Deceased Organ and Tissue Donation - Consent and Other Procedural Requirements

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Summary  This policy directive outlines the requirements of the Human Tissue Act 1983 for consent for deceased organ and tissue donation and incorporates procedures for health facilities to follow in relation to the process of coordination and retrieval of organs and tissue from deceased donors in NSW.

This policy will replace Chapter 5 of PD2005_341 Human Tissue, Use/Retention Including Organ Donation, Post Mortem Examination and Coronial Matters.

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Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
Deceased Organ and Tissue Donation – Consent and Other Procedural Requirements

PURPOSE

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

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

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

MANDATORY REQUIREMENTS

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

Chief Executives of LHDs are responsible for ensuring that:

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

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

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

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

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

Designated specialists in health facilities are responsible for:

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

Designated officers in hospital and forensic facilities:

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

REVISION HISTORY

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Deceased Organ and Tissue Donation – Consent and Other Procedural Requirements

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1 BACKGROUND

1.1 About this document

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

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

This Policy Directive also establishes requirements for:

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

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

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

1.2 Key definitions

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

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

**Child**

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

**Child in care.**

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

- Who is under the parental responsibility of the Minister administering the *Children and Young Persons (Care and Protection) Act 1998*, or
- For whom the Director-General of the Department of Community Services or a designated agency has the care responsibility under Section 49 of the *Children and Young Persons (Care and Protection) Act 1998*, or
- Who is a protected person within the meaning of Section 135 of the *Children and Young Persons (Care and Protection) Act 1998*, or
- Who is the subject of an out-of-home care arrangement under the *Children and Young Persons (Care and Protection) Act 1998*, or
- Who is the subject of a sole parental responsibility order under Section 149 of the *Children and Young Persons (Care and Protection) Act 1998*, or
- Who is otherwise in the care of a service provider.

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

**Death**

The *Human Tissue Act 1983* defines death as:

(a) Irreversible cessation of all function of the person’s brain, or

(b) Irreversible cessation of circulation of blood in the person’s body.

**Designated Officer**

A Designated Officer is:

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

**Designated specialist**

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

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

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

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

**Medical or scientific purpose**

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

**Records**

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

**Requesting health professional**

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

**Senior Available Next of Kin**

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

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

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

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

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

**Tissue**

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

**1.3 Legal and legislative framework**

The current policy is underpinned by the requirements of:

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

**2 Consent for deceased organ and tissue donation**

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

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

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

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

2.1 Written Consent

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

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

2.2 Consent by other prescribed means

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

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

The following elements of the consent discussion must be recorded

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

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

¹ The relevant NSW Health policy on consent is PD2005_406 Consent to Medical Treatment - Patient Information
2.3 Consent for organ and tissue donation by children in the care of the State

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Act makes no provision for families to override prior patient consent for organ and tissue donation. However, for prudential and compassionate reasons family agreement is generally sought. There may be cases in which donation is considered inappropriate for clinical or other reasons, regardless of the donor’s decision. Each case should be considered on its merits. It is recognised that obtaining family support for organ/tissue donation requires complex and sensitive communication, regardless of whether the donor’s decisions are known.

If a deceased person had given their consent to the removal of tissue but a health practitioner determines that the removal of tissue should not proceed due to the objection of the deceased person’s family, then the relevant health practitioner must document the reasons for not proceeding. A form has been developed to assist requesting health professionals meet their obligations under this policy. The form (Attachment 3) should be completed and signed by the requesting clinician, and then signed by the Designated Officer.

3 **Discussion of organ and tissue donation**

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

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

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

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

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

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

### 3.1.1 Documenting the decision not to proceed with donation.

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

### 3.1.2 Designated Officer role when family objection overrides potential donor consent

The Designated Officer’s role is to review the documentation and confirm that the reasons for family objection are documented and that the donation will not proceed. The completed and signed form should be included in the patient’s medical record.

### 3.1.3 Tissue donation requests

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

### 3.2 Determining the most recent views of the deceased

Section 23 of the Act has been amended to allow a Designated Officer to consider the most recent views of the deceased when determining whether or not to authorise the

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2 UK Human Tissue Authority *Code of Practice 2 – Donation of solid organs for transplantation, 2012*
removal of tissue where the deceased may previously have registered an objection to donation.

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

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

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

3.3 Substitute decision makers and the Human Tissue Act 1983

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

A person who fulfils any of the following functions in relation to a deceased person is not able to give consent under the Human Tissue Act 1983 unless they are also the senior next of kin:

- Persons appointed as Guardians under the Guardianship Act 1997,
- Persons who hold a “Power of Attorney”,
- Persons nominated as a “person responsible” in a hospital or medical record, or
- Persons nominated as a “person to notify” in a hospital or medical record.

4 Organ and tissue donation protocol

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

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

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

4.1.1 Multi-organ donation pathways

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

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


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

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

For further specific information regarding identification of donors in whom donation after cardiac (circulatory) death is being considered see GL2011_005 Organ Donation after Cardiac Death.

4.1.2 Tissue-only donation pathway

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

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

The minimum information must include:

- Name and date of birth of the deceased;
- Time and date of death; and
- Ward and hospital.

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

Donation Specialist Nurses are located in selected NSW hospitals. Their role includes management of the process for referring potential donors to the NSW OTDS.
Contact details for the local Donation Specialist Nurse should be available in wards and hospital units where potential multi-organ and/or tissue only donors are likely to be admitted.

On referral the Donation Specialist Nurse will require the following information:

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

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

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

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

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

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

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

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

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

During this discussion, information on the donation process will be given to the family. The following points should also be canvassed where relevant:
The potential donor’s consent or decision in relation to donation must be provided where it is known.

The duration of the organ and tissue donation process and the investigations required (i.e. blood samples for virology testing and tissue typing and purpose).

That retrieval of organs may not proceed if the donor is deemed medically unsuitable, test results are abnormal, or there are no suitable transplant recipients.

If death occurred under circumstances where it must be reported to the Coroner, Coronial permission must be sought and formal identification of the body for the Coroner is required by law.

As consent to the removal and use of organs and tissues from a deceased person must be authorised by a Designated Officer prior to the removal of the organ and tissue, the Designated Officer may wish to contact the family to satisfy themselves as to any specific issues raised in the discussion and that the consent accurately reflects the family’s understanding of the procedures.

If organs and/or tissues are removed and are subsequently unable to be transplanted, they will be returned with the body of the donor (unless permission for research was granted) or disposed of as per the next of kin’s wishes.

4.5 Classification of the Multi-organ donor for billing purposes

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

4.6 Certification of Death

The Human Tissue Act 1983 prescribes that a person has died when the following has occurred:

(a) Irreversible cessation of all function of a person’s brain (brain death); or

(b) Irreversible cessation of circulation of blood in a person’s body (commonly referred to as cardiac death).

4.6.1 Determination of Brain Death


Where brain death criteria are used, two (2) medical practitioners who have practiced medicine for at least five (5) years in the previous eight (8) years must certify that death has occurred.
One of the medical practitioners must be a Designated Specialist appointed by the governing body of the hospital.

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

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

4.6.2 Determining death by circulatory (cardiac) criteria

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

Chapter 5 “Donation After Cardiac Death” of The ANZICS Statement on Death and Organ Donation edition 3.1, 2010 (www.anzics.com.au/death-and-organ-donation) recommends that death be determined when the following features are present:

- Immobility;
- Apnoea;
- Absent skin perfusion; and
- Absence of circulation as evidenced by absent arterial pulsatility for a minimum of two minutes, as measured by feeling the pulse, or preferably by monitoring intra arterial pressure.

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

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

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

Health facility staff should also act in accordance with Guideline GL2011_005 Organ Donation after Cardiac Death.

4.7 Coronial cases and organ and tissue donation

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

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

4.7.1 Coronial consent – Organ donation after cardiac (circulatory) death (DCD)

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

4.8 Designated Officer’s authority

In accordance with the Act once consent to the removal of organs and tissues for the purposes of donation has been obtained, a Designated Officer must be contacted to authorise the removal in accordance with the consent.

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

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

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

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

Senior available next of kin contact details should the Designated Officer wish to discuss authorisation.

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

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

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

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

4.10 Donor maintenance and care


As the condition of potential organ and tissue donors may become unstable and/or deteriorate the treating team managing the potential donor should alert the NSW OTDS Donation Specialist Nurse or medical staff of any specific physiological and metabolic changes occurring in the donor.

For potential donors for whom donation after cardiac (circulatory) death is being considered staff must be aware of GL2011_005 Organ Donation after Cardiac Death. In particular interventions specifically for the benefit of future organ recipients cannot be administered, for example the use of pre-mortem procedures or drugs to optimise organ function.

Continuation of eye care is paramount for eye donation.

4.11 Blood specimens

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

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

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

4.11.2 Blood sampling for tissue typing and serological testing

Multi-organ retrieval surgery cannot proceed until routine serology testing has been completed. The approximate turn around time for virology results is 3-4 hours. However, should prospective nucleic acid testing (NAT) be required, results will be available 8 hours from the time of the request. If prospective NAT is required organ retrieval surgery cannot proceed until results are available (see PD 2010_002 Organ Donation and Transplantation - Managing Risks of Transmission of HIV, HCV and HBV).

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

4.11.3 Blood sample collections

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

4.12 Organisation of retrieval surgery

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

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

4.12.1 Tissue-only retrieval

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

4.12.2 Retrieval of Organ and tissues for Research
Organ and tissue may only be removed for research purposes where specific consent for
research use was granted by the senior available next of kin or their delegate and with
the specific permission of the forensic pathologist and Coroner (if the death was
reportable to the Coroner).
In addition, organ and tissue can only be used for research purposes if the research has
ethics approval.
Where organs are deemed unsuitable for transplantation but suitable for research, the
retrieving surgeons or transplant centre must inform the Donation Specialist Coordinator.

4.12.3 Disposal of Non-utilised Allocated Organs
Where consent for research has not been granted by the senior available next of kin and
procured allocated organs/tissues have been retrieved and subsequently deemed not
suitable to transplant, the retrieving surgeon and/or tissue bank must notify the donor
specialist or tissue bank coordinator.
The retrieving surgeon and/or transplant centre must either respectfully dispose, use for
research or return organs to the body, depending on family wishes. The family’s wishes
for this situation should be recorded when obtaining consent.

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

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

1. Consent and authority for removal of tissue after death form
2. Delegation of authority of the senior next of kin form.
3. Documenting family objection to organ/tissue donation contrary to the known wishes of the donor form
4. GIVE Clinical Trigger Poster
5. Certification of brain death form
6. Certification of cardiac death form
7. Implementation Checklist
Consent and Authority For Removal Of Tissue After Death

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

Consent (Circle either A, B or C)

A. Consent of Deceased (Attach written consent of the deceased or a copy of the consent document and proceed to the Authorisation by Designated Officer). Or

B. Consent of Senior Available Next-of-kin /Delegate (Attach written authorisation of delegate if applicable) Or

C. Consent by audio or audio-visual recording (Complete the following information and proceed to the authorisation by the Designated Officer).

Audio Recording Device No. __________ Date __________ Time __________

I. Age __________

(Address of senior available next-of-kin)

hereby state:

1. I have no reason to believe that the deceased has expressed an objection to the removal of:

   Blood vessels, lymphoid tissue, section of spleen and blood for tissue typing. Blood for disease screening, cross matching and transplantation purposes. ( Routinely retrieved).

   (*delete if not applicable)

   — Heart/Cardiovascular tissue (heart valves)
   — Lungs
   — Liver
   — Pancreas/Pancreas islets
   — Kidneys
   — Eyes
   — Musculoskeletal tissue (bones from upper and lower limbs, including the pelvis, tendons and ligaments from knees and ankles)

   — Section of spleen for research
   — Other (please specify) __________

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

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

2. I consent to the removal of the above mentioned tissues for such purposes.

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

4. The purposes and likely consequences of removal of the tissue have been explained to me to my satisfaction. I understand that support interventions will continue until the removal of tissue and that procedures to preserve organ function will be undertaken as appropriate.

5. Any tissue removed and not utilised in accordance with point 1, (subject to Coronial approval as applicable), is to be (*delete if not applicable):

   — Reunited with the body;
   — Disposed of respectfully in accordance with hospital procedures.

Name (print) of senior available next-of-kin: __________

Signature: __________

Relationship to the deceased: __________

Date: __________

Officer requesting consent:

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

Name (print): __________

Signature: __________

Designation: __________

Date: __________

Healthcare Interpreter (if applicable): __________

Signature: __________

Date: __________
Removal of tissue cannot be authorized without written consent of the deceased or consent of a senior available next-of-kin, if the deceased did not provide written consent during their lifetime and no next-of-kin is available to consent either in writing or by audio or audio visual means, the Designated Officer cannot authorize the removal of tissue.

I, (Name of Designated Officer) ________________________________,
hereby state that, having made such enquiries as are reasonable in the circumstances, I am satisfied that:

1. The above named deceased person had during his/her lifetime, consented in writing to the removal after death of tissue from his/her body for the purpose(s) set out below and that he/she had not revoked the consent (attach deceased’s written consent document);

Or

2. Hereby state that the above named deceased had not during his/her lifetime, expressed an objection to the removal of tissue from his/her body after his/her death, or, if he/she had expressed such an objection, based on the most recent views expressed by him/her, he/she no longer had an objection to the removal of tissue from his/her body

And

3. That the senior available next of kin or their delegate has provided written consent, or an audio or audio visual consent to the removal after death of tissue from the deceased’s body for the purpose(s) set out below

And

4. Where applicable that the consent of the Coroner to the removal and use of tissue after death has been given subject to the following conditions:

   (specify Coroner’s conditions on removal and use of tissue if applicable)

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

   Blood vessels; lymphoid tissue; section of the spleen and blood for tissue typing; Blood for disease screening, cross matching and transplantation purposes:

   - [ ] Heart/ Cardiovascular tissue (heart valves)
   - [ ] Lungs
   - [ ] Liver
   - [ ] Pancreas/Pancreas Islets
   - [ ] Kidneys
   - [ ] Eyes
   - [ ] Musculoskeletal tissue (bones from the upper and lower limbs, including the pelvis, tendons and ligaments from the knees and ankles)
   - [ ] Section of spleen for research
   - [ ] Other (please specify) ________________________________

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

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

Signature: ________________________________

(Designated officer) ________________________________

Date: / /

Definitions

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 a hospital, or
- In relation to a forensic institution, a person appointed under s5 (1) (a) of the Human Tissue Act 1983, to be a Designated Officer for the forensic institution, or
- In relation to a private hospital within the meaning of the Private Hospitals and Day Procedures Centres Act 1996 a person appointed by a governing body (defined by the Act as the licensee) of the hospital

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

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

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

1. a parent of the child
2. where a parent to the child is not available, a brother or a sister of the child, who has attained the age of 18 years
3. where no person referred to in point 1 or 2 is available, a person who is guardian of the child immediately before the child’s death.
s5A of the Human Tissue Act 1983 provides that a next of kin may authorise, in writing, another person to exercise his or her functions under the Act as a next of kin of the deceased person.

Name of Deceased: 

MRN: __________________________ Date of Birth: _______ / _______ / _______

Date of Death: _______ / _______ / _______ Location: _______________________

Full name of next-of-kin:
Surname: __________________________ First Name: __________________________

Of (Address) __________________________

Relationship to deceased __________________________

Statement by next-of-kin:
I hereby authorise;
Surname: __________________________ First Name: __________________________
(Full name of delegate)

Of (Address) __________________________

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

Print name of next-of-kin: __________________________

Signature: __________________________ Date: _______ / _______ / _______

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

Print name of authorised person (Delegate): __________________________

Signature: __________________________ Date: _______ / _______ / _______
Deceased Organ and Tissue Donation – Consent and Other Procedural Requirements

DOCUMENTING FAMILY OBJECTION TO ORGAN/TISSUE DONATION CONTRARY TO KNOWN WISHES OF THE DONOR

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

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

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

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

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

☐ No
☐ Yes
If so, describe
_______________________________________________________________________
_______________________________________________________________________

Requesting clinician
Full name: Surname _______________________ First name _______________
Person’s Position: ____________________________________________________
Signature of requesting clinician_____________________ Date: ____/_____/______

Designated Officer
I confirm that the donation will not proceed because of these objections. I have reviewed the above documentation and confirm that reasons for family objection are cited.
Full name: Surname________________ First name__________________________
Signature of Designated Officer ________________________Date: ____/_____/______
### Certification of Brain Death

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

#### Known cause of irreversible loss of brain function

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

**Doctor A:** Specify condition

**Doctor B:** Specify condition

#### Period of continuous observation of apparent loss of neurological function

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

This period began at (Date and time)

### Determination of brain death by clinical examination *

**Preconditions**

1. Hypothermia is not present – temperature is > 36°C Specify Temperature:
2. Blood pressure is adequate (eg MAP>60 in an adult)
3. Sedative drug effects are excluded
4. There is no severe electrolyte, metabolic or endocrine disturbance
5. Neuromuscular function is intact
6. It is possible to examine the brain-stem reflexes (including at least one ear and one eye)
7. It is possible to perform apnoea testing

**Clinical Testing**

1. There is no motor response in the cranial nerve distribution to noxious stimulation of the face, trunk and four limbs and there is no response in the trunk or limbs to noxious stimulation within the cranial nerve distribution
2. There are no pupillary responses to light
3. There are no corneal reflexes
4. There is no gag (pharyngeal) reflex
5. There is no cough (tracheal) reflex
6. There are no vestibulo-ocular reflexes on ice-cold caloric testing
7. Breathing is absent (despite arterial PCO2 > 60mmHg (8kPa) and arterial pH < 7.30)
8. Specify PCO2 in mmHg or kPa (circle one) and pH at end of apnoea

**PCO2**

**pH**

### Determination of brain death when clinical examination cannot be done:

- There is no intracranial blood flow
- (Delete one as appropriate) This has been demonstrated by either intra-arterial angiography or other suitably reliable method

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

**Doctor A (Name):**

**Doctor B (Name):**

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*Based on criteria developed by the Australian/New Zealand Intensive Care Society, the ANZICO statement on Death and Organ Donation, edition 3.1, 2010*
Organ donation - certification of death determined by absence of vital signs following circulatory death.

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

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

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

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

C. All of the following features were present: (please mark with X)
   - Immobility
   - Apnoea
   - Absent Skin Perfusion
   - Absence of pulsatility on the arterial line of at least 2 minutes duration

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

Doctor (print name): _______________________________

Status: __________________________________________

Signature: _______________________________________
Attachment 7: Implementation checklist
See PD 2009_029 Policy Distribution System (PDS) for NSW Health section 3.3

| LHD/Facility: |  |
| Assessed by: | Date of Assessment: |

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