseases under the Public Health Act 2010)⁵

- Laboratories must notify positive results of scheduled medical conditions in the deceased to NSW Department of Health in accordance with the current NSW Public Health Act therefore licence holders are not required to undertake notification of results of Infectious disease testing or contact tracing of body donors.
- Licence holders should however have procedures in place for informing the next-of-kin that the donation of either the body or tissues will not be accepted.
- Licence holders can provide the details of contacts of body donors who may be at risk of infection to the local Public Health Unit if required to do so to facilitate contact tracing. Provision of contact details in these circumstances would not be in breach of statutory confidentiality provisions.

LIST OF ATTACHMENTS

1. Application guidelines
2. Example of a Designated Officers Authority
3. Inspection audit checklist and guidelines
   3.1 Examples of Anatomy Registers

⁵ Polices will be amended subsequent to the commencement of the Public Health Act 2010.
Attachment 1: Application Guidelines.

1. **Proposed Licensee(s)**
   - Name
   - Position
   - Address
   - Phone number(s)
   - Email address

   Include all relevant information for both proposed licensees if application is for a joint licence.

2. **Location of anatomy facility**
   This can be the actual or proposed facility.

3. **Access to the facility**
   Specify the types of students and staff who will use the facility and their approximate number per year. Outline the proposed security process for ensuring only bona fide students and staff (as specified) have access to the facility.

4. **Proposed anatomical activities**
   This can be a general statement on the range of activities to be undertaken in the facility. For example, ‘The study and practice of anatomy within the terms of the Anatomy Act and NSW Health anatomy policy guidelines using tissues for the purposes of anatomical dissection and surgical technique.’

5. **Accessing cadaver material**
   Outline the proposed process for obtaining cadaver material, including details of the facilities where tissue may be sourced from.

6. **Registering tissues/specimens**
   Outline the proposed process for registering all tissue and specimens.

7. **Disposal of tissues/specimens**
   Outline the proposed process for the disposal of tissues/specimens as determined by the requirements of the Anatomy Act 1977 and NSW Health anatomy guidelines.

8. **Ethics committee statement**
   Where necessary, statements in support of an application from referees and institution ethics committees are to be provided. (NSW Health will advise applicants if such statements of support are required as part of their licence application.)

**Lodging Applications:**
All applications are to be addressed to:

Director-General of Health
NSW Health Department
Locked Mail Bag 961
North Sydney NSW 2059
Attachment 2: Example of a Designated Officers Authority for Anatomical Examination

Authority by a Designated Officer for the Anatomical Examination and Release of a Body from the Hospital to a Licensed Anatomical Facility

I __________________________________________________________________________
(Name of Designated Officer)

1. Hereby state that I am satisfied that [Tick where applicable]

☐ The above mentioned deceased had given their written consent to the anatomical examination of their body after death and that consent had not been revoked or objected to by the senior available next-of-kin.

OR

☐ The above mentioned deceased had not during their lifetime expressed an objection to an anatomical examination of their body after death and the senior available next-of-kin has given their consent in writing to the anatomical examination of the deceased. There is no senior available next-of-kin of the same or higher order in the hierarchy of senior available next-of-kin who objects to the removal of tissue from the person’s body.

2. Hereby authorise anatomical examination and the release of the above mentioned deceased to the:

______________________________________________________________________
(Name of Licensed Anatomical Facility)
in accordance with any terms or conditions placed on the consent by the deceased or senior available next-of-kin.

Designated Officer signature: ____________________________

Date: ____________________________

Coroner consent
A Designated Officer or a senior available next-of-kin cannot authorise the anatomical examination of the body of a person in respect of whose death a coroner has jurisdiction to hold an inquest under the Coroners Act 2009 unless a Coroner has given consent to the examination.
### Attachment 3: Inspection Audit Checklist And Guidelines

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Body preparation</strong>&lt;br&gt;Vehicle reception area screened from public view</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Wash hand basin; hot and cold water; non-hand operated taps soap and disposables paper towel or air dryer</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Slabs, tables, fittings and fixtures in good repair</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Adequate sinks with hot and cold water for cleaning equipment and appliances</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Hoses fitted with backflow prevention</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Refrigerated storage area temperature 1-5°C</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Containers for general and clinical waste</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td><strong>Waste disposal</strong>&lt;br&gt;Different types of waste containers located appropriately</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Liquid waste: water authority approval for contaminated waste</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Clinical wastes: disposed in accordance with appropriate environmental guidelines</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td><strong>Handling bodies</strong>&lt;br&gt;Policy for handling infectious bodies</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td><strong>Labelling</strong>&lt;br&gt;Sufficient systems for permanent non-identifying labelling of bodies and specimens</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Sufficient systems to track all bodies/specimens within register</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td><strong>Management of chemicals</strong>&lt;br&gt;MSD sheets available for easy reference</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Satisfactory storage of chemicals</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Appropriate mechanical ventilation systems in place</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td><strong>Storage</strong>&lt;br&gt;Sufficient refrigerated storage compartments at appropriate temperature for the number of cadavers</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Adequate Storage of embalmed body parts</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td><strong>Anatomy rooms</strong>&lt;br&gt;Occupational health and safety policy for the activities undertaken</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>Appropriate attire and PPE available (e.g. gowns, gloves, masks, glasses)</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>First aid/Emergency assistance procedures available</td>
<td></td>
<td>□</td>
</tr>
<tr>
<td><strong>Security</strong>&lt;br&gt;Access only for bona fide staff and students or authorised personnel</td>
<td></td>
<td>□</td>
</tr>
</tbody>
</table>
## Construction of facility

<table>
<thead>
<tr>
<th>Component</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walls</td>
<td></td>
</tr>
<tr>
<td>Floors</td>
<td></td>
</tr>
<tr>
<td>Ceilings</td>
<td></td>
</tr>
<tr>
<td>Lighting</td>
<td></td>
</tr>
<tr>
<td>Ventilation</td>
<td></td>
</tr>
<tr>
<td>Toilet and Showering facilities</td>
<td></td>
</tr>
<tr>
<td>Pest Control program in place</td>
<td></td>
</tr>
</tbody>
</table>

**General comments on overall standards:**

**Action required:**

**Name of inspector:**

**Signature:**

**Date:**

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Administration management

- Discussion with head of school/institution overseeing the functions of the facility and licence holder.

- Discussion on assessment of any complaints lodged with the institution regarding the application and functions of the licence and mechanisms to address those complaints.

- Evidence of protocols and procedures to ensure all users conduct an anatomical examination in a manner that affords the deceased ongoing dignity between the time of their death and burial or cremation.

- Copies of inspection reports maintained.

- Compliance with the time period to make necessary changes identified by the inspection.

- Compliance with reasonable conditions imposed by inspector (on licence).

Audit of consent forms

- Evidence of the use of a standard comprehensive consent form that allows terms and conditions to be specified on the consent.

- Evidence that anatomical examinations are conducted with the written authority of the deceased, or if the deceased did not consent during their lifetime, the written consent of a senior available next-of-kin.

- Evidence of the inclusion of the wishes of the deceased or next-of-kin relating to the disposal of bodies and/or human tissue.

- Evidence of written consent for permanent retention of human tissue.

- Contact details of next-of-kin.

Audit of Register

Minimum requirements of register:

- Name and address of the person who had lawful possession of the body and who delivered the body into the holder’s possession.

- Date on which the holder took possession of the body.

- Date, place and cause of death of the deceased and the sex, name, age and last place of abode of the deceased.

- Evidence of tracking of any human tissue removed from a body to ensure cross-referencing of all human tissue removed from a specific body.
Retention

- Evidence that no body is retained for more than 8 years from the date of death of the deceased.
- Evidence that no body exceeds an authorised retention period.
- Evidence that no human tissue exceeds the authorised retention period.
- Evidence of formal approval for any extension of retention period.

Transfer of bodies and human tissue

- Evidence of transfer of a body or human tissue from one institution to another providing it is not contrary to the authority given by the deceased or next-of-kin.
- Evidence that when bodies or human tissue are transferred, the following minimum details are entered on the register:
  1. the fact that the body or human tissue was transferred;
  2. the date on which the body or human tissue was transferred;
  3. the name and address of the person to whom the body or human tissue was transferred;
  4. the name of the licensed premises, hospital, or other place where human tissue is to be retained; and
  5. details of the arrangements made with respect to the return of the human tissue.
- Evidence that bodies are only transferred to other licence holders or, with the approval of an inspector, to a person in charge of anatomical examinations outside NSW.
- Evidence that human tissue from a body in the licence holder’s possession is only transferred to other licence holders, authorised officers of State or interstate hospitals, or persons approved by the Director-General.
- Evidence of return of a body or human tissue unless it has been wholly or substantially destroyed.

Disposal

- Evidence that bodies are disposed of within 4 years from the date of death of the deceased person unless retained in accordance with an inspectors written authorisation.
- Evidence of a Cremation Certificate issued by the attending practitioner pursuant to clause 48 Public Health (Disposal of Bodies) Regulation 2002.
- Evidence that when bodies are disposed of, the following minimum details are entered on the register:
  1. the fact that the body was disposed of;
  2. the date of disposal; and
  3. the name and address of the person engaged to dispose of the body.
- Evidence that bodies are disposed of, as far as practicable, in accordance with any wishes of the deceased.
26. TISSUE/ORGAN 

☐ Evidence that bodies are disposed of, as far as practicable, in accordance with any wishes of the senior available next-of-kin of the deceased if the deceased’s wishes are not practicable, or deceased has expressed no such wishes.

☐ Evidence that human tissue is disposed of within 4 years from the date of death of the deceased person unless retained in accordance with an inspectors written authorisation or consented for permanent retention.

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Attachment 3.1: Anatomy Register Example

NAME OF DECEASED: ______________________

SEX: ______________________

DATE BODY RECEIVED: ______________________

RECEIVED FROM: ______________________

NAME: ______________________

ADDRESS: ______________________

PHONE: ______________________

DATE OF DEATH: ______________________

PLACE OF DEATH: ______________________

LAST PLACE OF ABODE: ______________________

CAUSE OF DEATH: ______________________

REMOVAL DATE FOR CREMATION/BURIAL: ______________________

REMOVED BY: ______________________

CONTRACTING FUNERAL DIRECTOR (Please PRINT Name, Address & Contact Number): ______________________

____________________________

132(11/08/11)
<table>
<thead>
<tr>
<th>DONOR NUMBER</th>
<th>BODY PARTS USED</th>
<th>RECIPIENT</th>
<th>DATE TAKEN</th>
<th>TAKEN WHERE</th>
<th>DATE RETURNED</th>
<th>REASON</th>
<th>DATE OF DISPOSAL</th>
<th>METHOD OF DISPOSAL</th>
</tr>
</thead>
</table>

132(11/08/11)
PD2013_002 should be read in conjunction with PD2013_001.

PURPOSE

The Purpose of this policy is to provide advice to Local Health Districts, Specialty Health Networks and NSW Health Pathology Departments and Institutes of Forensic Medicine regarding the appointment and responsibilities of Designated Officers. The policy provides the standard procedures for Designated Officers in authorising donations to anatomical examinations, non-coronial post-mortems and organ and tissue donations.

The role of the Designated Officer is governed by the Human Tissue Act 1983 and the Anatomy Act 1977 and failure to comply with the requirements may constitute an offence.

MANDATORY REQUIREMENTS

1.1 Appointment of Designated Officers

- Local Health Districts, Specialty Health Networks, NSW Health Pathology Departments and Institutes of Forensic Medicine and private hospitals must appoint a Designated Officer in any facility where bodies may be donated for anatomical examination, non-coronial post mortems are carried out, or tissue is donated for transplantation.
- Designated Officers must be appointed in accordance with Section 5 of the Human Tissue Act 1983 by the governing body of a hospital or NSW Health Pathology Departments and Institutes of Forensic Medicine.
- The licencee of a private hospital appoints Designated Officers for a private facility.
- LHDs, Specialty Health Networks and NSW Health Pathology Departments and Institutes of Forensic Medicine must ensure that arrangements are in place for staff to easily identify and contact Designated Officers at all times, for example, via the hospital switchboard.
- Appropriate staff at NSW Health Pathology Departments and Institutes of Forensic Medicine must have similar information including 24 hour contact details for Designated Officers for Departments of Forensic Medicine.
- All Designated Officers must successfully complete the NSW Health online Designated Officer training course, in order to be eligible for appointment or reappointment after 30 June 2013.
- To remain eligible for appointment Designated Officers must successfully complete the online training every two years, or as required.

1.2 Designated Officers Authorisation

- For authorisation, Designated Officers must follow the procedures outlined in the attached document.
- Designated Officers authorisation must be in writing

IMPLEMENTATION

The Chief Executives of Local Health District, Specialty Health Networks and NSW Health Pathology Departments and Institutes of Forensic Medicine are responsible for:

- Implementation of this policy regarding the appropriate appointment and administration of Designated Officers (Sections 2.1 – 2.4).
26. TISSUE/ORGAN

- Ensuring that this policy is brought to the attention of Designated Officers and staff responsible for the administration of Designated Officers and maintenance of the Designated Officer Register.

Designated Officers are responsible for:
- Authorising procedures within the scope of their role

1. BACKGROUND

1.1 About this document

This document provides an overview of the role of the Designated Officer as prescribed by the Anatomy Act 1977 and the Human Tissue Act 1983 and in relation to compliance with the provisions of the Coroners Act 2009.

Designated Officers must also familiarise themselves with the requirements of the following related policies:

1.2 Key definitions

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

Child in care
A child or young person under the age of 18 years:
- Who is under the parental responsibility of the Minister administering the Children and Young Persons (Care and Protection) Act 1998, or
- 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
- Who is a protected person within the meaning of section 135 of the Children and Young Persons (Care and Protection) Act 1998, or
- Who is the subject of an out-of-home care arrangement under the Children and Young Persons (Care and Protection) Act 1998, or
- 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
- 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.

Consent – ‘Other Manner Prescribed’ (other than written)
For the purpose of sections 23(3) (b) and 24 (3) of the Human Tissue Act 1983, the senior available Next of Kin may give consent verbally to organ and tissue donation from a deceased person if:

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26. TISSUE/ORGAN

- An audio or audiovisual recording is made of the consent; and
- The senior available Next of Kin has consented to the making of that audio or audiovisual recording.

(Human Tissue Regulation 2010, section 8(1))

**Designated Officer**
A Designated Officer means:
- 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, or
- In relation to a forensic institution, a person appointed under s5(3) of the Human Tissue Act 1983, to be a Designated Officer for the forensic institution, or
- In relation to a private hospital within the meaning of the Private Hospitals and Day Procedure Centres Act 1988 - a person appointed by the governing body (defined in the Act as the licensee) of the hospital.

**Designated Specialist**
The Human Tissue Act 1983 authorises the governing body of each hospital, whether public or private to appoint designated specialists. For the purposes of the Human Tissue Act 1983 medical specialists with the following qualifications are automatically eligible for appointment as designated specialists:
- Fellows of the Australasian College of Emergency Medicine
- Fellows of the Australian and New Zealand College of Anaesthetists
- Fellows of the College of Intensive Care Medicine of Australia and New Zealand
- Fellows of the Royal Australasian College of Physicians
- Fellows of the Royal Australasian College of Surgeons
- Fellows of the Royal Australian College of Obstetricians and Gynaecologists

Medical specialists with equivalent overseas qualifications are also eligible for appointment as designated specialists subject to approval in each case by the Chief Executive of the Local Health District (as a delegate of the Director-General of the Ministry of Health) or the governing body of a private hospital.

Other appropriately qualified and experienced medical practitioners who hold specialist registration but are not a member of the one of the colleges listed above (such as those who have been granted specialist registration by the Medical Board of Australia) may be considered by the Chief Executive of the Local Health District (as a delegate of the Director-General of the Ministry of Health).

**Principal Care Officer**
The Principal Officer of a designated agency has supervisory responsibility for a child in the care of the State, under the Children and Young Persons (Care and Protection) Act 1998.

**Senior available Next of Kin**
The order of senior available Next of Kin is defined in S4 of the Human Tissue Act 1983.

a) In relation to a deceased child;
   1. Parent of the child;
   2. Sibling of the child who is 18 years of age or over where a parent is not available;
   3. Guardian of the child at the time of death where none of the above is available.

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However, where the child is in the care of the state specific provisions for consent to organ and tissue donation apply (see section 7).

b) In relation to any other deceased person (i.e. adult);
   1. Spouse (which can include a de facto spouse and same sex partner);
   2. Son or daughter of the deceased person (18 years of age or over), where the above is not available;
   3. Parent, where none of the above is available;
   4. Sibling of the deceased person (18 years of age or over), where none of the above is available.

**Tissue**

Tissue refers to an organ or part of a human body and a substance extracted from a human body or from part of a human body. It does not include tissue blocks and slides, which may be retained without specific consent.

### 1.3 Legal and legislative framework

**Anatomy Act 1977**

The *Anatomy Act 1977* regulates the conduct of anatomical examinations in NSW, including the issue of licences, appointment of inspectors, the pre-conditions of taking possession of bodies or human tissue, requirements for keeping registers of bodies and human tissue and for the disposal of bodies. Section 8 of the *Anatomy Act 1977*, states that a Designated Officer of a hospital or forensic institution may, by instrument in writing, authorise the anatomical examination of a body of a person in accordance with the consent given by either the deceased or their senior available Next of Kin and subject to the provisions of the *Anatomy Act*.

Failure to comply with the requirements of the *Anatomy Act 1977* may constitute an offence.

**Human Tissue Act 1983**

Designated Officers are appointed in accordance with Section 5 of the *Human Tissue Act 1983* by the governing body of a hospital or forensic institution. The *Human Tissue Act 1983* regulates activities that are concerned with the lawful removal, authorisation, use and disposal of human tissue. Consent is the fundamental principle that underpins the requirements of the legislation and the Act specifies whose consent is needed and the format in which the consent should be recorded before the Designated Officer can authorise the removal and use of human tissue.

**Coroners Act 2009**

Section 56 of the *Coroners Act 2009* states that a Coroner has a right to take possession of and retain the remains of a deceased person whenever the Coroner has jurisdiction to hold an inquiry concerning the death of the person. This right of the Coroner has priority over any other right to possession of a body of a deceased such as a potential donation.

### 2 ADMINISTRATION AND APPOINTMENT OF THE DESIGNATED OFFICER

#### 2.1 Appointment of Designated Officers

In NSW, the governing body of a hospital (public or private) appoints Designated Officers under Section 5 of the *Human Tissue Act 1983*. 

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For public hospitals, this is the hospital’s Local Health District (LHD)/Specialty Health Network Chief Executive. For private hospitals, the licensee appoints Designated Officers.

2.2.1 Who can be appointed

It is a matter for the governing body of a hospital to determine who may be appointed as a Designated Officer subject to the person meeting the training requirements set out at 2.2 below prior to appointment.

2.1.2 Access to a Designated Officer

The appointment of several Designated Officers may be necessary to ensure that one is available when required, particularly after hours. LHDs and Specialty Health Networks may consider appointment of Designated Officers across facilities to support easy access to a Designated Officer by a smaller facility.

2.2 Training requirements

All Designated Officers must successfully complete the NSW Health online Designated Officer training course, in order to be eligible for appointment or reappointment after 30 June 2013.

Thereafter, to remain eligible for appointment Designated Officers are required to successfully complete the online training every two years, or when notified by email that relevant modules must be reviewed, for example following legislative amendment.

Successful completion of requires a pass mark of 80% of all modules in the training course.


Access to the course is restricted to individuals who have been nominated by a LHD/Speciality Network Chief Executive or private hospital licensee.

2.3 Designated Officer Register

A state wide register of Designated Officers created via the online Designated Officer training course will be hosted by the NSW Ministry of Health. Chief Executives of LHDs and Specialty Health Networks and their delegates will be able to access data from the register relevant to their LHD. It is responsibility of the Chief Executives to maintain the accuracy of their LHD/Speciality Network’s data on Designated Officers.

The Register has four functions:
- To provide Chief Executives of LHDs and Specialty Health Networks with a list of certified Designated Officers;
- To provide relevant agencies outside NSW Health with a list of Designated Officers;
- To provide notification for recertification of Designated Officers; and
- To improve the re-appointment process for Designated Officers that relocate to a different LHD/Specialty Health Network.
2.4 Local procedures for contact

LHDs, Specialty Health Networks and NSW Health Pathology Departments and Institutes of Forensic Medicine must ensure that arrangements are in place for staff to easily identify and contact Designated Officers at all times, for example, via the hospital switchboard.

3 DESIGNATED OFFICERS ROLES AND AUTHORISATION

3.1 Role of the Designated Officer

The role of the Designated Officer is to authorise, in accordance with relevant legislation:

• The release of a body for anatomical examination;
• A non coronial post mortem examination;
• The use of tissue removed for the purposes of non coronial post mortem examination; and
• The removal of tissue from a body for transplant or other therapeutic, medical or scientific purpose; and

The Designated Officer also has responsibilities in the circumstance where a potential living donor revokes their consent to donation of tissue for the purpose of transplantation (see section 6).

The Designated Officer has discretionary authority. Before an authority is given by a Designated Officer, the Designated Officer must be satisfied as to certain matters before giving written authority for a procedure. However, a Designated Officer is not obligated to authorise that procedure.

The role may require conflict resolution and high level communication and negotiation skills.

3.2 General principles and responsibilities

When issuing authorisations under the Human Tissue Act 1983 or the Anatomy Act 1977:

• In Coronial cases, a Designated Officer cannot authorise the removal or use of tissue for any purpose unless the Coroner has given permission to the use of the tissue. See section 3.2.1;
• A Designated Officer may make reasonable inquiries in order to be satisfied of the relevant criteria before authorising procedures. See section 3.2.2;
• A Designated Officer may rely on inquiries made by others. See section 3.2.3;
• A Designated Officer’s authority must be in writing. A Designated Officer should never sign an incomplete form. See section 3.2.4;
• A Designated Officer cannot act in any case where they have had a clinical or personal involvement. See section 3.2.5;
• A Designated Officer must not disclose the deceased’s identity to the public. See section 3.2.6.

3.2.1 Coronial cases

The Designated Officer is required to ascertain whether there is a requirement to report a death to the Coroner and seek consent from the Coroner.
Where a Coroner has jurisdiction to hold an inquest under the *Coroner’s Act 2009* into an individual’s death, a Designated Officer for a hospital or forensic institution cannot authorise:

- The use of any tissue removed from a body during a post mortem examination;
- Donation of the body for anatomical examination;
- Donation of organs/tissue; or
- Any procedure in relation to a child in care of the State

Unless a Coroner has given their consent which may be subject to conditions.

The Coroner’s consent is in addition to any other consent which may be required under the Act. It is an offence to authorise the use of tissue in these circumstances without the Coroner’s consent.

The Coroner or their delegate may rely on the Designated Officer to alert the Coroner to any potential problems. The Designated Officer needs to establish whether the circumstance surrounding the death require a report of the death to the State Coroner (see attachment 1 for reportable deaths).

A verbal consent given by the Coroner should be confirmed by a written certificate as soon as practical. However a Designated Officer does not need to sight the written certificate from the Coroner in order to proceed with authorisation. The verbal authorisation of the Coroner will suffice.

The NSW Organ and Tissue Donation Service Donor Specialist Coordinator will ensure that the written certificate from the Coroner is obtained and a copy added to the donor’s record.

### 3.2.2 Obligation to investigate and make ‘reasonable inquiries’

Designated Officers are obligated to make ‘reasonable inquiries’ before authorising removal and use of tissue. Examples of reasonable inquiries include:

- Ascertaining whether the death is reportable to the Coroner and if so being satisfied that the necessary Coronial authority has been given to either the Designated Officer or their delegate and documented;
- Ascertaining that a deceased child is not a child in care of the State;
- Ascertaining whether the deceased consented in writing to the donation of the body for anatomical examination, post mortem examination, organ and tissue donation or removal of tissue for medical, scientific or therapeutic purposes;

Where no written consent exists:

- Ascertaining whether the deceased subsequently revoked their consent;
- Ascertaining whether the deceased had expressed an objection to the donation of the body for anatomical examination, post mortem examination, organ and tissue donation or removal of tissue for medical, scientific or therapeutic purposes and if so, whether that objection was the most recent views of the deceased;
- Ascertaining the existence or whereabouts of the Next of Kin of the deceased and their views regarding the proposed removal and use of tissue; and
- Establishing that no other senior Next of Kin of the same or a higher order objects to the proposed donation or non coronial post mortem.
3.2.3 Delegation of ‘reasonable inquiries’

A Designated Officer may delegate reasonable inquiries to another responsible health professional. However, the Designated Officer remains ultimately responsible for demonstrating they have acted reasonably in relying on such information when authorising removal and use of tissue. In addition, it remains for the Designated Officer to be satisfied that the criteria in the relevant legislative provisions have been satisfied prior to authorising the removal or use of tissue.

3.2.4 Authority in writing and completion of consent forms

The Designated Officer’s authority must be in writing. ‘In writing’ includes authorisation via email, provided that the email clearly states the name and position of the Designated Officer who is providing authority. It cannot be given orally and then confirmed later in writing. The authority in writing must be given before the procedures (such as a non coronial post mortem or the removal of tissue from a dead body) can be performed. The value of a written consent and authorisation is that it provides evidence of adherence to the consent process.

To enable Designated Officers to provide their authorisation in writing, hospitals and health facilities must ensure that appointed Designated Officers have access to copies of relevant documents. They may be on site to physically sign a document, or have access to scanned and printed documents or faxed and emailed documents.

Only completed consent forms should be lodged with the Designated Officer for their written authorisation. Designated Officers must never sign an incomplete form.

3.2.5 Conflict of interest

The Designated Officer must be seen to be a neutral third party in the cases they authorise. The Designated Officer cannot be involved in cases where they provided clinical care to the deceased while living or are a relative or friend of the deceased.

If the Designated Officer discovers that they have a clinical or personal involvement in the case, they must terminate their involvement as the Designated Officer.

3.2.6 Disclosure of information

It is an offence for a Designated Officer who has given an authority under the Human Tissue Act 1983 to disclose information which may result in the identity of a person (whether living or deceased) becoming publicly known, unless the person to whom the information relates is an adult and has consented to the disclosure, or the disclosure is required for legal reasons, in connection to the administration of the Human Tissue Act 1983 or in connection with bona fide medical research as approved by Human Research Ethics Committee or with other lawful excuse.

The Designated Officer is deemed to have published a record if they permit or facilitate access to that record by another person.

4 DESIGNATED OFFICER AUTHORISATION PROCESS

Designated Officers are required to authorise the removal and use of tissue from a deceased’s body in a number of clinical contexts. These include:
26. TISSUE/ORGAN

- Donation of the body for anatomical examination;
- Non Coronial post mortem examinations; and
- Removal of tissue from a body for transplant or other therapeutic, medical or scientific purpose.

The specific requirements of the Designated Officer’s role in each of these procedures are found within the following policies:

- PD2011_052: Conduct of Anatomical examinations and Anatomy Licensing in NSW
- PD2013_001: Deceased organ and Tissue Donation – Consent and Other Procedural Matters

4.1 General authorisation process

In general a Designated Officer may authorise the removal of tissue from a deceased person after death for the above purposes where:

- The adult person during their lifetime has given their consent in writing to anatomical examination body donation, the performance of a non coronial post mortem examination, organ and tissue donation or the removal of tissue for medical, scientific or therapeutic purposes and such consent had not been revoked.
- If the person during their lifetime has not given written consent or was a child (apart from a child in care of the State) the Designated Officer may authorise removal of tissue after death only where:
  - It has been established that the deceased has not expressed an objection during their lifetime, or if an objection had been expressed, the Designated Officer is satisfied, based on the most recent views expressed by the deceased person, the person no longer had an objection to the removal of tissue from the person’s body;
  - A senior available Next of Kin has given consent in writing (or in another manner as prescribed by the regulations - see Section 1.2.3); and
  - The Designated Officer has ascertained that there is no senior available Next of Kin of the same standing or higher order who objects.
- If the person during their lifetime objected in writing, the Designated Officer may authorise removal of tissue after death only where:
  - The Designated Officer is satisfied, after making reasonable inquiries, that based on the most recent views of the deceased, the deceased no longer held an objection to the removal of tissue from the person’s body; and
  - A senior available Next of Kin has given consent in writing (or in another manner as prescribed by the regulations); and
  - The Designated Officer has ascertained that there is no senior available Next of Kin of the same standing or higher order who objects.

4.2 Certification and documentation of death for organ and tissue donation

The current NSW legal definition of death is set out as follows in the Human Tissue Act 1983:

- Irreversible cessation of all function of the person’s brain; or
- Irreversible cessation of circulation of blood in the person’s body.

Under s26 two doctors, including one designated specialist appointed under the Human Tissue Act 1983, are required to certify death according to brain or circulatory criteria for the purpose of organ and tissue donation.
These are distinct from death certificates which are required in many situations including:

- When a person has died in a hospital or the body of a deceased person has been brought into a hospital; and
- If at the time when the person died or at any time thereafter the person’s respiration or the circulation of the person’s blood was being maintained by artificial means.

### 4.3 Consent for children

Before a Designated Officer can authorise any procedures on a child and, where applicable, the retention of tissue for subsequent non-diagnostic purposes, the Designated Officer must ensure that the child is not a child in care of the State and they must be satisfied that:

- The child had not during their lifetime expressed an objection to organ and tissue donation or the removal of tissue for medical, scientific or therapeutic purposes;
- The child’s senior available Next of Kin has given their written consent (or in another manner as prescribed by the regulations; and
- No Next of Kin of the same or a higher class than the child’s senior available Next of Kin objects.

See section 7 for consent for a child in care of the State.

### 4.4 Donation of sperm (gametes) from deceased persons

There is a complex interplay between the *Human Tissue Act 1983*, the *Assisted Reproductive Technology Act 2007*, and a recent supreme court decision that impact who is required to remove sperm; when this is permissible; and where they may be lawfully stored. Designated Officers should not authorise removal of gametes without prior consultation with Legal Branch, Ministry of Health.

### 5 ASSESSING OBJECTION TO ORGAN/TISSUE DONATION

#### 5.1.1 Objection by the deceased

The Designated Officer needs to ascertain whether the deceased has expressed an objection or revoked a previous consent to organ and tissue donation or the removal of tissue for medical, scientific or therapeutic purposes.

A recorded objection on the Australian Organ Donor Register or in an advanced care directive is usually a clear, unequivocal expression of objection and would usually indicate to the Designated Officer that they should not provide authorisation. However, Designated Officers may use their discretion to reassess objections based on information from the deceased’s relatives indicating that the deceased had changed their decision.

If a Designated Officer is satisfied, after making any reasonable inquiries that:

- The person had (when living) changed their decision after their written objection to organ and tissue donation or the removal of tissue for medical, scientific or therapeutic purposes and prior to death the deceased no longer held the objection; and
- The senior available Next of Kin has given their consent in writing, or in any other manner prescribed by the regulations, to the above procedure; and
- No Next of Kin of the same or a higher class than the senior available Next of Kin objects.
then the Designated Officer may authorise the donation of the deceased’s organs/tissue in accordance with the terms and any conditions of the senior available Next of Kin’s consent.

5.1.2 Disagreement between and objection from equal senior available Next of Kin

Where the wishes of the deceased are unknown, consent is required from the senior available Next of Kin. There may be multiple senior available Next of Kin on the same level of hierarchy, for example both parents of child. For the consent to be valid, all senior available Next of Kin must not object to that procedure.

If a consensus is able to be reached, only one senior available Next of Kin needs to give consent.

If a consensus is unable to be reached, and one senior available Next of Kin objects to the donation or non coronial post mortem, then the Designated Officer must not authorise the donation or non coronial post mortem.

5.1.3 When family objection overrides a potential donor’s known wishes

Legally, given an existing valid consent from the deceased, the Designated Officer could authorise the procedures when a family objects. However it is common practice for agencies not to proceed with the donation in the face of serious and continuing distress and sustained objection exhibited by the family.

The decision not to proceed with donation because of family objections, contrary to the patient’s known decision, rests with the clinicians managing the patient and overseeing the end-of-life discussions, including consideration of organ donation.

In this circumstance a standard form must be completed and signed by the requesting clinician, and then signed by the Designated Officer. The information which must be included on the form includes:

- Details of information provided to the family (considering the above). This should include the names and roles of all those participating in the discussion;
- Details of objections raised by the family;
- Other rationale for acceding to family objection e.g. potential harm to the family/senior available Next of Kin in proceeding; and
- Extenuating family or patient circumstances that are considered relevant to the decision to not proceed with donation.

The Designated Officer may attend the family interview consistent with local practice and their discretionary authority to assess objections. The Designated Officer must review the documentation and confirm that the reasons for family objection have been documented by the requesting clinician and that donation is not proceeding because of these objections.

A completed and signed form must be included in the patient’s medical record.

Refer to PD2013_001 Deceased Organ and Tissue Donation – Consent and Other Procedural Aspects for the form.
6 REVOCATION OF CONSENT IN LIVING DONATION

It is a potential living donor’s right to revoke consent at any time up until the commencement of surgery. Under the *Human Tissue Act 1983 (s16)* the Designated Officer has the following responsibilities where a potential living donor indicates they wish to revoke their consent, or in the case of a child, that the child is no longer in agreement with the proposed removal and transplantation of the tissue:

- The person to whom the potential donor indicates they revoke their consent (if that is not the Designated Officer) must inform the Designated Officer for the hospital of the revocation of the consent. It is an offence under the *Human Tissue Act 1983 (s16)* for the person to whom the donor revoked the consent not to inform the Designated Officer;
- If it appears to the Designated Officer, after making such inquiries (if any) as are reasonable in the circumstances, that any other medical practitioner is proposing to remove tissue from the body of the donor pursuant to the consent, the Designated Officer must inform that other medical practitioner that the consent is revoked. It is an offence under the *Human Tissue Act 1983 (s16)* for the Designated Officer not to inform the medical practitioner proposing to remove tissue that the consent has been revoked; and
- The Designated Officer should ensure that the revocation of the consent is recorded in the donor’s medical record.

7 CONSENT FOR CHILDREN IN CARE OF THE STATE

7.1 Anatomical examinations, non coronial post mortems, removal of tissue for scientific purposes

A Designated Officer must not authorise the anatomical examination, a non Coronial post mortem, or removal of tissue for scientific purposes on the body of a deceased child if the child was, immediately before death, a child in the care of the State.

7.2 Organ and Tissue Donation

Organs and tissue may be removed from the body of a deceased child who is classified as a child in care of the State only in the case of donation.

Before donation can commence, a three-way authorisation must be gained in writing from the Principal Care Officer, the Coroner, and the Designated Officer.

*Principal Care Officer*

The Principle Care Officer for the child checks the child’s file and contacts any interested or relevant parties for consultation regarding consent or objection to the donation. If the Principal Care Officer has given their consent in writing to the donation, they contact the Coroner and the Designated Officer, who must also authorise the donation.

*Coroner*

Under the *Human Tissue Act 1983 (s25)*, the Coroner must give consent to the removal of tissue from the deceased child’s body. The Principal Care Officer contacts the Coroner to ascertain whether or not s/he consents to the donation. The Coroner may place conditions on which organs and tissues can be removed.
Designated Officer

The Designated Officer must be satisfied that the child did not express an objection to the removal of organ and tissue for the purposes of its transplantation to the body of a living person during their lifetime, that the Principal Care Officer has consulted with interested parties, and that the Coroner has given their authorisation that the organ and tissue can be used for donation.

A Designated Officer who is unsure as to the status of the child may need to verify this status. If verification of the status of a child is necessary, an application for information can be made to the Local Police Command to ascertain the status of the child from the Department of Family Community Services.

8   SENIOR AVAILABLE NEXT OF KIN

As per 1.2.7 the Human Tissue Act defines the hierarchy of senior available Next of Kin.

8.1 Delegation of Functions

The Human Tissue Act makes provision for delegation of the functions of the senior available Next of Kin. This provision allows for cultural and religious requirements to be observed. The senior available Next of Kin can delegate their functions to another person by signing a delegate consent form.

The role of the Designated Officer is to ensure that the delegation instrument is valid and attached to the consent.

8.2 Locating senior available Next of Kin

In some circumstances it may be necessary for the Police to be involved in locating the senior available Next of Kin. In these cases, the Designated Officer or their delegate should direct an inquiry to the Duty Commander of the Local Police Command where the deceased lived. All relevant information regarding the deceased that will assist the Police to undertake a search should be given including:

- Name of the deceased;
- Last known residential address of the deceased (if known);
- Date of birth or age of the deceased;
- Sex of the deceased; and
- Name, last known address and relationship of the Next of Kin.

If senior available Next of Kin are found, the Police will notify them of the death and ask them to contact the Designated Officer or their delegate. Police will not be involved in obtaining any consent under the Act.

If, on inquiry, a deceased child is determined to be a child in care of the State, or, the sibling of a child in care of the State, the Police should inform the Designated Officer. All deaths of children in care of the State and their siblings must be referred to the Coroner. See section 3.2.1

9   LIST OF ATTACHMENTS

1. Guidelines of ‘reportable death’ to the Coroner
2. Release of a Body or Tissues for Anatomical Examination Checklist and Guideline
3. Non Coronial Post Mortem Checklist and Guideline
4. Organ and Tissue Donation Checklist and Guideline

Standard consent forms are provided in related policies.
Attachment 1: Meaning of “reportable death” to the Coroner

A medical practitioner must not issue a certificate as to cause of death under the *Births, Death 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 patient at the facility for the purpose of receiving care, treatment or assistance under the *Mental Health Act 2007* or *Mental Health (Forensic Provisions) Act 1990*.

OR

if the death is a death under s 23 *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 correctional centre within the meaning of the *Crimes (Administration of Sentences) Act 1999*,
   (iii) a lock-up,
(c) 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 s 24 *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

173(24/01/13)
(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.
**Attachment 2: Release of a Body or Tissues for Anatomical Examination Checklist and Guideline**

A Designated Officer may authorise Anatomical Examination for a deceased body or tissues where:

<table>
<thead>
<tr>
<th>(1) Licensed facility: For the donation to be valid, the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The request is made by a facility licensed by NSW Health to undertake anatomical examination.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(2) Certification of death: For the donation to be valid, the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>A valid Death Certificate has been completed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(3) Coroner’s permission: For the donation to be valid, one of the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The death is reportable and the permission of the on-duty Coroner for donation to a body donor program has been obtained.</td>
</tr>
<tr>
<td>The death is not reportable.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(4) Child in care of the State: For the donation to be valid, the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The deceased is not a child in care of the State.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(5) Consent from Patient or Next of Kin via either: For the donation to be valid, one of the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The deceased has given written consent during their lifetime which has not been revoked.</td>
</tr>
<tr>
<td>The deceased has not given consent nor objected during their lifetime and the senior available Next of Kin has provided consent. No other senior available Next of Kin’s have objected.</td>
</tr>
</tbody>
</table>

*Note: In practice, licensed anatomical examination facilities generally only accept tissues from persons who have themselves consented to donation for anatomical examination during their lifetime.*
**Attachment 3: Non Coronial Post Mortem Checklist and Guideline**

A Designated Officer may authorise a non coronial post mortem and/or use of tissues following a post mortem examination where:

<table>
<thead>
<tr>
<th>(1) Certification of death: For the post mortem to be valid, the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>A valid Death Certificate has been completed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(2) Coroner’s permission: For the post mortem to be valid, the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The death is not reportable.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(3) Child in care of the State: For the post mortem to be valid, the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The deceased is not a child in care of the State.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(4) Consent from Patient or Next of Kin via either: For the post mortem to be valid, one of the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The deceased has given written consent during their lifetime which has not been revoked.</td>
</tr>
<tr>
<td>The deceased has not given consent nor objected during their lifetime and the senior available Next of Kin has provided consent. No other senior available Next of Kin’s have objected.</td>
</tr>
</tbody>
</table>
26. TISSUE/ORGAN

Attachment 4: Organ and Tissue Donation Checklist and Guideline

A Designated Officer may authorise removal of organ and tissue for donation where:

<table>
<thead>
<tr>
<th>(1) Death confirmed by: For the donation to be valid, one of the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irreversible cessation of all functions of the person’s brain.</td>
</tr>
<tr>
<td>Irreversible cessation of circulation of blood in the person’s body.</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(2) Certification of death: For the donation to be valid, the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>A valid Death Certificate has been completed or a ‘Report of Death to the Coroner (form A)’ has been completed.</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(3) Coroner’s permission: For the donation to be valid, one of the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The death is reportable and the permission of the on-duty Coroner for organ and tissue donation has been obtained.</td>
</tr>
<tr>
<td>The death is not reportable.</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(4) Child in care of the State: For the donation to be valid, one of the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The deceased is a child in care of the State and the Principal Care Officer and the Coroner have provided their consent for donation.</td>
</tr>
<tr>
<td>The deceased is not a child in care of the State.</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(5) Consent from Patient or Next of Kin via either: For the donation to be valid, one of the following must be a ‘yes’</th>
</tr>
</thead>
<tbody>
<tr>
<td>The deceased has given written consent during their lifetime which has not been revoked.</td>
</tr>
<tr>
<td>The deceased has not given consent nor objected during their lifetime and the SANOK has provided consent. No other SANOKs have objected.</td>
</tr>
<tr>
<td>The deceased objected during their lifetime, but family have shown this objection is not current and the senior available Next of Kin has provided consent. No other senior available Next of Kin’s have objected.</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
<tr>
<td>No ☐ Yes ☐</td>
</tr>
</tbody>
</table>
MANAGEMENT OF THE ADULT BRAIN DEAD POTENTIAL ORGAN AND TISSUE DONOR  (GL2016_008)

PURPOSE
The Guideline provides an evidence based reference for managing physiological effects of brain death and standardising clinical therapies delivered to adult potential organ and tissue donors who are brain dead in order to improve the number and function of organs retrieved for transplantation.

KEY PRINCIPLES
Key principles underpinning management of brain dead potential organ and tissue donors are:

- Management of the adult brain dead potential organ donor follows generic intensive care principles to support and optimise organ function
- Donor management seeks to optimise the number and function of organs retrieved for transplantation in order to maximise the outcome for the recipient
- Frequent clinical assessment of organ function and response to interventions is key to optimal donor management
- Time from brain death to retrieval surgery should be as short as possible.

USE OF THE GUIDELINE
Chief Executives of Local Health Districts (LHDs)/Specialty Networks (SNs) must ensure that:

- Relevant staff are made aware of these Guidelines

Directors of Intensive Care and Emergency Departments must ensure that:

- Relevant local protocols are reviewed for consistency with these Guidelines.

Donation Specialist Staff in LHDs/SNs should:

- Support clinicians to manage adult brain dead potential organ donors.


ADULT-TO-ADULT LIVING DONOR LIVER TRANSPLANTATION GUIDELINES  
(GL2008_019)

This guideline provides guidance to health professionals and additional protection for prospective adult Living Donor Liver Transplantation (LDLT) donors. This guideline is aimed primarily at the jurisdictions that will endorse LDLT, the institutions that will provide LDLT, and the health professionals directly involved in this practice. To the extent that it is adopted by all jurisdictions in line with the particular requirements of their human tissue legislation, and applied in participating liver transplant units, it will promote ethical, lawful and consistent application of quality processes in provision of this complex procedure to donors, recipients and their families.