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CHAPTER 26 – TISSUE/ORGAN

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Updated as at September 2022

ORGAN AND TISSUE DONATION, USE AND RETENTION (PD2022_035)

PD2022_035 rescinds PD2016_001 and PD2020_012

POLICY STATEMENT

Consent must be obtained to proceed with living and deceased organ and tissue donation and transplantation.

NSW Health organisations must follow the requirements for obtaining consent from the intended donor and/or senior available next of kin; a Designated Officer to provide written authorisation for the removal of organ/s and/or tissue after death; and restrictions on living organ and tissue donation from adults and children.

SUMMARY OF POLICY REQUIREMENTS

NSW Health organisations must have local protocols and procedures in place which fit the requirements for both living and deceased organ and tissue donation.

This Policy outlines the process for obtaining written consent, or consent by other manner prescribed, prior to the removal of organ/s and/or tissue for medical, scientific or therapeutic use (apart from diagnostic purposes) in line with the requirements of the Human Tissue Act 1983 (NSW). Where the donor is deceased, and in the absence of their written consent, consent must be obtained from the senior available next of kin or their delegate.

The process for obtaining consent and certification to remove regenerative tissue from a living child for the purpose of transplantation into a parent or sibling, is also summarised.

A Designated Officer must provide written authorisation for the removal of organ/s and/or tissue after death for use for donation and transplantation or for other therapeutic, medical or scientific purposes. Where a family objects to the donation of organ/s from a deceased, contrary to the known wishes of the donor, the requesting clinician must document the reasons for family objection and have this documentation signed by the Designated Officer.

This Policy also summarises the process for assessing requests for the return of tissue to a patient and/or senior available next of kin.

The NSW Health State Forms referenced in this Policy, including those for consent and certification for the donation of organ/s and/or tissue from a deceased patient/senior available next of kin, living adult and/or child, must be used.

The full Organ and Tissue Donation, Use and Retention policy can be downloaded at https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2022_035

HUMAN TISSUE - REQUIREMENTS OF THE *HUMAN TISSUE ACT 1983* IN RELATION TO RESEARCH & USE OF TISSUE (GL2006_021)

GL2006_021 rescinds GL2005_046.

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.

LIVING KIDNEY DONATION AND TRANSPLANTATION (PD2022_036)

PD2022_036 rescinds PD2015_041 and PD2017_030.

POLICY STATEMENT

NSW Health supports nationally consistent protocols and standards to be adopted by NSW Health organisations to guide clinicians and institutions in the practice of paired kidney exchange by living donors and recipients.

Health professionals involved in the assessment, management and follow-up of living kidney donors and recipients must understand the standards and conditions for living kidney donation in NSW.

SUMMARY OF POLICY REQUIREMENTS

This Policy applies to all NSW Health organisations involved in the donation of a single kidney by an adult living person for transplantation into another person.

NSW Health staff must comply with the procedures for assessing, consenting and registering donors and donor-recipient pairs to the Australian and New Zealand Paired Kidney Exchange Program.

Informed consent must be obtained from the donor before becoming a living kidney donor. Consent must be given in accordance with the NSW Health *Consent to Medical and Healthcare Treatment Manual* ([the Manual](#)).

The surgeon who removes the kidney has an independent legal obligation to ensure that the donor has given valid consent and has been informed of risks and alternatives, regardless of whether the medical practitioner who referred the donor to the surgeon also discussed these issues with the donor.

In addition to the signed consent form for surgery, detailed information provided to the donor, including the discussion of risks, must be documented in the medical record.

Detailed information must also be provided to anyone who expresses willingness to become a kidney donor. Information must include, but is not limited to, a full description of the procedure, implications and risks to the donor, and the likely outcomes for the recipient.

The donor may choose not to proceed with donation at any time before surgery, and it is not a foregone conclusion that donation will occur once donor assessment has begun.

Non-directed kidney donation involves a kidney being donated to the “best matched” recipient in Australia or New Zealand (if part of the Australian and New Zealand Paired Kidney Exchange (ANZKX) Program). The non-directed living donor has no say in who will or who will not receive the kidney.

The privacy and confidentiality of each donor-recipient pair must be maintained according to section 37 of the *Human Tissue Act 1983* (NSW).

All non-directed donors must obtain a referral from their general practitioner to a relevant nephrologist, formally associated with a NSW kidney transplant service.

NSW Health organisations must not advertise for, or otherwise encourage individuals, to become non-directed donors.

The assessment of a donor's suitability for non-directed kidney donation must include discussions about allocation to the ANZKX Program or a single NSW recipient.

The NSW Transplant Advisory Committee will initially refer all suitable non-directed donors to the ANZKX Program. It will also facilitate agreement between the donor and recipient treating teams on the most suitable location for surgeries.

The assessment of a recipient must include discussion about the acceptance of a potential donation from a non-directed donor. The recipient must be informed at the time of allocation if they are to receive a non-directed kidney.

The ANZKX Protocols ([the Protocols](#)) are the agreed requirements and processes guiding paired kidney exchange in Australia, including assessment, informed consent and registration of donors and donor-recipient pairs in the ANZKX Program.

NSW Health staff must comply with the ANZKX Protocols, and the requirements outlined in this Policy to assess and manage non-directed donors.

The full Living Kidney Donation and Transplantation policy can be downloaded at https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2022_036

ORGAN DONATION AFTER CIRCULATORY DEATH (GL2021_012)

GL2021_012 rescinded GL2020_007

GUIDELINE SUMMARY

The Guideline describes the necessary requirements for health facilities to undertake organ donation after circulatory (formerly cardiac) death 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 organ donation after circulatory death 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.

KEY PRINCIPLES

Organ donation after circulatory death 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 cardiorespiratory 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 ischaemic time for the donor organs is minimised.

USE OF THE GUIDELINE

Chief Executives of local health districts and specialty health networks are to ensure that relevant staff are made aware of this Guideline, and that local protocols to support organ donation after circulatory death are documented and consistent with this Guideline.

The NSW Organ and Tissue Donation Service is responsible for ensuring that organ and tissue donation and retrieval protocols in NSW are consistent with this Guideline, and for facilitating education and training on organ donation after circulatory death for staff as required.

Intensivists, Treating Clinicians and Donation Specialists are to familiarise themselves with the donor referral criteria and management of potential organ donation after circulatory death donors, as outlined in this Guideline (section 2, 3 and 4).

Clinicians certifying death for the purposes of organ donation after circulatory death must do so according to the criteria outlined in the attached procedures and using the proscribed State form (section 2.3.7).

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 organ donation after circulatory death organs for transplantation are to familiarise themselves with the general principles of allocation of organ donation after circulatory death organs (section 5).

To view the Guideline go to

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=gl2021_012

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.

- 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.

1. 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.

2. 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.

3. 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.

4. 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 Regulation 2002)* 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.

5. 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.

6. 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.

7. 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*)¹

- 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

¹ 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

Body preparation	
Vehicle reception area screened from public view	<input type="checkbox"/>
Wash hand basin; hot and cold water; non-hand operated taps soap and disposable paper towel or air dryer	<input type="checkbox"/>
Slabs, tables, fittings and fixtures in good repair	<input type="checkbox"/>
Adequate sinks with hot and cold water for cleaning equipment and appliances	<input type="checkbox"/>
Hoses fitted with backflow prevention	<input type="checkbox"/>
Refrigerated storage area temperature 1-5°C	<input type="checkbox"/>
Containers for general and clinical waste	<input type="checkbox"/>
Waste disposal	
Different types of waste containers located appropriately	<input type="checkbox"/>
Liquid waste: water authority approval for contaminated waste	<input type="checkbox"/>
Clinical wastes: disposed in accordance with appropriate environmental guidelines	<input type="checkbox"/>
Handling bodies	
Policy for handling infectious bodies	<input type="checkbox"/>
Labelling	
Sufficient systems for permanent non-identifying labelling of bodies and specimens	<input type="checkbox"/>
Sufficient systems to track all bodies/specimens within register	<input type="checkbox"/>
Management of chemicals	
MSD sheets available for easy reference	<input type="checkbox"/>
Satisfactory storage of chemicals	<input type="checkbox"/>
Appropriate mechanical ventilation systems in place	<input type="checkbox"/>
Storage	
Sufficient refrigerated storage compartments at appropriate temperature for the number of cadavers	<input type="checkbox"/>
Adequate Storage of embalmed body parts	<input type="checkbox"/>
Anatomy rooms	
Occupational health and safety policy for the activities undertaken	<input type="checkbox"/>
Appropriate attire and PPE available (e.g. gowns, gloves, masks, glasses)	<input type="checkbox"/>
First aid/Emergency assistance procedures available	<input type="checkbox"/>
Security	
Access only for bona fide staff and students or authorised personnel	<input type="checkbox"/>

Construction of facility

- Walls
- Floors
- Ceilings
- Lighting
- Ventilation
- Toilet and Showering facilities available
- Pest Control program in place

General comments on overall standards:

Action required:

Name of inspector:

Signature:

Date:

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.

- 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.

Attachment 3.1: Anatomy Register Example

NUMBER: _____

NAME OF DECEASED:

SEX:

AGE:

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):

26. TISSUE/ORGAN

26.30

DONOR NUMBER	BODY PARTS USED	RECIPIENT	DATE TAKEN	TAKEN WHERE	DATE RETURNED	REASON	DATE OF DISPOSAL	METHOD OF DISPOSAL

DESIGNATED OFFICER POLICY AND PROCEDURES (PD2013_002)

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 licensee 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).

- 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:

- PD2011_052: Conduct of Anatomical examinations and Anatomy Licensing in NSW
http://www.health.nsw.gov.au/policies/pd/2011/PD2011_052.html
- PD2005_341: Human Tissue-Use/Retention Including Organ Donation, Post-Mortem Examination and Coronial Matters
http://www.health.nsw.gov.au/policies/PD/2005/PD2005_341.html

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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- 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.

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*.

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.

The NSW Health online Designated Officer training course is hosted on the NSW GEM website <https://gem.workstar.com.au/public/index.cfm>

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:

- 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
http://www.health.nsw.gov.au/policies/pd/2011/PD2011_052.html
- PD2013_001: Deceased organ and Tissue Donation – Consent and Other Procedural Matters
http://www.health.nsw.gov.au/policies/pd/2013/PD2013_001.html

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, or
- (e) while proceeding to an institution or place referred to in paragraph (d), for the purpose of being admitted as an inmate of the institution or place and while in the company of a police officer or other official charged with the person’s care or custody.

OR

if the death is a death under 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

- (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:

(1) Licensed facility: <i>For the donation to be valid, the following must be a 'yes'</i>		
The request is made by a facility licensed by NSW Health to undertake anatomical examination.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
(2) Certification of death: <i>For the donation to be valid, the following must be a 'yes'</i>		
A valid Death Certificate has been completed.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
(3) Coroner's permission: <i>For the donation to be valid, one of the following must be a 'yes'</i>		
The death is reportable and the permission of the on-duty Coroner for donation to a body donor program has been obtained.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
The death is not reportable.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
(4) Child in care of the State: <i>For the donation to be valid, the following must be a 'yes'</i>		
The deceased is not a child in care of the State.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
(5) Consent from Patient or Next of Kin via either: <i>For the donation to be valid, one of the following must be a 'yes'</i>		
The deceased has given written consent during their lifetime which has not been revoked.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
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.	No <input type="checkbox"/>	Yes <input type="checkbox"/>

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:

(1) Certification of death: <i>For the post mortem to be valid, the following must be a 'yes'</i>	
A valid Death Certificate has been completed.	No <input type="checkbox"/> Yes <input type="checkbox"/>
(2) Coroner's permission: <i>For the post mortem to be valid, the following must be a 'yes'</i>	
The death is not reportable.	No <input type="checkbox"/> Yes <input type="checkbox"/>
(3) Child in care of the State: <i>For the post mortem to be valid, the following must be a 'yes'</i>	
The deceased is not a child in care of the State.	No <input type="checkbox"/> Yes <input type="checkbox"/>
(4) Consent from Patient or Next of Kin via either: <i>For the post mortem to be valid, one of the following must be a 'yes'</i>	
The deceased has given written consent during their lifetime which has not been revoked.	No <input type="checkbox"/> Yes <input type="checkbox"/>
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.	No <input type="checkbox"/> Yes <input type="checkbox"/>

Attachment 4: Organ and Tissue Donation Checklist and Guideline

A Designated Officer may authorise removal of organ and tissue for donation where:

(1) Death confirmed by: <i>For the donation to be valid, one of the following must be a 'yes'</i>		
Irreversible cessation of all functions of the person's brain.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
Irreversible cessation of circulation of blood in the person's body.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
(2) Certification of death: <i>For the donation to be valid, the following must be a 'yes'</i>		
A valid Death Certificate has been completed or a 'Report of Death to the Coroner (form A)' has been completed.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
(3) Coroner's permission: <i>For the donation to be valid, one of the following must be a 'yes'</i>		
The death is reportable and the permission of the on-duty Coroner for organ and tissue donation has been obtained.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
The death is not reportable.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
(4) Child in care of the State: <i>For the donation to be valid, one of the following must be a 'yes'</i>		
The deceased is a child in care of the State and the Principal Care Officer and the Coroner have provided their consent for donation.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
The deceased is not a child in care of the State.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
(5) Consent from Patient or Next of Kin via either: <i>For the donation to be valid, one of the following must be a 'yes'</i>		
The deceased has given written consent during their lifetime which has not been revoked.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
The deceased has not given consent nor objected during their lifetime and the SANOK has provided consent. No other SANOKs have objected.	No <input type="checkbox"/>	Yes <input type="checkbox"/>
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.	No <input type="checkbox"/>	Yes <input type="checkbox"/>

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.

The full Management of the Adult Brain Dead Potential Organ and Tissue Donor: Guidelines can be downloaded at: https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2016_008

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.

The full Adult-to-Adult Living Donor Liver Transplantation Guidelines can be downloaded at: https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2008_019