Patient Matters Manual for Public Health Organisations

Chapter 26 – Tissue and Organ

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Note

Where a number appears at the bottom of an amended page [such as 252 (17/09/15) – amendment number, date] an alteration has been made or new section included. Amendment numbers are sequential, the date represents the date the source document was published on the Policy Distribution System (PDS).

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Organ and Tissue Donation, Use and Retention

Document number 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.

343 (17/08/22)

Use of Human Tissue for Research

Document number GL2023_008 rescinds 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 PRINCIPLES

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 post-mortem 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-ofkin. 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.

Living Kidney Donation and Transplantation

Document number PD2022_036 rescinds PD2017_030 and PD2015_041.

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.

343 (24/08/22)

Organ Donation After Circulatory Death

Document number GL2021_012 rescinds 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 prescribed 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).

Designated Officer

Document number PD2023_012 rescinds 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.

Management of the Potential Organ and Tissue Donor following Neurological Determination of Death

Document number GL2023_013 rescinds 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).

Adult-to-Adult Living Donor Liver Transplantation Guidelines

Dpcument number GL2008_019.

Purpose of the Guideline

The LDLT National Policy Framework has been endorsed by the Australian Health Ministers' Advisory Council (AHMAC). Recognising the clinical need, complexity and risks of the procedure, AHMAC undertook a national development and consultation process in preparing this National Policy Framework. It sets appropriate ethical principles and clinical standards for the practice of adult-to-adult living donor liver transplantation.

Recommended standards

NSW Health has adopted as a guideline for provision of LDLT in the NSW public health system the 'Adult-to-Adult Living Donor Liver Transplantation (LDLT) National Policy Framework'.

This guideline seeks to promote ethical, lawful and consistent application of quality processes in provision of this complex procedure to donors, recipients and their families; to provide guidance to health professionals; and additional protection for prospective adult Living Donor Liver Transplantation (LDLT) donors. It includes reference to donor selection criteria, necessary consent processes including use of an independent donor advocate, institutional requirements for provision of LDLT, and permissibility of LDLT in the emergency setting.

This guideline should be read in conjunction with: PD2005_406 Consent to Medical Treatment-Patient Information. It should also be read in conjunction with local policy developed by the participating liver transplant unit.

Implementation

Advice is intended for use by clinical and medical staff involved in transplants at institutions that will provide LDLT.

302 (02/03/16)