

## Anatomical Examinations and Anatomy Licensing

**Summary** NSW Health provides the procedures for the licensing, inspection, and regulation of anatomy facilities, including clear directives to licence holders of acceptable activities associated with the conduct of anatomical examinations under the provisions of the licence.

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**Distributed to** Ministry of Health, Public Health System, Government Medical Officers, Environmental Health Officers of Local Councils, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

**Audience** Administration;Directors of Clinical Governance & Clinical Operations;Nursing Staff;Mortuary Staff

## Anatomical Examinations and Anatomy Licensing

### POLICY STATEMENT

NSW Health provides the procedures for the licensing, inspection, and regulation of anatomy facilities, including clear directives to licence holders of acceptable activities associated with conducting anatomical examinations under the provisions of the licence.

A person in charge of conducting anatomical examinations must apply for an anatomy licence to lawfully possess deceased human bodies and tissue for examination purposes at a location specified in the licence.

Conducting anatomical examinations for the purpose of sponsored research, educational research and medical training is governed by the *Anatomy Act 1977* (NSW) and regulated by NSW Health.

### SUMMARY OF POLICY REQUIREMENTS

Anatomy licenses are issued by the Secretary, NSW Health, or their delegate, subject to satisfactory inspections. An anatomy inspector determines the duration of a licence based on their risk assessment of the facility and compliance of the licence holder. A licence may be issued with additional terms and conditions.

A licence holder can re-apply for an anatomy licence prior to the original licence expiring.

Written applications for an anatomy licence must be submitted to the Secretary, NSW Health.

The Secretary, NSW Health, may revoke the licence at any time from a licence holder as per Section 6(5) of the *Anatomy Act 1977* (NSW).

As part of the written application process, a local anatomy inspector will contact the applicant to arrange an inspection undertaken at the location where the bodies/ tissue/ anatomical specimens are to be used. It is suggested that facilities reapply for their licences at least three (3) months in advance to avoid licences lapsing during the assessment period.

Coronial (forensic) and non-coronial (hospital) autopsies are not covered by this Policy Directive and its regulations.

Licence holders must keep a register of all bodies and/or human tissue in their possession and produce the register to an inspector when requested. The register must contain information about acquiring and transferring bodies and human tissue as well as disposing bodies and human tissue which are not exempt from consent.

The register must be retained for as long as the deceased is in the possession of the licensee and for at least five (5) years after the final transfer or release of the deceased bodies.

A licence holder must dispose of a body, including human tissue, in their possession within four (4) years of the date of death of the deceased. However, a licence holder may apply in writing to an inspector for an extension to retain bodies or human tissue in their possession.

Written consent is required to authorise the use of a body for anatomical examination.

All body donation programs must provide clear donor consent forms for potential donors that include options for them to specify terms and conditions to their consent.

Licence holders can only hold a body for anatomical examination when they have the written authority of a Designated Officer or a senior available next of kin.

### REVISION HISTORY

Version	Approved By	Amendment Notes
December 2023 PD2023_044	Deputy Secretary, Population and Public Health & Chief Health Officer	<p>Updated policy directive to reflect changes in terminology and current practice:</p> <ul style="list-style-type: none"> <li>• Inclusion of a definition for inspectors and information on the hierarchy for senior available next of kin.</li> <li>• Requirement of a register to be available at all sites where a facility has multiple sites.</li> <li>• Clarification on the grounds for the revocation of a licence.</li> <li>• Clarification on the requirements for local disposal of tissue, where the tissue is not to be returned to its origin which is from outside NSW.</li> <li>• Removal of appendices and re-developed as editable resources in PDF available on the NSW Health website.</li> <li>• Emphasis on the importance of disposing the body according to the wishes of the deceased or their senior available next of kin.</li> <li>• Emphasis on the need for cultural consideration when consulting with and obtaining consent from patients and family/next of kin who identify as Aboriginal or Torres Strait Islander.</li> <li>• Consider culturally safe practices for appointing a Designated Officer during the consultation process with Aboriginal families.</li> <li>• Introduction of a risk-based approach to anatomy licensing and inspections. Removed the requirement to inspect licensed facilities annually.</li> </ul>
August 2011 (PD2011_052)	Deputy Director-General Population Health	A new policy replacing Section 9 of PD2005_341 <i>Use and Retention of Human Tissue</i> .

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## **1. BACKGROUND**

Anatomical examination involves dissecting a dead human body for the purposes of medical or scientific, including educational, training and research.

Anatomical examinations are primarily undertaken in anatomy departments at universities, colleges and other tertiary institutes, some public hospitals and medical schools for the teaching and training of students and staff, and in associated facilities for conducting research.

The anatomical training and research undertaken in facilities would either form part of a university degree or a specialised training workshop for medical and health professionals.

### **1.1. About this document**

This Policy Directive outlines the procedures for the licensing, inspection, and regulation of facilities conducting anatomical examinations.

It aims to provide clear directives to licence holders of acceptable activities under the provisions of a licence and minimum information to be included in information packages for body donor programs.

Sealed pathology specimens and plastinated specimens held in pathology museums used for teaching/ training purposes are covered by this document.

Coronial (forensic) and non-coronial (hospital) autopsies are not covered by this Policy Directive.

## 1.2. Key definitions

<b>Anatomical examination</b>	<p>As per section 4 of the <i>Anatomy Act 1977</i> (NSW) this includes the use of the body for medical or scientific purposes. However, does not include a postmortem examination.</p> <p>Any reference to medical or scientific purposes in this Policy Directive includes educational purposes connected with medicine or science.</p>
<b>Body</b>	<p>As per section 4 of the <i>Anatomy Act 1977</i> (NSW) it means a dead human body.</p>
<b>Child</b>	<p>As per section 4 of the <i>Anatomy Act 1977</i> (NSW), a child is a person who has not attained the age of 18 years and who is not married.</p>
<b>Clinical sharps waste</b>	<p>Any clinical object capable of inflicting a penetrating injury which may or may not be contaminated with blood and/ or other bodily fluids. This includes needles, ampoules and any other sharp objects or instruments designed to perform penetrating procedures.</p> <p>See NSW Health Policy Directive <i>Clinical and Related Waste Management for Health Services</i> (<a href="#">PD2020_049</a>).</p>
<b>Clinical waste (including pathological waste)</b>	<p>Clinical waste with the potential to cause injury, infection, or offence may include:</p> <ul style="list-style-type: none"> <li>• Unrecognisable human tissue (excluding hair, teeth, nails and anatomical waste)</li> <li>• Bulk blood or other body fluids (or body substances)</li> <li>• Material and equipment visibly stained by blood or body fluids</li> <li>• Lab specimens, cultures, or other waste from lab investigations</li> <li>• Waste from medical or veterinary research</li> <li>• Genetically Modified Organisms (GMOs)</li> </ul> <p>See NSW Health Policy Directive <i>Clinical and Related Waste Management for Health Services</i> (<a href="#">PD2020_049</a>).</p>

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<b>Designated Officer</b>	<p>As per section 4 of the <i>Anatomy Act 1977</i> (NSW) and section 5 of the <i>Human Tissue Act 1983</i> (NSW) a 'Designated Officer' is:</p> <ul style="list-style-type: none"> <li>• In relation to a public hospital, a person appointed in writing by the governing body of a hospital to be a Designated Officer for the hospital, or</li> <li>• In relation to a private hospital, a person appointed in writing by the governing body (licensee) of the private hospital to be a Designated Officer for the hospital, or</li> <li>• In relation to a forensic institution, a person appointed in writing by the governing body of a forensic institution to be a Designated Officer for the forensic institution.</li> </ul>
<b>Dispose</b>	<p>As per section 4 of the <i>Anatomy Act 1977</i> (NSW), to dispose of the body by burial, cremation, or other lawful means.</p>
<b>Human tissue</b>	<p>As per section 4 of the <i>Human Tissue Act 1983</i> (NSW) and section 4 of the <i>Anatomy Act 1977</i> (NSW) human tissue refers to an organ or part of a human body. The definition includes human bone and a substance extracted from the human body.</p>
<b>Inspector</b>	<p>In the <i>Anatomy Act 1977</i> (NSW), a person who has been appointed by the Minister (or their delegate) who may be:</p> <ul style="list-style-type: none"> <li>(a) an officer of NSW Health</li> <li>(b) an employee of the Local Health District or Specialty Health Network</li> <li>(c) an employee of a public health organisation within the meaning of the <a href="#">Health Services Act 1997</a> (NSW).</li> </ul> <p>An inspector may inspect at any time any licensed facility.</p>
<b>Remains</b>	<p>The body or what is left of the body (or any part of the body) of the deceased person.</p>
<b>Senior available next of kin</b>	<p>As per section 4 of the <i>Anatomy Act 1977</i> (NSW), in relation to a deceased child:</p> <ul style="list-style-type: none"> <li>• a parent of the child</li> <li>• where a parent of the child is not available, a sibling of the child who is 18 years of age or over, or</li> <li>• where none of the above is available, a person who was a guardian of the child immediately before the death of the child.</li> </ul>



	<p>Where the child is in the care of the state, specific provisions for consent apply (see section 4.3).</p> <p>In relation to any other deceased person a senior available next of kin is a:</p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• 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</li> <li>• where no person referred to above is available (that is no spouse, son or daughter of the deceased person are available), a parent of the deceased person, or</li> <li>• where no person referred to above is available, a brother or sister of the deceased person who has attained the age of 18 years.</li> </ul>
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### 1.3. Legal and legislative framework

This Policy Directive must be read in conjunction with:

NSW Health Policy Directives	
<a href="#">PD2013_051</a>	<i>Non-Coronial Post Mortems</i>
<a href="#">PD2022_035</a>	<i>Organ and Tissue Donation, Use and Retention</i>
<a href="#">PD2023_012</a>	<i>Designated Officer</i>

#### **Anatomy Act 1977 (NSW)**

The [Anatomy Act 1977](#) (NSW) regulates the conduct of anatomical examinations in NSW, including:

- the issue of licences
- appointment of inspectors
- the conditions of taking possession of bodies or human tissue
- the requirements for keeping registers of bodies and human tissue, and for the disposal of bodies.

#### **Human Tissue Act 1983 (NSW) – Designated Officers**

Section 5 of the [Human Tissue Act 1983](#) (NSW) provides for the appointment of Designated Officers by the governing body of a hospital or forensic institution.

Section 8 of the *Anatomy Act 1977* (NSW) states that a Designated Officer may, by instrument in writing, authorise the anatomical examination of a body of a person in accordance with written consent provided by the person during their lifetime or (subject to

certain additional requirements set out at section 8(3) of the *Anatomy Act 1977* (NSW)) their senior available next of kin.

### ***Coroners Act 2009 (NSW) – Coronal Consent***

Section 56 of the [Coroners Act 2009](#) (NSW) states that a Coroner has a right to hold and retain the remains of a deceased person where the Coroner has jurisdiction to hold or is holding an inquest concerning the death of the person. This right of the Coroner has priority over any other right to possession such as a potential donation to a school of anatomy.

A person must not deliver, or hand over remains for anatomical or medical research without authorisation (Section 100(2) *Coroners Act 2009* (NSW)). The Act sets out a number of mechanisms which constitute an 'appropriate disposal authorisation' including a notice given by a medical practitioner in accordance with the *Births, Deaths and Marriages Registration Act 1995* (NSW). Similarly, if an order authorising the disposal of remains has been made by the Coroner under Section 101 of the *Coroners Act 2009* (NSW), a licence holder may proceed with the potential donation. A copy of the Coronal order for disposal of the remains must be retained with the consent paperwork.

### ***Public Health Regulation 2022 (NSW)***

Anatomy licence holders wanting to use donated bodies and human tissue must determine the body or human tissue is not infected with any of the prescribed infectious diseases listed in clause 79 of the [Public Health Regulation 2022](#) (NSW).

## **2. ANATOMY LICENCES AND INSPECTIONS**

A person in charge of conducting anatomical examinations must hold an anatomy licence to lawfully possess deceased human bodies and tissue for examination purposes at a location specified in the licence. The licence holder must be available to ensure compliance and supervision.

An application for a licence may be made by any person who is in charge of the conduct of anatomical examinations at any university, college, school, or other educational institution or at any research or medical institution. If an applicant wishes to apply for a licence as a corporation, it must demonstrate that it meets the threshold requirements stipulated in section 6 of the *Anatomy Act 1977* (NSW) in their submitted documentation.

As per section 6 of the *Anatomy Act 1977* (NSW) licences are issued by the Secretary, NSW Health, or their delegate, to enable licence holders to conduct anatomical examinations at a place specified in the licence. A licence may be issued with additional terms and conditions to ensure appropriate risk management practices are administered or to address non-compliance.

A risk-based regulatory approach is to be applied when issuing a licence and inspecting facilities. An inspector must assess the inherent risk of a facility and compliance observed during an inspection of a licence holder's facility and administrative practices. This approach enables inspectors to determine the duration that licences are issued for (see Table 1) and to subject appropriate administrative oversight on high risk and/ or non-compliant licensed facilities. Newly issued licences will include an expiration date.

Section 2.6 in this Policy Directive provides further information about the inspection review process.

A licence holder can re-apply for an anatomy licence (see section 2.4) prior to the original licence expiring.

**Table 1. Risk assessment to determine the duration of licence and frequency of inspection**

Level of risk	Duration of licence and frequency of inspection	Explanation on assigning risk categories for inherent risk and non-compliance
Low/ no risk	Three (3) years	Low or no inherent risks identified, and no non-compliances observed during the inspection. For example, the laboratory may primarily undertake a dry process and employ digital and virtual anatomy technologies, models, and skeletal material. Anatomical examinations of human tissue and specimens only include low risk procedures.
Medium/ some risk	Two (2) years	The laboratory includes wet processes and anatomical examinations of human tissue and specimens with low to medium risks. Also, minor non-compliances were identified during the laboratory inspection and/ or historic non-compliance.
High risk	One (1) year	The laboratory primarily includes wet processes and examinations of human tissue and specimens that present a higher level of risk and the need to employ comprehensive infection control procedures. Also, several non-compliances were identified during the laboratory inspection with consequent breaches of the <i>Anatomy Act 1977</i> (NSW) and <i>Human Tissue Act 1983</i> (NSW). The facility has a history of contravening the <i>Anatomy Act 1977</i> (NSW) and <i>Human Tissue Act 1983</i> (NSW). Enforcement action has been taken against the facility in the past, and complaint investigations have confirmed non-compliances. The facility has failed to apply for a renewal of their anatomy licence prior to its expiry.

## 2.1. Applying for an anatomy licence

Written applications for an anatomy licence must be submitted to the Secretary, NSW Health.

The information required in an application is outlined on the [NSW Health website](#).

The time frame for the assessment of applications and issuing of an anatomy licence may vary (often between two (2) weeks to a month). Time frames are dependent on the complexity of the facility and the current workload experienced by the local public health unit.

It is suggested that facilities reapply for their licences at least three (3) months in advance to avoid licences lapsing during the assessment period.

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## 2.2. Application inspections

NSW Health will advise the inspector to contact the applicant to arrange an inspection when it receives a written application for an anatomy licence.

An inspection is undertaken at the facility where it is proposed the bodies/ tissue/ anatomical specimens are to be used, as part of the application process.

The inspection involves an audit of the physical environment of the facility and a review of its policies and the register of specimens. Once completed, the inspector will forward the inspection report with their recommendations to the NSW Ministry of Health.

Depending on the report outcomes, a licence may be issued with standard and additional conditions, or it may be refused.

Refer to the *Anatomical Examination Inspection Checklist* on the [NSW Health website](#) for a comprehensive overview of the inspection process.

## 2.3. One-off licences

A person wishing to conduct a one-off anatomical workshop or training session must apply in writing to NSW Health for an anatomy licence for the specified time period of the event.

The applicant must address each criterion listed on the [Application to Conduct Anatomical Examinations](#), except providing a human ethics committee statement.

An overview of the event, including the venue, dates, purpose, and objectives, is to accompany the application. This may be in the form of a course program or workshop brochure, or as a document prepared specifically for the submission.

## 2.4. Re-applying for licences

A licence holder who wishes to reapply for a licence is recommended to submit a written application to the Secretary, NSW Health, at least three (3) months before their current licence expires to prevent the licence from lapsing during the assessment period.

The written application must address the criteria on the [Application to Conduct Anatomical Examinations](#).

The Secretary, NSW Health, must be notified in writing of any change to the designated licence holder of a facility. Reapplying for a licence can be requested at any time to accurately reflect changes to staff or duties within the anatomical facility. For example, where a licence holder no longer works at the facility or has moved to another area within the same organisation.

Reapplying for a licence must be considered when the current licence holder will be absent from their regular duties for greater than three (3) months.

## 2.5. Revocation of licence

The Secretary, NSW Health, may revoke the licence at any time from a licence holder as per Section 6(5) of the *Anatomy Act 1977* (NSW). This may include for, but is not limited to, instances of:

- 
- Falsifying records.
  - Misleading an inspector through the concealment of facts.
  - Inadequate record keeping.
  - The facility is maintained in an unsatisfactory condition.
  - The holder of a licence disposes of a body without obtaining appropriate consent, or as far as practicable fails to dispose of the body in accordance with the wishes of the deceased or their senior next of kin.
  - Unsatisfactory security measures are maintained at the facility, for example unauthorised persons are not prevented from entering the facility.
  - Undertaking anatomical investigation without appropriate experience or training.
  - Failing to comply with the Act or conditions imposed under a licence.
  - Failing to conform to the requirements of the Policy Directive.
  - Transfer of bodies or human tissue outside of NSW without approval.

Failure to commence the process of reapplying for a licence before a current licence expires will result in the facility ceasing to be a licensed anatomy facility. Accordingly, all anatomical processes must cease, and arrangements made to transfer bodies and human tissue to a licensed anatomy facility until a new licence has been granted.

NSW Health will commence formal reviews of licences where evidence indicates that licence holders have failed to act in accordance with the *Anatomy Act 1977* (NSW) and licence conditions.

### **2.5.1. Withdrawal of an anatomy licence**

If the Secretary (or their delegate) revokes a person's anatomy licence or if the anatomy licensee requests in writing to cancel their licence, NSW Health will advise the person in writing of their obligations to transfer bodies and human tissue to other facilities and they may be required to submit a new application to be considered for approval.

## **2.6. Inspections**

The frequency of routine inspections must correspond to the duration of the licence (see Table 1).

Anatomy inspectors can inspect a licensed facility at any time.

Where practicable the licence holder will be notified of the time of the inspection and must fully cooperate.

Anatomy inspectors must review the:

- details of the designated holder of the licence to check they are current
- compliance with any standard and additional licence conditions
- register of anatomical specimens to ensure it conforms with the requirements of the *Anatomy Act 1977* (NSW), and

- anatomy laboratory facility to ensure it conforms to required standards.

An [Anatomical Examination Inspection Checklist](#) is available to assist inspectors and can also be used for the inspection required for an initial application.

After each inspection, the licence holder will be sent a report that may include recommendations and/ or directions to ensure compliance with licence conditions and the requirements of the *Anatomy Act 1977* (NSW). The inspector will monitor the implementation of any recommendations or directions by the licence holder.

In instances of non-compliance an inspector may recommend the Secretary (or their delegate) impose additional conditions on a licence, issue a warning or seek to revoke the licence.

### 3. REGISTER FOR ANATOMICAL SPECIMENS

Licence holders must keep a register of all bodies and/ or human tissue in their possession. The register must contain information about:

- Obtaining bodies and human tissue
- transferring bodies and human tissue, and
- disposing bodies and human tissue (which are not exempt from consent).

Registers must be in electronic or hard copy format. Examples of a register can be found [here](#).

The licence holder must produce the register to an inspector when requested. If the register is kept in electronic format, it must be accessible to the inspector during an inspection and be printed for signature.

If a licensed facility covers more than one site, for example a separate laboratory and separate storage area, a register must be available at each site where bodies (including human tissue) are kept, as well as a tracking system.

The register must be retained for as long as the body is in the possession of the licensee and for at least five (5) years after its final transfer or disposal of the remains.

#### 3.1. Taking possession of a body/ tissue

When a licence holder acquires a body (including human tissue), they must enter the following information in the register:

- name and address of the person who had lawful possession of the body and who delivered the body into the licence holder's possession
- date on which the licence holder took possession of the body, and
- the date, place and cause of death of the deceased; and
- the sex, name, age and last place of abode of the deceased.



### **3.2. Transfer of a body**

When a licence holder transfers a body either within or outside NSW, a copy of the details about the body from the register must be provided with the body. The licence holder must also enter the following information in their register:

- notification and date of the transfer, and
- name, address/ contact details of person receiving the body.

### **3.3. Transfer of tissue**

When a licence holder transfers human tissue either within or outside NSW, the following information must be entered by the licence holder in their register:

- notification and date of the transfer
- the name, address/ contact details of the person to whom the human tissue was transferred
- the location (licensed premises, hospital, or other place) where the human tissue will be retained, and
- details of the arrangements about returning the human tissue.

Where the human tissue's origin is from outside of NSW, the licence holder is responsible for ensuring that any agreements with the suppliers (interstate or international) of imported human tissue clarify the requirements of the original consent about disposing the tissue. Appropriate documentation must be specified when tissue is disposed of locally.

If the human tissue is for local disposal, the supplier must ensure it is accompanied by the appropriate documentation to allow the licence holder to dispose the human tissue.

## **4. CONDITIONS FOR DONATION OF BODIES FOR ANATOMICAL EXAMINATION**

### **4.1. Consent**

Written consent is required for authorising the use of a body for anatomical examination.

Consent can be given either through a pre-registered body donation to a licensed anatomical facility (this is by a deceased person in their lifetime) or (subject to threshold requirements being met) given by the senior available next of kin of the deceased.

#### **4.1.1. Obtaining consent from Aboriginal and Torres Strait Islander communities**

It is important to recognise that the Aboriginal and Torres Strait Islander family system has an extended family structure which can differ from the immediate family structure. This means the child rearing responsibilities may extend beyond the immediate family group and may include aunts, uncles, cousins, and grandparents.

While the *Anatomy Act 1977* (NSW) includes specific obligations that only apply to persons who meet the statutory definition of senior available next of kin, additional engagement with broader family and support networks in Aboriginal and Torres Strait Islander family systems may also be appropriate depending on the circumstances of a case.

Where appropriate, a Designated Officer who identifies as Aboriginal or an Aboriginal Health Worker (such as an Aboriginal Health Practitioner or Senior Aboriginal Health Worker) could be engaged to provide support and offer information about body donation programs during discussions about consent. The [Aboriginal Health Worker Guidelines for NSW Health](#) 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.

#### **4.1.2. Written consent by the deceased: hospital or forensic institution**

If the body of a deceased adult is in a hospital or forensic institution, a Designated Officer may authorise the anatomical examination of the body if they are satisfied the deceased (during their lifetime) had given their written consent to the anatomical examination of their body after death and consent had not been revoked (see Sections 8(1) and 8(2) of the *Anatomy Act 1977* (NSW)).

The Designated Officer's authorisation must be in writing and comply with any terms or conditions of the consent provided by the deceased adult. The anatomy facility must ensure a copy of the Designated Officer's written authority is received at the time the body is transferred to their facility. An example of a Designated Officer's Authority for donating a body for anatomical examination can be found [here](#).

#### **4.1.3. No written consent by the deceased: hospital or forensic institution**

Section 8(3) of the *Anatomy Act 1977* (NSW) also sets out if there is no written consent by the deceased person to the anatomical examination of their body after death, or if the deceased is a child, the Designated Officer may authorise the anatomical examination. This is provided that the Designated Officer is satisfied, having made reasonable inquiries, that:

- the deceased person had not during their lifetime objected to the anatomical examination of their body after death; or if they had expressed such an objection, based on their most recent views expressed, they no longer had an objection to the anatomical examination of their body after their death, and
- a senior available next of kin consented in writing to the anatomical examination of the deceased, and
- there is no next of kin of the same or higher order in the hierarchy of senior available next of kin who objects to the anatomical examination of the deceased's body.

The Designated Officer's authorisation must be in writing and comply with any terms or conditions of the consent of the senior available next of kin.



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#### **4.1.4. Written consent by the deceased: location not at a hospital or forensic institution**

Section 8A of the *Anatomy Act 1977* (NSW) sets out if the body of a deceased adult is at a place other than a hospital or forensic institution, and the deceased had (during their lifetime) given their consent in writing to the anatomical examination of their body after death and consent had not been revoked, the anatomical examination of that person's body is authorised, and complies with any terms or conditions placed on the consent.

#### **4.1.5. No written consent by the deceased: location not at a hospital or forensic institution**

If the body of a deceased is at a place other than a hospital or forensic institution, and the deceased had not given written consent during their lifetime to an anatomical examination then the senior available next of kin can consent to the anatomical examination of that person's body.

The senior available next of kin must make reasonably inquiries to establish that the deceased did not object to the anatomical examination of their body during their lifetime and there is no objection from any other next of kin of the same or higher order (see Section 8A(4)(b) of the *Anatomy Act 1977* (NSW)).

#### **4.1.6. Coroner's consent**

If the Coroner has jurisdiction to hold an inquest into the death of a person under the *Coroners Act 2009* (NSW) then a Designated Officer or the senior available next of kin must not authorise the anatomical examination of the body of the deceased unless the Coroner consents to the examination (as per section 8B of the *Anatomy Act 1977* (NSW)).

A copy of the Coroner's authorisation for anatomical examination must be retained with other documents relating to the deceased person. The Coroner may set specific conditions to their consent.

Information for health practitioners and relatives of a deceased person whose death has been referred to the Coroner can be viewed in the NSW Health Policy Directive *Coroners Cases and the Coroners Act 2009* ([PD2010\\_054](#)).

### **4.2. Effect of authority**

In section 8C of the *Anatomy Act 1977* (NSW), the authority provided by:

- a Designated Officer (in relation to a body of a deceased which was not at a hospital or forensic institution); or
- a senior available next of kin (where the body of the deceased was not at a hospital or forensic institution); or
- the written consent of the deceased adult whose body is not at a hospital or forensic institution

is sufficient for:

- a person who has lawful possession of a body (excluding a funeral director or other person entrusted with the body for disposal-purposes only) to cause or permit the body to be used by a licence holder for anatomical examination
- for the licence holder (or person authorised by the licence holder) to conduct an anatomical examination of the body, at licensed facilities, in accordance with the authority, subject to the terms and conditions of the consent.

### 4.3. Children in the care of the State

The anatomical examination of the body of a deceased child must not be authorised if the child was, immediately before death, a child in the care of the State (see section 15 of the *Anatomy Act 1977* (NSW)).

A *child in the care of the State* means where the Minister administering, or the Secretary under, the [\*Children and Young Persons \(Care and Protection\) Act 1998\*](#) (NSW) had sole parental responsibility in respect of the child (or young person).

### 4.4. Taking possession of a body

Licence holders can only acquire a body for anatomical examination (other than a body transferred from another licence holder) when they have the written authority of a Designated Officer (where the body of the deceased was at a hospital or forensic institution); or the written consent of the deceased or a senior available next of kin (where the body of the deceased was at a place other than a hospital or forensic institution).

Licence holders accepting deliveries of bodies from the Coroner must ensure that they also receive the relevant documentation authorising the release of the body.

### 4.5. Tissue acquisition

Human tissue can be acquired as either a transfer from another licensed facility (including interstate and international institutions) or by a specific body or specimen donation program.

Human tissue acquisition in NSW is covered by Section 11A of the *Anatomy Act 1977* (NSW). Licence holders who source tissue from interstate or international institutions are responsible for obtaining statements from the supplying licence holder that demonstrate the acquired human tissue complies with the consent requirements and provisions of the *Anatomy Act 1977* (NSW).

In addition, the licence holder must ensure any agreements with suppliers of imported human tissue clarify the requirements of the original consent about disposal. If the human tissue is for local disposal, the supplier must ensure it is accompanied by the appropriate documentation to allow disposal in NSW.

If an applicant wants to use human tissue/ body specimens from an international institution, they must also ascertain the body specimen complies with the requirements under the *Public Health Regulation 2022* (NSW) regarding the prescribed infectious diseases listed in clause 79.

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## **4.6. Transfer of human bodies or tissues**

### **4.6.1. Transfer of a body**

A licence holder may transfer a body in their possession to another licence holder within NSW without prior approval from an inspector. A transfer to any person in charge of the conduct of anatomical examinations at any place outside NSW is permitted with prior approval of an inspector. A copy of the details contained on the register must also be transferred with the body.

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

If the body is to be disposed of by the receiving licensed facility all relevant paperwork (including cremation certificates and medical referee's permit) must accompany the body.

The licence holder must dispose of the body as far as practicable in accordance with any expressed wishes of the deceased or the deceased's senior available next of kin.

### **4.6.2. Transfer of tissue**

Transferring human tissue for medical or scientific purposes within NSW does not require prior approval from an inspector, if being transferred from one licence holder to:

- another licence holder
- an authorised officer of a NSW or interstate hospital
- a person approved, in writing, by the Secretary, NSW Health.

A licence holder must not transfer human tissue if they have reason to believe the transfer would be contrary to the wishes of the deceased or their senior available next of kin.

The licence holder must ensure arrangements are made for returning human tissue as soon as practicable, and by no later than the end of the period within which the tissue is required to be disposed. This does not apply to human tissue that will be or has been at least substantially destroyed as part of its use for medical or scientific purposes or if the permanent retention of the tissue has been expressed in writing by the deceased during their lifetime or by their senior available next of kin.

## **5. RETENTION OF HUMAN BODIES OR TISSUE FOR ANATOMICAL EXAMINATION**

### **5.1. Extension to retain human bodies and tissue**

In the *Anatomy Act 1977* (NSW), a licence holder must dispose of a body, including human tissue, in their possession within four (4) years of the date of death of the deceased.

However, a licence holder may apply in writing to an inspector for an extension to retain bodies or human tissue in their possession. The request for an extension must include the relevant donor details. An example of an application form and inspection checklist can be found on the [NSW Health website](#).

An inspector may authorise retaining a body or tissues for a maximum of an additional 4 years. All bodies and tissues (from those bodies) must be disposed of within eight (8) years of the date of death of the deceased.

An inspector must not give an extension if it is inconsistent with the terms of the original consent of the deceased or their senior available next of kin.

Further authorisation is not required for retaining tissue slides, tissue blocks or museum pathology specimens in sealed containers beyond four (4) years.

When determining whether to authorise an extension, an inspector considers:

- any conditions placed by the deceased or senior available next of kin qualifying their original consent that would prevent extension
- the purposes for which extended retention of the body or human tissue is sought
- justification for why the body or human tissue had not been utilised in the four (4) year period
- the condition of the body or human tissue.

The licence holder must comply with any terms or conditions imposed by an inspector in granting an authorisation for retaining a body or human tissue (including historical tissue) and must enter details of the authority in the register and return or release specimens.

## 5.2. Permanent retention of tissue

Section 12(5) of the *Anatomy Act 1977* (NSW) provides for the permanent retention of tissue where written consent has been given by the deceased prior to death.

Where no consent has been given and the wishes of the deceased are unknown, the senior available next of kin may consent to the permanent retention of tissue.

Where there is no senior available next of kin, the facility must have a system in place to investigate the origin of such specimens so that arrangements can be made for the appropriate permanent retention and inclusion on its register or alternatively the appropriate disposal of the human tissue.

No consent is required for the permanent retention of small samples of tissue in the form of tissue blocks and slides. 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. Specific consent is not required to retain tissue in the form of a tissue slide or tissue block which enables microscopic examination of the tissue.

## 6. DISPOSAL OF BODIES OR TISSUE

### 6.1. General requirements for disposal of bodies

The licence holder is required to dispose of a body in their possession (including any human tissue from that body) within four (4) years of the death of the deceased person, or in line with the terms of an authorisation or extension granted by an inspector.

As far as practicable, a licence holder must dispose of a body that comply with the wishes of the deceased or if that is not practicable, of their senior available next of kin.

Refer to sections 3.3 Transfer of Tissue and 4.5 Tissue Acquisition on the requirements for disposing tissue obtained outside of NSW.

### **6.1.1. Update the register of anatomical specimens**

After disposing a body, the licence holder must enter onto the register of anatomical specimens the:

- notification and date of the body's disposal, and
- name, address/ contact details of the person who disposed of the body.

### **6.1.2. Disposal of permanently retained tissues**

There are many circumstances that require the disposal of human tissue separately from the rest of the body from which the tissue originated. These circumstances include where the licensed facility has consent to permanently retain tissue that is no longer in a usable state.

Decisions on the usable state of tissues are to be taken on a case-by-case basis by anatomy facilities and referred to the inspector. If the specimens are to be disposed of, the licence holder must ensure records detailing the method and reason for disposal are maintained.

Depending on the original consent, options for disposal may include:

- contact with the senior available next of kin to arrange the collection of the tissues, usually by a funeral director of their choice to arrange for cremation or burial, or
- appropriate disposal of the human tissue by the licensed premises. Arrangements for respectful and sensitive disposal are to be made at local level.

These practices must be explained to donors through the donation program information.

An appropriate dignified disposal of unidentified human tissue (for example, human skeletons) would include a forensic anthropological examination of skeletons and completion of other documentation such as a statutory declaration by the licence holder.

### **6.1.3. Requirements for the disposal of anatomical waste tissue**

Anatomical waste must be managed in line with the requirements in the NSW Health Policy Directive *Clinical and Related Waste Management for Health Services* ([PD2020\\_049](#)).

Practices for disposing deceased bodies need be explained to donors through the donation program information.

## **7. BODY DONATION PROGRAMS**

Cadaveric material is commonly sourced from the willed-body donation programs of the schools of anatomy at universities within NSW and interstate. A person may decide in their lifetime to donate their body, after death, to a facility for medical training and research.

Prospective donors are provided with information about the donation program to which they are considering committing their body once they are deceased. The institution will arrange for

prospective donors to complete a consent form to document this decision. Donated body parts intended for research purposes must be approved by a suitable human ethics committee.

Institutions may consider accepting body donations from prospective donors who have lived in the United Kingdom between 1980 and 1996. This is in response to the Therapeutic Goods Administration's (TGA) decision to overturn the ban on blood donations in July 2022. The previous ban aimed to prevent the spread of variant Creutzfeldt-Jakob disease (vCJD) from potentially affected people in December 2020.

## **7.1. Written consent**

The standard of consent for a body donation program in NSW is written consent. All body donation programs must provide clear donor consent forms for potential donors that include options for potential donors to specify terms and conditions to their consent.

A body donation program can refuse to accept a body of a deceased person (who gave written consent to donate their body during their lifetime). The reasons for non-acceptance must be outlined in the information about the body donation program. A statement about the possibility of non-acceptance by the program must be included on the consent form signed by potential donors.

### **7.1.1. No written consent by the deceased**

Body donor programs will not usually accept body donations from the senior available next of kin if there is not a signed and witnessed consent made by the deceased in their lifetime. However, there is no legislative impediment to consent to body donation from the senior available next of kin, if the deceased and other next of kin did not express an objection. Institutions must provide appropriate forms for next of kin consent.

## **7.2. Consent forms**

Donor consent forms developed by body donation programs will vary in content depending on the opportunities offered to the prospective donor to authorise specific activities and place terms and conditions on the use of their body.

Consent forms at a minimum must allow the prospective donor to consent or not consent to the:

- use of their body for certain activities, such as sponsored research, educational research, training students or other activities.
- transfer of their body to other organisations.
- permanent retention of human tissue and allow for authorisation if specific organs are to be retained, including for museum displays.
- release of their prior medical history and/ or records to the licence holder or their delegate for determining medical suitability of the donation or for research purposes.

The form must also contain a statement:



- for the Designated Officer to authorise the donation (for donations from hospitals and/or forensic institutions)
- to the reasons why a body donation program may choose to not accept a prospective body donation at the time of death
- outlining the screening tests that the program may choose to undertake on a donated body and the reason for those tests. For example, the screening for blood borne viruses and other pathogens before it is accepted.

The person providing consent needs to be informed that if screening tests for blood-borne viruses on a donated body are returns a positive result, additional actions may need to be undertaken, as determined by public health authorities.

These actions might include supplementary tests, discussion with the person's treating general practitioner/ medical professional and on occasion, discussion with the person's next of kin/ contacts that could be at risk of contracting the virus.

Licence holders must review the range of activities within their licence and are reflected in the consent options.

### **7.3. Revocation of consent**

A person can change their consent to donation during their lifetime. Body donation programs need to include a form to revoke their consent within their body donation program information.

### **7.4. Donor information**

Body donation programs must provide detailed information for prospective donors which explain the potential uses of donated bodies and the terms and conditions that a facility may place on accepting and using the donation.

It is recommended that the relevant institutional human ethics committee or other appropriate governance body review the donor program, its information, and materials prior to publication.

**Table 2. Information that body donation programs must provide**

Subject	Description
Uses of donated bodies/ body parts/ tissue	Donor information must explain how bodies can have different uses, (such as for teaching, research, and training), and define 'anatomical examination' to outline the intended use of a body. For example, a body donor program that wishes to use the body/ human tissue for public display in anatomy museums or where other activities such as forensic experimentation may be conducted.
Retention	Body donor program information must include the length of time a deceased body can be retained, from the date of death, for medical use.  Programs need to provide an option for permanent retention on their consent forms.

Subject	Description
Disposal of bodies, tissue, and anatomical waste	Information on the options for disposing bodies or human tissue need to be outlined for prospective donors. This must include information that small amounts of tissue such as body fluids, fat, skin etc. may be disposed of as anatomical waste through appropriate clinical waste guidelines, as outlined in NSW Health Policy Directive <i>Clinical and Related Waste Management for Health Services</i> ( <a href="#">PD2020_049</a> ).  Information must also be provided on the permanent retention of tissue slides and tissue blocks.
Public display	The fundamental principle of the <i>Anatomy Act 1977</i> (NSW) is that obtaining consent is required for the donation, storage and use of relevant material which has come from a deceased human body for certain purposes.  Mandatory donor consent forms include an option for the potential donor to authorise the use of their body or tissue for activities which may be considered by the body donor program, including public display.
Use of images	The making and displaying of images (including photographs, films, and electronic images) requires body donor programs to implement systems to ensure the dignity of the deceased is maintained at all times and to prevent the inappropriate use of images of deceased persons or body parts.
Transfer of body	Body donor programs must advise prospective donors that their body, body parts or tissues, may be transferred to other organisations for use. It needs to be clear that transfer can occur both within and outside Australia and allow donors the opportunity to consent to this use.

## 7.5. Occupational health and safety and screening of donated bodies or tissue

Licence holders need to ensure donated bodies or tissue specimens are appropriately screened for blood borne viruses (including Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus) before accepting the body and/ or tissue.

This may include the use of donor screening tools, medical and social history questionnaires, and/ or the use of specific cadaveric screening tests.

This information must be communicated in the consent form for the potential donor.

### 7.5.1. Notification mechanisms

Laboratories and medical practitioners must notify positive results of scheduled medical conditions in the deceased body to NSW Health according to the *Public Health Act 2010* (NSW). Licence holders are not required to notify results of infectious disease testing or contact tracing of body donors.

Licence holders need to have procedures in place for informing the senior available next of kin if the donation of either the body or tissues will not be accepted.

Licence holders can provide the contact details of body donors who may be at risk of infection to the local Public Health Unit if required to facilitate contact tracing. Providing contact details in these circumstances would not breach statutory confidentiality provisions.



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For more information, refer to the NSW Health Information Bulletin *Notification of Infectious Diseases under the Public Health Act 2010* ([IB2013\\_010](#)).

## 8. RESOURCES AND TEMPLATES

Useful resources and templates can be found on the [NSW Health website](#):

- Application to conduct anatomical examinations
- Authority for Anatomical Examination – Designated Officer or senior available next of kin
- Anatomical examination inspection checklist
- Example register of anatomical specimens
- Example register for the transfer of anatomical specimens
- FAQs on anatomy facilities, licences, and specimens