

**Summary** This Policy Directive provides an overview of the process for appointing Designated Officers and their responsibilities as prescribed by the Anatomy Act 1977 (NSW), Human Tissue Act 1983 (NSW), and compliance with the provisions of the Coroners Act 2009. A Designated Officer can authorise 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 (such as a transplant).

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Audience Designated Officers; Nursing Unit Managers; Chief Executive; Pathologists; Forensic Departments; Intensive Care Specialists; Intensive Care Units; Emergency Department; Physicians; Surgery; Anaesthesia; Obstetrics and Gynaecology



# NSW Health POLICY DIRECTIVE

## **Designated Officer**

#### **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 post-mortems 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.

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# **NSW Health**POLICY DIRECTIVE

## **REVISION HISTORY**

Version	Approved By	Amendment Notes
PD2023_012 May-2023	Deputy Secretary, Population and Public Health & Chief Health Officer	<ul> <li>Consider culturally safe practices for appointing a Designated Officer</li> <li>Reference to updated State Forms which are related to the implementation of the Policy Directive</li> <li>Update to the 'Principal Care Officer' definition due to legislative changes to the <i>Human Tissue Act 1983 (NSW)</i>.</li> </ul>
PD2013_002 January-2013	Deputy Secretary, Population and Public Health	New Policy. To be read in conjunction with PD2013_001.

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#### 1. BACKGROUND

This Policy Directive provides an overview of the role of the Designated Officer as prescribed by the *Anatomy Act 1977* (NSW), the *Human Tissue Act 1983* (NSW), and in relation to compliance with the provisions of the *Coroners Act 2009* (NSW).

This Policy Directive must also be read in conjunction with:

NSW Health Policy Directives, Guidelines and Manuals	
PD2011_052 Conduct of Anatomical Examinations and Anatomy Licensing in NSW	
PD2013_051	Non-Coronial Post Mortems
PD2022 035	Organ and Tissue Donation, Use and Retention
Consent Manual	Consent to Medical and Healthcare Treatment Manual
Privacy Manual	Privacy Manual for Health Information

State Forms in conjunction with this policy are referenced in Appendix 9.4 NSW Health State Forms and can be ordered from Stream Solutions.

#### 1.1. About this document

The Policy provides the standard procedures for Designated Officers in authorising donations to anatomical examinations, non-coronial post-mortems and the removal and use of organ and tissue (including donations) from a deceased person.

## 1.2. Key definitions

Child	A person who has not attained the age of 18 years and who is not married (section 4 <i>Human Tissue Act 1983</i> (NSW)).	
Child in care	As per the <i>Children and Young Persons (Care and Protection) Act 1988</i> (NSW) a child or young person who is less than 18 years old:	
	<ul> <li>who is under the parental responsibility of the Minister administering the Children and Young Persons (Care and Protection) Act 1998 (NSW), or</li> </ul>	
	<ul> <li>where the Secretary of the Department of Communities and Justice or a designated agency has the care responsibility, or</li> </ul>	
	<ul> <li>who is a protected person, or</li> </ul>	
	<ul> <li>who is the subject of an out-of-home care arrangement, or who is the subject of a sole parental responsibility order, or</li> </ul>	
	<ul> <li>who is otherwise in the care of a service provider.</li> </ul>	



## **Designated Officer**

	Parental responsibility, in relation to a child or your means all the duties, powers, responsibilities and a by law, parents have in relation to their children.	
Consent – 'Other Manner Prescribed' (other than written)	As per sections 23(3)(b) and 24(3) of the <i>Human T</i> 1983 (NSW) and clause 8(1) of the <i>Human Tissue</i> 2020 (NSW), the senior available next of kin may giverbally to organ and tissue donation from a decea	Regulation jive consent
	<ul> <li>an audio or audio-visual recording is made of consent, and</li> </ul>	of the
	<ul> <li>the senior available next of kin has consented making of that audio or audio-visual recording</li> </ul>	
Designated Officer	As per section 5 of the <i>Human Tissue Act 1983</i> (Notes of the Human Tissue Act 1983)	SW) a
	<ul> <li>in relation to a public hospital, a person app writing by the governing body of a hospital to Designated Officer for the hospital, or</li> </ul>	
	<ul> <li>in relation to a private hospital, a person approximation writing by the governing body (licensee) of the hospital, or</li> </ul>	
	<ul> <li>in relation to a forensic institution, a person writing by the governing body of a forensic in be a Designated Officer for the forensic institution.</li> </ul>	nstitution to
Designated Specialist	As per section 5(1)(b) of the <i>Human Tissue Act 19</i> 'Designated Specialist' is a person who holds a speregistration in one or more of the following specialt appointed as a Designated Specialist:	ecialist
	Anaesthesia	
	Emergency medicine	
	Intensive care medicine	
	<ul> <li>Obstetrics and gynaecology</li> </ul>	
	Physician	
	Surgery.	
Principal Care Officer	In relation to a child in care of the State, for the pur Designated Officer's role and the <i>Human Tissue A</i> (NSW), the Principal Care Officer is the Secretary <i>Children and Young Persons (Care and Protection</i> (NSW) [section 4(8) <i>Human Tissue Act 1983</i> (NSW delegate.	ct 1983 under the ) Act 1998
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#### **Designated Officer**

## Senior available next of kin

As per section 4 of the *Human Tissue Act 1983* (NSW) in relation to a child who is living:

- a parent of the child, or
- if a parent is not available, a person who is a guardian of the child.

As per section 4 of the *Human Tissue Act 1983* (NSW) In relation to a deceased child:

- a parent of the child
- where a parent of the child is not available, a sibling of the child who is 18 years of age or over, or
- where none of the above is available, a person who was a guardian of the child immediately before the death of the child.

Where the child is in the care of the State, specific provisions for consent for organ and tissue donation apply (see section 7 *Consent for Children in Care of the State*).

In relation to any other deceased person a senior available next of kin is a:

- person who was a spouse of the deceased person immediately before their death (which can include a de facto spouse and same sex partner)
- where there is no spouse or the spouse is not available, a son or daughter of the deceased person who has attained the age of 18 years
- where no person referred to above is available (that there
  is no spouse, son or daughter of the deceased person
  available), a parent of the deceased person, or
- where no person referred to above is available, a brother or sister of the deceased person who has attained the age of 18.

#### **Tissue**

As per section 4 of the *Human Tissue Act 1983* (NSW) tissue refers to an organ or part of a human body and a substance extracted from, or from a part of, the human body.

As per section 34 *Human Tissue Act 1983* (NSW) tissue blocks and slides may be retained without specific consent when removed for the purpose of carrying out tests.

## 1.3. Legal and legislative framework

This Policy Directive is underpinned by the requirements of the following legislation:



#### **Designated Officer**

- Anatomy Act 1977 (NSW)
- Children and Young Persons (Care and Protection) Act 1998 (NSW)
- Coroners Act 2009 (NSW)
- Human Tissue Act 1983 (NSW)
- <u>Human Tissue Regulation 2020</u> (NSW)

#### 2. APPOINTMENT OF THE DESIGNATED OFFICER

Designated Officers require a thorough understanding of the applicable legislation (see section 1.3) and policies and an appreciation of the clinical and ethical issues that are associated with the role.

In NSW, the governing body of a hospital (public or private) appoints Designated Officers under section 5 of the *Human Tissue Act 1983* (NSW).

For public hospitals, this is the hospital's local health district/ speciality health network Chief Executive. For private hospitals, the licensee of the facility appoints Designated Officers.

For a forensic institution that is managed by NSW Health Pathology, this is NSW Health Pathology's Chief Executive or Director of Forensic and Analytical Science Service. Whereas for an accredited pathology laboratory under the *Health Insurance Act 1973* (Commonwealth) it is the person in charge of the laboratory who appoints Designated Officers.

It is a matter for the governing body to determine who may be appointed as a Designated Officer subject to the person meeting the training requirements (see section 2.2) prior to their appointment.

If culturally safe, the governing body could consider the appointment of an Aboriginal Health Worker such as an Aboriginal Health Practitioner or Senior Aboriginal Health Worker to undertake the role and authorisation of a Designated Officer. The <u>Aboriginal Health Worker Guidelines for NSW Health</u> refers to the four categories of Aboriginal Health Workers. Their scope of practice provides flexible, holistic and culturally sensitive health services to Aboriginal clients and the community to achieve better access to health services for Aboriginal people.

#### 2.1. Access to a Designated Officer

The appointment of several Designated Officers may be necessary to ensure 24-hour coverage so that one is available when required, particularly after hours. Local health districts, specialty health networks and forensic institutions may consider appointment of Designated Officers across facilities to support easy access to a Designated Officer by a smaller facility.

As outlined in section 2.3, a register helps ensure that arrangements are in place for staff to easily identify and contact Designated Officers at all times.

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#### 2.2. Mandatory training requirements

All Designated Officers must successfully complete the NSW Health online course *Designated Officer – Learning Path* (48880324), to be eligible for appointment.

To remain eligible for appointment, Designated Officers are required to successfully complete the online course *Designated Officer – Reaccreditation Learning Path* (171665547) every two years, or when notified by email that relevant modules must be reviewed, for example, following a legislative amendment. Successful completion requires a pass mark of 80% of all modules in the online learning path.

The learning pathways provide Designated Officers with essential information about key processes related to organ, tissue, and body donation which they are legally obligated to authorise and regulate. For staff working in the NSW Health system the two online Designated Officer learning paths are hosted on the My Health Learning system.

For staff working in private hospitals and facilities the training is accessible on the <u>NSW GEM</u> website.

Access to the learning paths is restricted to individuals who have been nominated by a local health district/ specialty health network Chief Executive, forensic institution governing body or private hospital licensee. In most circumstances, the local administrator responsible for staff enrolment in mandatory training can provide access to those nominated and seeking reaccreditation to the online Designated Officer learning paths.

Once the nominated individual has been enrolled and successfully completed the *Designated Officer – Learning Path*, they will automatically be given access in the future to the *Designated Officer – Reaccreditation Learning Path*.

## 2.3. Designated Officer register

Chief Executives of local health district/ specialty health network/ forensic institutions including NSW Health Pathology (and their delegates) are responsible for maintaining an accurate register of their Designated Officers.

The register provides:

- the NSW Ministry of Health and Chief Executives of local health district/ specialty health network and forensic institutions with a list of certified Designated Officers
- relevant agencies outside NSW Health with a list of certified Designated Officers
- · notification for recertification of Designated Officers, and
- notification and approve re-appointment process for Designated Officers that relocate to a different facility.

Local health districts, specialty health networks, NSW Health pathology departments and institutes of forensic medicine must ensure that arrangements are in place for staff to easily identify and contact Designated Officers at all times, for example, via the hospital switchboard.

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#### 3. DESIGNATED OFFICERS ROLES AND AUTHORISATION

## 3.1. Role of the Designated Officer

The role of the Designated Officer is to authorise, in accordance with relevant legislation:

- the release of a body for anatomical examination
- a non-coronial post-mortem examination
- the use of tissue removed for the purposes of non-coronial post-mortem examination
- the removal and use of tissue from a body for transplant or other therapeutic, medical or scientific purpose.

The Designated Officer also has responsibilities in the circumstance where a potential living donor revokes their consent to donate tissue for the purpose of transplantation (see section 6).

The Designated Officer has discretionary authority. Before an authority is given by a Designated Officer, the Designated Officer must be satisfied as to certain matters (such as making reasonable inquiries, assessing an objection or consent is from the most appropriate senior available next of kin) before giving written authority for a procedure. However, they are not obligated to authorise that procedure.

The role also requires conflict resolution and high-level communication and negotiation skills.

## **3.2.** General principles and responsibilities

When issuing authorisations under the *Human Tissue Act 1983* (NSW) or the *Anatomy Act 1977* (NSW), a Designated Officer:

- in coronial cases, cannot authorise the removal or use of tissue for any purpose unless the Coroner has given permission
- may make reasonable inquiries in order to be satisfied of the relevant criteria before authorising procedures (or not authorising)
- may rely on inquiries made by others
- must never sign an incomplete form and their authority must be in writing
- cannot act in any case where they have had a clinical or personal involvement
- must not disclose the deceased's identity to the public.

#### 3.3. Coronial cases

The Designated Officer is required to ascertain whether the Coroner has jurisdiction to hold an inquest. Where a Coroner has jurisdiction to hold an inquest under the *Coroners Act 2009* (NSW) into an individual's death, a Designated Officer must not authorise the following unless they have the Coroner's consent:

- the use of any tissue removed from a body during a post-mortem examination
- donation of the body for anatomical examination

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- donation of organs/ tissue
- any procedure in relation to a child in care of the State.

Where the Coroner provides their consent, it may be subject to conditions. The Coroner's consent is in addition to any other consent which may be required under the *Human Tissue Act 1983* (NSW). It is an offence to authorise the use of organs and tissue in these circumstances without the Coroner's consent.

The Coroner or their delegate may rely on the Designated Officer to alert the Coroner to any potential problems. The Designated Officer needs to establish whether the circumstances surrounding the death require a report of the death to the Coroner (see section 3.3.2).

A verbal consent given by the Coroner must be confirmed by a written certificate as soon as practicable. A Designated Officer does not need to sight the written certificate from the Coroner to proceed with authorisation. The verbal consent of the Coroner will suffice.

The NSW Organ and Tissue Donation Service Donation Specialist Coordinator will ensure that the written certificate from the Coroner is obtained and a copy added to the donor's record.

#### 3.3.1. Coroner's jurisdiction

Under section 21 of the *Coroners Act 2009* (NSW), a Coroner has jurisdiction to hold an inquest if:

- the person's death is (or is reasonably suspected to be) a reportable death, or
- a medical practitioner has not given (or there is reasonable cause to suspect that a medical practitioner has not given) a medical certificate as to cause of death.

#### 3.3.2. Meaning of 'reportable death' to the Coroner

A person's death is 'reportable' under section 6 of the Coroners Act 2009 (NSW) if:

- (a) the person died a violent or unnatural death
- (b) the person died a sudden death the cause of which is unknown
- (c) the person died under suspicious or unusual circumstances
- (d) the person died in circumstances where the person's death was not the reasonably expected outcome of a health-related procedure carried out on the person
- (e) the person died while in or temporarily absent from a declared mental health facility within the meaning of the *Mental Health Act 2007* (NSW) and while the person was a patient at the facility for the purpose of receiving care, treatment or assistance under the *Mental Health Act 2007* (NSW) or *Mental Health and Cognitive Impairment Forensic Provisions Act 2020* (NSW).

OR

Where the death is a death in custody or as a result of a police operation (section 23 of the *Coroners Act 2009* (NSW)), such as where the person died:

(a) while in the custody of a police officer or in other lawful custody

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- (b) while escaping, or attempting to escape, from the custody of a police officer or other lawful custody
- (c) as a result of a police operation
- (d) while in, or temporarily absent from, any of the following institutions or places of which the person was an inmate:
  - i. a detention centre within the meaning of the *Children (Detention Centres) Act* 1987 (NSW)
  - ii. a correctional centre within the meaning of the *Crimes (Administration of Sentences) Act 1999* (NSW)
  - iii. a lock-up
- (e) while proceeding to an institution or place referred to in paragraph (d), for the purpose of being admitted as an inmate of the institution or place and while in the company of a police officer or other official charged with the person's care or custody.

#### OR

Where the death is a death of a child or disabled person under certain circumstances (section 24 of the *Coroners Act 2009* (NSW)), such as where person who died was:

- (a) a child in care
- (b) a child in respect of whom a report was made under Part 2 of Chapter 3 of the Children and Young Persons (Care and Protection) Act 1998 (NSW) within the period of 3 years immediately preceding the child's death
- (c) a child who is a sibling of a child in respect of whom a report was made under Part 2 of Chapter 3 of the *Children and Young Persons (Care and Protection) Act 1998* (NSW) within the period of 3 years immediately preceding the child's death
- (d) a child whose death is or may be due to abuse or neglect or that occurs in suspicious circumstances
- (e) a person (whether or not a child) who, at the time of death was living in, or temporarily absent from, a specialist disability accommodation or assisted boarding house
- (f) a person (other than a child in care) who has a disability (whether physical, psychiatric, intellectual, or sensory) and who receives assistance from a regulated service provider to enable the person to live independently in the community.

## 3.4. Obligation to investigate and make 'reasonable inquires'

Designated Officers are obliged to make 'reasonable inquiries' before authorising removal and use of organ and tissue. Examples of reasonable inquiries include:

- Ascertaining whether the death is reportable to the Coroner and if so, being satisfied that Coronial consent has been given to the Designated Officer (or their delegate) and documented as required under section 25(1) of the *Human Tissue Act 1983* (NSW)
- Ascertaining that a deceased child is not a child in care of the State

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 Ascertaining whether the deceased consented in writing to the donation of the body for anatomical examination, post-mortem examination, organ and tissue donation or removal of tissue for medical, scientific, or therapeutic purposes.

Where no written consent of the deceased person exists:

- Ascertaining whether the deceased subsequently revoked their consent
- Ascertaining whether the deceased had expressed an objection to the donation of the body for anatomical examination, post-mortem examination, organ and tissue donation or removal of tissue for medical, scientific, or therapeutic purposes and if so, whether that objection was the deceased's most recent view
- Ascertaining the existence or whereabouts of the senior available next of kin and their views regarding the proposed removal and use of tissue
- Establishing that no other senior available next of kin of the same or a higher order objects to the proposed donation or non-coronial post-mortem.

#### 3.4.1. Delegation of 'reasonable inquiries'

A Designated Officer may delegate reasonable inquiries to another responsible health professional. However, the Designated Officer remains ultimately responsible for demonstrating they have acted reasonably in relying on such information when authorising removal and use of organ and tissue.

In addition, the Designated Officer needs to be satisfied that the criteria in the relevant legislative provisions have been met prior to authorising the removal or use of tissue.

#### 3.5. Authority in writing and completion of consent forms

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 authority in writing must be given before the procedures (such as a non-coronial post-mortem or the removal of organs and tissue from a dead body) can be performed. The written consent and authorisation provide evidence of adherence to the consent process.

To enable Designated Officers to provide their authorisation in writing, hospitals and health facilities must ensure that appointed Designated Officers have access to copies of relevant documents. They may be on site to physically sign a document or have access to scanned and printed documents or faxed and emailed documents.

Only completed consent forms are to be lodged with the Designated Officer for their written authorisation. Designated Officers must never sign an incomplete form.

#### 3.6. Conflict of interest

The Designated Officer must be a neutral third party in the cases they authorise. They cannot be involved in cases where they provided clinical care to the deceased while living or after death or are a relative or friend of the deceased.

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If the Designated Officer discovers that they have a clinical or personal involvement in the case, they must terminate their involvement as the Designated Officer immediately so that a new Designated Officer can take on the role.

#### 3.7. Disclosure of information

It is an offence for a Designated Officer who has given an authority under the *Human Tissue Act 1983* (NSW) to disclose information which may result in the identity of a person (whether living or deceased) becoming publicly known.

Unless the person to whom the information relates is an adult and has consented to the disclosure, or the disclosure is required for legal reasons, in connection to the administration of the *Human Tissue Act 1983* (NSW) or in connection with medical research as approved by a Human Research Ethics Committee or with other lawful excuse.

The Designated Officer is deemed to have published a record if they permit or facilitate access to that record by another person.

#### 4. DESIGNATED OFFICER AUTHORISATION PROCESS

Designated Officers are required to authorise the removal and use of organs and tissue from a deceased's body in several clinical contexts. These include:

- donation of the body for anatomical examination
- · non-coronial post-mortem examinations, and
- removal of organs and tissue from a body for transplant or other therapeutic, medical, or scientific purpose.

## 4.1. General authorisation process

A Designated Officer may authorise the removal of organs and tissue from a deceased person after death where the adult during their lifetime has given their consent in writing to anatomical examination body donation, the performance of a non-coronial post-mortem examination, organ and tissue donation or the removal of tissue for medical, scientific, or therapeutic purposes and such consent had not been revoked.

If the person during their lifetime has not given written consent or was a child (apart from a child in care of the State) the Designated Officer may authorise removal of tissue after death only where:

- it has been established that the deceased has not expressed an objection during their lifetime, or
- if an objection had been expressed, the Designated Officer is satisfied, based on the most recent views expressed by the deceased, they no longer had an objection to the removal of their organs and tissue
- the senior available next of kin has given consent in writing (or in another manner prescribed under clause 8 of the *Human Tissue Regulation 2020* (NSW)), and

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 the Designated Officer has ascertained that there is no senior available next of kin of the same standing or higher order who objects.

If the deceased during their lifetime objected in writing, the Designated Officer may authorise removal of organs and tissue after death only where:

- the Designated Officer is satisfied, after making reasonable inquiries, that based on the most recent views of the deceased, they no longer held an objection to the removal of organs and tissue from their body, and
- a senior available next of kin has given consent in writing (or in another manner prescribed under the *Human Tissue Regulation* 2020 (NSW)), and
- the Designated Officer has ascertained that there is no senior available next of kin of the same standing or higher order who objects.

## 4.2. Certification and documentation of death for organ and tissue donation

In NSW the legal definition of death defined in section 33 of the *Human Tissue Act 1983* (NSW), states a person has died when there is:

- · irreversible cessation of all function of the person's brain, or
- irreversible cessation of circulation of blood in the person's body.

Under section 26 of the *Human Tissue Act 1983* (NSW), where:

- a person has died in a hospital or the body of a deceased person has been brought into a hospital, and
- if at the time when the person died or at any time thereafter the person's respiration or the circulation of the person's blood was being maintained by artificial means,

a Designated Officer cannot give authority unless two medical practitioners (who are not involved in the transplantation process or the care of the patient recipient) each certify that they:

- examined the person while the person's respiration or circulation was being artificially maintained, and
- at that time, irreversible cessation of the person's brain function had already occurred.

At least one of the medical practitioners must be a designated specialist appointed under section 5(2) of the *Human Tissue Act 1983* (NSW).

#### 4.3. Consent for children

Before a Designated Officer can authorise any procedures on a deceased child and, where applicable, the retention of tissue for subsequent non-diagnostic purposes, the Designated Officer must ensure that the deceased child is not a child in the care of the State. Where the deceased child was not a child in the care of the State, the Designated Officer must be satisfied that:

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- the child had not during their lifetime expressed an objection to organ and tissue donation or the removal of tissue for medical, scientific, or therapeutic purposes
- the child's senior available next of kin has given their written consent (or in another manner prescribed under the *Human Tissue Regulation 2020* (NSW))
- no next of kin of the same or a higher class than the child's senior available next of kin objects.

Section 7 outlines consent requirements for a deceased child, who immediately before death, was in the care of the State.

#### 4.4. Donation of sperm (gametes) from deceased persons

There is a complex interplay between the *Human Tissue Act 1983* (NSW) and the *Assisted Reproductive Technology Act 2007* (NSW). Recent Supreme Court decisions impact who is authorised to remove gametes, when this is permissible, and where they may be lawfully stored.

Under section 23 of the *Human Tissue Act 1983* (NSW), where there is no written consent of the person to the specific removal of their gametes, the Designated Officer may have discretion to authorise removal of tissue under certain circumstances.

However, the *Assisted Reproductive Technology Act 2007* (NSW) does not allow gametes to be stored or used in NSW unless the deceased person had given written consent for their storage and posthumous use.

The Designated Officer must not authorise removal of gametes unless:

- the deceased person provided prior written consent for the removal and use of their gametes, or
- there is a court order obtained by the deceased's family authorising removal.

#### 5. ASSESSING OBJECTION TO ORGAN/ TISSUE DONATION

## 5.1. Objection by the deceased

The Designated Officer needs to ascertain whether the deceased has expressed an objection or revoked a previous consent to organ and tissue donation or the removal of tissue for medical, scientific, or therapeutic purposes.

A recorded objection on the Australian Organ Donor Register or in an advanced care directive is a clear, unequivocal expression of objection. However, Designated Officers may use their discretion to reassess objections based on information from the deceased's relatives indicating that the deceased had changed their decision.

If a Designated Officer is satisfied, after making reasonable inquiries, that:

- the deceased had (when living) changed their decision after their written objection and the deceased no longer held the objection, and
- the senior available next of kin has given their consent in writing, or as prescribed by the regulations, to the above procedure, and



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no next of kin of the same or a higher class objects,

then the Designated Officer may authorise the donation in accordance with the terms and any conditions of the senior available next of kin's consent.

#### 5.2. Disagreement from equal senior available next of kin

Where the wishes of the deceased are unknown, consent is required from the senior available next of kin. There may be multiple senior available next of kin on the same level of hierarchy, for example both parents of the child.

For the consent to be valid, all senior available next of kin must not object to the procedure, for example both parents of the deceased child must agree. If there is agreement, only one senior available next of kin needs to give consent.

Where agreement is not reached, and one senior available next of kin objects to the donation or non-coronial post-mortem, then the Designated Officer must not authorise the procedure.

## 5.3. Family objection overrides potential donor's known wishes

Legally, given an existing valid consent from the deceased, the Designated Officer could authorise the procedures when a family objects. However, it is common practice for staff involved in organ and tissue donation not to proceed with the donation in the face of serious and continuing distress, and sustained objection exhibited by the family.

The decision not to proceed with donation because of family objections, contrary to the deceased's known decision, rests with the clinicians managing the deceased and overseeing the end-of-life discussions, including consideration of organ and tissue donation.

In this circumstance a standard form must be completed and signed by the senior available next of kin, the requesting clinician, and then signed by the Designated Officer. The information which must be included on the form are:

- details provided to the family. This must include the names and roles of all those participating in the discussion
- details of objections raised by the family
- other rationale for acceding to family objection, such as potential harm to the family/ senior available next of kin in proceeding
- extenuating family (or deceased) circumstances that are considered relevant to the decision.

The Designated Officer may attend the family interview consistent with local policy and guidelines, and their discretionary authority to assess objections. The Designated Officer must review the documentation and confirm that the reasons for family objection have been documented by the requesting clinician and that donation is not proceeding because of these objections.

A completed and signed form must be included in the deceased's medical record. Refer to the NSW Health Policy Directive *Organ and Tissue Donation, Use and Retention* (PD2022\_035) and the NSW Health State Form *Documenting Family Objection to Organ/Tissue Donation Contrary to the Known Wishes of the Donor* (SMR10516) form.





#### 6. REVOCATION OF CONSENT IN LIVING DONATION

It is a living donor's right to revoke consent at any time up until the commencement of surgery. Under section 16 of the *Human Tissue Act 1983* (NSW) health practitioners and the Designated Officer have the following responsibilities where a donor indicates they wish to revoke their consent, or are no longer in agreement with the proposed removal and transplantation of the tissue:

- The health professional to whom the donor indicates they revoke their consent must inform the Designated Officer of the revocation of the consent. It is an offence under section 16 of the *Human Tissue Act 1983* (NSW) not to inform the Designated Officer
- If after making such inquiries (if any) as are reasonable in the circumstances, the
  Designated Officer (or medical practitioner) must inform any other medical practitioner
  who is proposing to remove tissue from the donor that the consent is revoked. It is an
  offence under section 16 of the *Human Tissue Act 1983* (NSW) for the Designated
  Officer (or the medical practitioner) not to inform the other medical practitioner
  proposing to remove tissue that the consent has been revoked, and
- The Designated Officer must ensure that the revocation of the consent is recorded in the donor's medical record.

#### 7. CONSENT FOR CHILDREN IN CARE OF THE STATE

A Designated Officer must not authorise the anatomical examination, a non-coronial postmortem, or removal of tissue for scientific purposes on the body of a deceased child if the child was, immediately before death, a child in the care of the State as per section 34A of the Human Tissue Act 1983 (NSW).

Organs and tissue may be removed from the body of a deceased child who was a child in the care of the State only for transplantation purposes as per section 23A of the *Human Tissue Act 1983* (NSW).

Where the deceased child has died in hospital or whose body has been brought into the hospital, the Designated Officer can authorise the removal of tissue for transplantation but only if satisfied, after making reasonable inquiries, that:

- the deceased child had not expressed an objection to the removal of their tissues for transplantation purposes
- the Principal Care Officer has given their consent in writing, and
- the Coroner has given their consent in writing.

#### Principal Care Officer

The Principal Care Officer for the child checks the child's file and should make reasonable efforts to contact any interested or relevant parties (such as the parents, family members) for consultation regarding consent or objection to the donation. They are to consider both whether the child had expressed an objection to organ and tissue donation (which had not been withdrawn) and the views of family members.

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#### Coroner

The Coroner has jurisdiction over a deceased child who was in the care of the State (section 24 of the *Coroners Act 2009* (NSW)).

Under section 25 of the *Human Tissue Act 1983* (NSW), the Coroner must consent before the Designated Officer can authorise the removal of tissue of a deceased child who is in a hospital. The Coroner may place conditions on which organs and tissues can be removed.

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Before authorising the removal of tissue from a deceased child who is at hospital and who was in the care of the State before dying, the Designated Officer must be satisfied that:

- the child did not express an objection to the removal of organ and tissue for the purposes of transplantation during their lifetime
- the Principal Care Officer has provided consent
- the Coroner has given their consent that the organ and tissue can be used for donation.

A Designated Officer who is unsure as to the status of the child may need to verify this status. If verification of the status of a child is necessary, an application for information can be made to the local police command to ascertain the status of the child from the Department of Communities and Justice.

#### 8. SENIOR AVAILABLE NEXT OF KIN

#### 8.1. Delegation of functions

Section 5A of the *Human Tissue Act 1983* (NSW) makes provision for delegation of the functions of the senior available next of kin. This provision allows for cultural and religious requirements to be observed. In these circumstances it is important for the treating team to engage with Aboriginal Health Workers, Aboriginal Health Practitioners and Multicultural Health Workers to ensure the appropriate people have been consulted.

The senior available next of kin can delegate their functions to another person by signing a delegate consent form. Refer to the NSW Health State Form *Authorisation to Delegate Responsibilities of the Senior Available Next of Kin* (SMR020031) form.

The Designated Officer must ensure that the delegation instrument is valid and attached to the consent.

## 8.2. Locating senior available next of kin

In some circumstances it may be necessary for the police to be involved in locating the senior available next of kin. In these cases, the Designated Officer or their delegate must direct an inquiry to the duty commander of the local police command where the deceased lived. All relevant information regarding the deceased must be given to the police to assist including:

Name of the deceased

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- Last known residential address of the deceased (if known)
- Date of birth or age of the deceased
- Sex of the deceased
- Name, last known address, and relationship of the next of kin.

If the senior available next of kin are found, the police will notify them of the death and ask them to contact the Designated Officer or their delegate. Police will not be involved in obtaining any consent under the *Human Tissue Act 1983* (NSW).

If, on inquiry, a deceased child is determined to be a child in care of the State, or the sibling of a child in care of the State, the police should inform the Designated Officer. All deaths of children in care of the State and their siblings must be referred to the Coroner as per section 24 of the *Coroners Act* 2009 (NSW) (see sections 3.3 and 7).

#### 9. APPENDICES

The checklists are a guide, and its use is not mandatory. It is provided in related policies.

- 1. Release of a Body or Tissues for Anatomical Examination Checklist
- Non-Coronial Post Mortem Checklist
- 3. Organ and Tissue Donation Checklist
- 4. NSW Health State Forms

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# 9.1. Appendix 1: Release of a Body or Tissues for Anatomical Examination Checklist

A Designated Officer may authorise anatomical examination for a deceased body or tissues where:

(1) Licensed facility: For the donation to be valid, the following must be a 'yes'		
The request is made by a facility licensed by NSW Health to undertake anatomical examination.	No 🗆	Yes □
(2) Certification of death: For the donation for anatomical examination to be wanted by a 'yes'	alid, the f	ollowing
A valid death certificate has been completed.	No □	Yes □
(3) Coroner's consent: For the donation for anatomical examination to be validation following must be a 'yes'	id, one of	the
The death is reportable and the consent of the on-duty Coroner for donation to a body donor program has been obtained.	No 🗆	Yes □
The death is not reportable.	No □	Yes □
<b>(4) Child in care of the State:</b> For the donation for anatomical examination to following must be a 'yes'	be valid, t	he
The deceased is not a child in care of the State.	No □	Yes □
(5) Consent from patient or Senior Available Next of Kin: For the donation to be valid, one of the following must be a 'yes'		
The deceased has given written consent during their lifetime which has not been revoked.	No □	Yes □
The deceased has not given consent nor objected during their lifetime and the senior available next of kin has provided consent.	No □	Yes □

Note: In practice, licensed anatomical examination facilities generally only accept tissues from persons who have themselves **consented to donation for anatomical examination** during their lifetime.



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## 9.2. Appendix 2: Non-Coronial Post-Mortem Checklist

A Designated Officer may authorise a non-coronial post-mortem and/or use of tissues following a post-mortem examination where:

(1) Certification of death: For the post-mortem to be valid, the following must		,
A valid death certificate has been completed.	No □	Yes □
(2) Coroner's consent: For the post-mortem to be valid, the following must be	a 'yes'	
The death is not reportable.	No □	Yes □
Coroner's referral checklist is completed by the treating medical practitioner	No □	Yes □
(3) Child in care of the State: For the post-mortem to be valid, the following m	nust be a	'yes'
The deceased is not a child in care of the State.	No □	Yes □
(4) Consent from patient or Senior Available Next of Kin: For the post-mort one of the following must be a 'yes'	em to be	valid,
The deceased has given written consent during their lifetime which has not been revoked.	No 🗆	Yes □
The deceased has not given consent nor objected during their lifetime and the senior available next of kin has provided consent. No other senior available next of kins (higher or equal) have objected.	No 🗆	Yes □



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## 9.3. Appendix 3: Organ and Tissue Donation Checklist

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

(1) Death confirmed by: For the donation to be valid, one of the following mus	st be a 'ye	es'
Irreversible cessation of all functions of the person's brain	No □	Yes □
Irreversible cessation of circulation of blood in the person's body	No □	Yes □
(2) Certification of death: For the donation to be valid, the following must be	a 'yes'	
A valid death certificate has been completed or a 'Report of Death to the Coroner (form A)' has been completed.	No 🗆	Yes □
(3) Coroner's consent: For the donation to be valid, one of the following must	be a 'yes	,
The death is reportable and the permission of the on-duty Coroner for donation to a body donor program has been obtained.	No 🗆	Yes □
The death is not reportable.	No □	Yes □
(4) Child in care of the State: For the donation to be valid, the following must	be a 'yes	,
The deceased is a child in care of the State and the Principal Care Officer and the Coroner have provided their consent for donation.	No 🗆	Yes □
The deceased is not a child in care of the State.	No □	Yes □
(5) Consent from patient or Senior Available Next of Kin: For the donation the following must be a 'yes'	to be valid	d, one of
The deceased has given written consent during their lifetime which has not been revoked.	No 🗆	Yes □
The deceased has not given consent nor objected during their lifetime and the senior available next of kin has provided consent. No other senior available next of kins (higher or equal) have objected.	No 🗆	Yes □
The deceased objected during their lifetime, but family has shown this objection is not current and the senior available next of kin has provided consent. No other senior available next of kins (higher or equal) have objected.		Yes □



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## 9.4. Appendix 4: NSW Health State Forms

NSW Health State Forms relevant to this Policy Directive		
SMR010516	Documenting Family Objection to Organ/Tissue Donation Contrary to the Known Wishes of the Donor	
SMR10517	Neurological Determination of Death (also called brain death)	
SMR10518	Organ Donation - Circulatory Determination of Death	
SMR020020	Consent to Regenerative Tissue Donation – Child Incapable of Understanding	
SMR020030	Consent and Authority for Removal of Tissue After Death	
SMR020031	Authorisation to Delegate Responsibilities of the Senior Available Next of Kin	
SMR020033	Authorisation for the Release of Human Tissue to a Patient or Senior Available Next of Kin	
SMR020034	Consent and Authority for the Retention and use of Tissue Removed or Expelled During Treatment of a Now Deceased Patient	
SMR020035	Human Tissue Act 1983 Consent and Certification for the Donation of Tissue by a Living Adult	
SMR020036	Human Tissue Act 1983 Consent and Certification for the Donation of Regenerative Tissue by a Living Child	