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CHAPTER 26 – TISSUE/ORGAN

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Last updated August 2023

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

343(17/08/22)

USE OF HUMAN TISSUE FOR RESEARCH (GL2023 008)

GL2023_008 resplaced GL2006_021

GUIDELINE SUMMARY

This Guideline represents NSW Health's interpretation of the requirements of the Human Tissue Act 1983 (NSW) for consent to the use of human tissue for research purposes.

It has been developed to assist health professionals, researchers and research support office staff to ensure that research involving human tissue and biospecimens is in accordance with the Human Tissue Act 1983 (NSW), the National Statement on Ethical Conduct in Human Research (2007) and NSW Health Consent Toolkit (2018).

It also provides clarity and consistency for Human Research Ethics Committees assessing research applications involving human tissue.

KEY PRINICIPLES

A person may legally consent to the use of their tissue for research purposes in general or for a limited scope, given the individual is sufficiently informed according to relevant sections of the National Statement on Ethical Conduct in Human Research (2007) (National Statement).

Human tissue removed prior to 1 November 2003 from a deceased person for the purpose of postmortem examination can be lawfully used for research purposes. Otherwise, consent must be obtained from a person authorised by relevant legislation and a Designated Officer of a hospital.

Human tissue removed prior to 1 November 2003 from a living person as part of standard care procedures can be legally used for research purposes. Access to the tissue for research purposes may require consent according to National Statement Section 3.2.5. Informed consent is required prior to removing human tissue for research purposes.

Human tissue removed on or after 1 November 2003 from a living person as part of standard care procedures can only been used for research purposes if consent has been obtained from that person (or their parent or guardian if they are a child) before or after the removal. If the person passed away without giving consent, consent must be obtained from their next-of- kin.

Human tissue removed on or after 1 November 2003 from a deceased person can only be used for research purposes, written consent to the use of the tissue for research purposes needs to be obtained from their next-of-kin.

Under no circumstances are tissues to be removed from the body of a deceased child who is or was a ward of the state for research purposes, with or without consent.

Human Research Ethics Committees (HRECs) must adhere to legal requirements as well as standards set out in the National Statement when assessing research protocols involving human tissue. Its decision to grant waiver of consent is subject to the legal requirements and must be made according to the requirements in the National Statement.

The *Human Tissue Act 1983 (NSW)* allow the use of lawfully removed small tissue samples to be used for analyses or tests as part of certain quality assurance programs or as necessary for accreditation or the delivery of services at or by certain entities.

The full version of the Use of Human Tissue for Research guideline is available at https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2023_008

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

343(24/08/22)

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.

132(11/08/11)

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 Regulation2002)* with regard to List B diseases.

5.4 Transfer of Human bodies or Human Tissues

5.4.1 Transfer of a Body

A licence holder may transfer a body in their possession to another licence holder within NSW without prior approval of an inspector. A transfer to any person in charge of the conduct of anatomical examinations at any place outside NSW is permitted with prior approval of an inspector.

Transfer of a body is not permitted if the licence holder has reason to believe that the transfer would be contrary to the wishes of the deceased or the senior available next-of-kin.

If the body is to be disposed of by the receiving institution it is a requirement that all relevant paperwork (including cremation certificates and medical referee's permit) accompany the body.

5.4.2 Transfer of human tissue

The *Anatomy Act 1977* allows for the transfer of human tissue from one licence holder to another, or to an authorised officer of a NSW hospital, or to a person approved, in writing, by the Director-General within NSW without prior approval of an inspector for use for medical or scientific purposes.

Transfer of tissue will not be permitted if the licence holder has reason to believe that the transfer would be contrary to the wishes of the deceased or the senior available next-of-kin.

The licence holder must ensure that arrangements are made for the return of the human tissue as soon as practicable, and by no later than the end of the period within which the tissue is required to be disposed.

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

132(11/08/11)

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

	(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 deceases to the:
	(Name of Licensed Anatomical Facility) in accordance with any terms or conditions placed on the consent by the deceased or senion available next-of-kin.
De	esignated Officer signature:
Da	te:

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

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:	

Admir	istration 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
Minim	um 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.

Reten	tion
	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.
Trans	fer 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.
Dispos	sal
	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 <i>Public Health (Disposal of Bodies) Regulation 2002</i> .
	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.

26. TISSUE/ORG	GAN	26.26
Attachment 3.1:	Anatomy Register Example	
NAME OF DECEA	NUMBER:	
SEX:	AGE:	
DATE BODY REC	EIVED:	
RECEIVED FROM	[:	
NAME:		
ADDRESS		
PHONE:		
DATE OF DEATH	: PLACE OF DEATH:	
LAST PLACE OF A	ABODE:	
CAUSE OF DEATI	Н:	
REMOVAL DATE	FOR CREMATION/BURIAL:	
REMOVED BY :		
CONTRACTING F	FUNERAL DIRECTOR (Please PRINT Name, Address & Contact N	lumber):

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

DESIGNATED OFFICER (PD2023 012)

PD2023_012 replaced PD2013_002

POLICY STATEMENT

A Designated Officer is responsible for authorising the release of a body for anatomical examination, non-coronial post-mortem examination and the removal and use of organs and tissue from a deceased body for medical, scientific, or therapeutic purposes (including transplant). They must do so in accordance with the Anatomy Act 1977 (NSW) and the Human Tissue Act 1983 (NSW).

SUMMARY OF POLICY REQUIREMENTS

Local health districts, specialty health networks, NSW Health Pathology departments, forensic institutions including NSW Health Pathology must appoint a Designated Officer in any facility where bodies may be donated for anatomical examination, non-coronial postmortems are carried out, or where organ and tissue is removed from a deceased person and used, including donated for transplantation. The licensee of a private hospital appoints Designated Officers for a private facility.

Designated Officers must be appointed in accordance with section 5 of the Human Tissue Act 1983 (NSW) by the governing body of a hospital or NSW Health pathology departments and forensic institutes. NSW Health organisations must ensure that arrangements are in place for staff to easily identify and contact Designated Officers at all times. The appointment of several Designated Officers may be necessary to ensure 24-hour coverage so that one is available when required, particularly after hours. Appropriate staff at NSW Health Pathology departments and forensic institutions including

NSW Health Pathology must have information including 24-hour contact details for Designated Officers for Departments of Forensic Medicine.

Designated Officers must complete mandatory training to become accredited and appointed. To remain eligible for reappointment, Designated Officers are required to successfully complete reaccreditation training every two years.

The Designated Officer has discretionary authority. They are not obligated to authorise a procedure. Designated Officers are obligated to make 'reasonable inquiries' before authorising procedures. The

Designated Officer's authority must be in writing (not orally). This includes authorisation via email, provided that the email clearly states the name and position of the Designated Officer who is providing authority.

The full version of the Designated Officer policy can be downloaded at: https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=pd2023_012

MANAGEMENT OF THE POTENTIAL ORGAN AND TISSUE DONOR FOLLOWING NEUROLOGICAL DETERMINATION OF DEATH (GL2023 013)

GL2023 013 replaced GL2016 008

GUIDELINE SUMMARY

This Guideline provides recommendations for managing and delivering standardised clinical therapies to potential organ and tissue donors following neurological death. The goal is to support and optimise organ and tissue function and improve organ retrieval for transplantation.

The Guideline must be read in conjunction with the State Form SMR010517 Neurological Determination of Death (also known as Brain Dead) and the NSW Health Policy Directive Organ and Tissue Donation, Use and Retention (PD2022 035).

KEY PRINCIPLES

The criteria for neurological determination of death are established by Australian and New Zealand Intensive Care Society (ANZICS) and set out in section 1.2 Neurological determination of death in the Australian and New Zealand Intensive Care Society (ANZICS) The Statement on Death and Organ Donation edition 4.1 (2021) (ANZICS Statement).

The management of the potential organ and tissue donor after neurological determination of death aims to support organ function and optimise the number of organs retrieved for transplantation.

This includes frequent clinical assessment of organ function and response to interventions as well as ensuring that the time from determination of death to retrieval surgery is as short as possible.

The recommendations are largely based on physiological rationale, consensus statements and limited clinical research with a non-negligible risk for bias.

Consent is another key principle of all donations as outlined in the NSW Health Policy Directive Organ and Tissue Donation, Use and Retention (PD2022_035).

A valid consent is essential for any donation, refer to the NSW Health Consent to Medical and Healthcare Treatment Manual (The Consent Manual). The hospital's Designated Officer must also have granted authorisation to remove the organ/s and/or tissue.

In NSW the Organ and Tissue Authority's Best Practice Guideline for Offering Organ and Tissue Donation in Australia (Best Practice Guideline) is used to support families make an informed decision about donation and ensures that a Donation Specialist participates in the Family Donation Conversation.

Consent must be in writing or by other manner prescribed as per the NSW Health Policy Directive Organ and Tissue Donation, Use and Retention (PD2022_035) and the NSW Health Consent to Medical and Healthcare Treatment Manual (The Consent Manual).

The full version of the Management of the Potential Organ and Tissue Donor following Neurological Determination of Death Guideline can be downloaded at: https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2023 013

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 Transplanation Guidelines can be downloaded at: https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2008 019

302(02/03/16)