

Conduct of Anatomical Examinations and Anatomy Licensing in NSW

Document Number PD2011_052

Publication date 11-Aug-2011

Functional Sub group Corporate Administration - Governance
Clinical/ Patient Services - Human Tissue
Clinical/ Patient Services - Medical Treatment
Population Health - Environmental

Summary This document outlines the procedures for the licensing, inspection and regulation of Anatomy facilities conducting anatomical examinations, and provides clear directives to licence holders of acceptable activities and government regulation under the provisions of the licence. The activity of conducting anatomical examination is governed by the Anatomy Act 1977 and regulated by NSW Health.

This policy replaces Section 9 of PD2005_341 Use and Retention of Human Tissue.

Author Branch Office of the Chief Health Officer

Branch contact Malynda Flarey 9391 9524

Applies to Local Health Districts, Speciality Network Governed Statutory Health Corporations, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Affiliated Health Organisations, Private Hospitals and Day Procedure Centres, Public Health Units, Public Hospitals

Audience Administration, Directors of Clinical Governance & Clinical Operations, Nursing, Mortuary Staff

Distributed to Divisions of General Practice, NSW Ambulance Service, NSW Department of Health, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

Review date 11-Aug-2016

Policy Manual Patient Matters

File No. 11/2762

Director-General

Status Active

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

THE CONDUCT OF ANATOMICAL EXAMINATIONS AND ANATOMY LICENSING IN NSW

PURPOSE

The activity of conducting anatomical examinations is governed by the *Anatomy Act 1977* and regulated by NSW Health.

This document outlines the procedures for the licensing, inspection and regulation of Anatomy facilities conducting anatomical examinations, and provides clear directives to licence holders of acceptable activities and government regulations under the provisions of the licence.

Failure to comply with requirements of the *Anatomy Act 1977* may constitute an offence.

MANDATORY REQUIREMENTS

Anatomy Licences

- The licence is issued to an individual or the holder of an identified position for a specific facility location.
- Anatomy licences are issued by the Director-General, NSW Department of Health, or their delegate, for a 2 year period subject to satisfactory annual inspections. The Director-General may revoke the licence at any time. Once a licence has been granted the NSW Department of Health must be notified in writing of any change to the designated licence holder of an institution.
- Licence holders are required to submit an application to the Director-General, NSW Department of Health, to reapply for their anatomy licence prior to the expiration of their current licence.
- A person wishing to conduct an anatomical workshop or training session as a one-off event is required to apply to the NSW Department of Health for a licence for the specified time period.

License Applications and Inspections

- All applications must be received in writing. An inspection of the proposed facility and subsequent report will be undertaken as part of the licence application process.
- Inspections are conducted by the local Public Health Unit Director or their delegate.
- Licensed facilities will be inspected annually. An inspector can also inspect a licensed premise at any time. The holder of a licence must comply with any terms or conditions included on the licence.

Registers

- All licence holders are required to keep a register of all bodies and/or human tissue in their possession. The register must also be used to contain information relating to the transfer of bodies and/or human tissue from or to another licence holder.
- The licence holder must produce the register to an inspector as requested.
- The register must be retained for at least 5 years from the date of the most recent entry.

Conditions on taking possession of a human body for anatomical examination

- Written consent must be obtained for a body to be used for anatomical examination. Consent is either that of the individual written during their lifetime or received from the senior available next-of-kin after an individual's death.
- If the body of the deceased is at a hospital or forensic institution, a Designated Officer must authorise the use of the body prior to the body being transferred to the licence holder.
- A Designated Officer or a senior next- of -kin cannot authorise the anatomical examination of the body of a person whose death has been reported under the *Coroners Act 2009*, unless a Coroner has consented to the examination.
- A person must not authorise the anatomical examination of the body of a deceased child if the child was, immediately before death, in the care of the State.

Acquisition and retention of donated bodies and human tissue

- Bodies and human tissue specimens can be acquired by a licence holder as either a transfer from another licensed institution (including international institutions) or from a specific body donation program. Minimum standards must be met for information to be included in the donation program information package.
- A transfer of a body or human tissue to another licence holder outside NSW is permitted only with prior approval of a NSW inspector. A licence holder may transfer a body in their possession to another licence holder within NSW without prior approval.
- A body can be retained for a maximum of 4 years. Upon application an inspector may authorise the retention of a body for an additional 4 year period. Generally bodies must be appropriately disposed of within 8 years from the date of death of the deceased.
- Specific provision has been made in the *Anatomy Act* for the permanent retention of tissue (anatomical specimens) where written consent has been given by the deceased prior to death. Where no consent has been given and the wishes of the deceased in this respect are unknown, the senior available next of kin may consent to permanent retention of tissue.

IMPLEMENTATION

- Applicants for licences: must ensure that the application includes information as detailed in the attached procedure and that it is accompanied by additional documentation where required.
- Licence holders: must ensure that they meet all legislative requirements of the *Anatomy Act 1977* and relevant provisions of the *Human Tissue Act 1983*, *The Coroners Act 2009* and the *Public Health (Disposal of Bodies) Regulation 2010* or any subsequent regulation made under the *Public Health Act*. Licence holders must satisfy all terms and conditions set by the licence.
- Public Health Unit anatomy inspectors: must undertake inspections as required by this policy or as directed by the Director- General or delegate. Guidelines for facility inspections and the inspection of registers of bodies and human tissue are in the attached procedures.
- Designated Officers in health facilities and forensic institutions: must authorise the release of a body from a hospital or forensic institution for anatomical examination. A body must not be released from a hospital to an authorised licence holder until a Designated Officer has authorised its release.(See attached procedures).

REVISION HISTORY

Version	Approved by	Amendment notes
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>

ATTACHMENTS

1. The Conduct of Anatomical Examinations and Anatomy Licensing in NSW: Procedures and Guidelines.

CONTENTS

1	BACKGROUND	1
1.1	About this document	1
1.2	Key definitions	1
1.3	Legal and legislative framework	2
2	ANATOMY LICENCES	2
2.1	General Information	2
2.1.1	Applying for an Anatomy Licence	2
2.1.2	Application inspections	3
2.1.3	One-off licences	3
2.1.4	Reapplying for licences	3
2.1.5	Re-issue of licence to reflect changes to a licence holder	3
3	INSPECTIONS	3
3.1	Annual inspections	4
4	ANATOMY REGISTER	4
4.1	Taking possession of a body/tissue	4
4.2	Transfer of a body	4
4.3	Transfer of human tissue	5
5	DONATION OF BODIES FOR ANATOMICAL EXAMINATION	5
5.1	General Information	5
5.1.1	Written consent: hospital or forensic institution	5
5.1.2	No written consent: hospital or forensic institution	5
5.1.3	Written consent: not at hospital or forensic institution	5
5.1.4	No written consent: not at hospital or forensic institution	6
5.1.5	Coroner consent	6
5.1.6	Effect of authority	6
5.1.7	Children in the care of the State	6
5.2	Taking possession of a body	6
5.3	Human tissue acquisition	6
5.4	Transfer of Human bodies or Human Tissues	7
5.4.1	Transfer of a Body	7
5.4.2	Transfer of human tissue	7
6	RETENTION OF BODIES OR TISSUE FOR ANATOMICAL EXAMINATION	7
6.1	Extension to retain bodies and human tissue	7
6.2	Permanent retention of human tissue	8
7	DISPOSAL OF BODIES OR TISSUE	8
7.1	General Requirements for disposal of bodies	8
7.1.1	Register	8
7.1.2	Disposal of permanently retained tissues	8
7.1.3	Requirements for the disposal of anatomical waste tissue	9

8	BODY DONATION PROGRAMS	9
8.1	Written consent	9
8.1.1	No written consent by the deceased	9
8.2	Consent forms	10
8.2.1	Revocation of consent	10
8.3	Donor information	10
8.4	Occupational health and safety and screening of donated bodies or human tissue.	11
8.4.1	Notification mechanisms	11
9	LIST OF ATTACHMENTS	12
Attachment 1	Application Checklist	
Attachment 2	Example of a Designated Officers Authority	
Attachment 3	Inspection Audit Guidelines and Checklist	
Attachment 3.1	Anatomy Register Proforma	

1 BACKGROUND

1.1 About this document

The practice of anatomical examination in NSW is the dissection of a dead human body for the purposes of medical, scientific and educational training and research. This activity is predominately undertaken in university anatomy departments or medical schools for the teaching and training of students and staff and in associated facilities for conducting research. The anatomical training and research undertaken in facilities would either form part of a university degree or be a specialised training workshop for medical and health professionals.

This document outlines the procedures for the licensing, inspection and regulation of anatomy facilities conducting anatomical examinations, and provides clear directives to licence holders of acceptable activities under the provisions of the licence.

Included in these procedures are guidelines for

1. Application for a Licence (Attachment 1).
2. Inspection of facilities (including the Inspection Checklist at Attachment 2).
3. Suggested pro-forma for a register of donated bodies and dissections (Attachment 3).
4. Minimum Information to be included in body donor programs.

1.2 Key definitions

Anatomical examination of a body includes use of the body for medical or scientific purposes. However, an anatomical examination does not include a post mortem examination. Medical or scientific purposes include educational purposes connected with medicine or science. (*NSW Anatomy Act 1977 Part 1 Section 4*).

Anatomical waste in this document means a discarded biologic product, such as blood or other bodily fluid, fat, skin or other small amounts of human tissue removed from a cadaver that is undergoing preparation or dissection for anatomical examination. This waste material may be disposed of as clinical waste according to relevant requirements.

Body in this document means a dead human body. (*NSW Anatomy Act 1977 Part 1 Section 4*).

Designated Officer means a person appointed to be a Designated Officer for the hospital, or a forensic institution. (*NSW Human Tissue Act 1983 Part 1 Section 5*).

Dispose means dispose of the body by burial, cremation or other lawful means. (*NSW Anatomy Act 1977 Part 1 Section 4*).

Human tissue means an organ or part of a body. (*NSW Anatomy Act 1977 Part 1 Section 4*).

Senior available next-of-kin means the most senior next-of-kin in the hierarchy of next-of-kin within the *Anatomy Act 1977*.

1.3 Legal and legislative framework

Anatomy Act 1977

The Anatomy Act 1977 regulates the conduct of anatomical examinations in NSW, including the issue of licences, the appointment of inspectors, the conditions of taking possession of bodies or human tissue, the requirements for keeping registers of bodies and human tissue and for the disposal of bodies. In addition the Act outlines general offences.

Failure to comply with the requirements of the *Anatomy Act 1977* may constitute an offence.

Human Tissue Act 1983 – Designated Officers

Designated Officers are appointed in accordance with Section 5 of the *Human Tissue Act 1983* by the governing body of a hospital or forensic institution. Section 8 of the *Anatomy Act 1977* states that a Designated Officer of a hospital or forensic institution may, by instrument in writing, authorise the anatomical examination of a body of a person in accordance with the consent given by either the deceased or their senior available next of kin.

Coroners Act 2009 – Coronial Consent

Section 56 of the *Coroners Act 2009* states that a Coroner has a right to take possession of and retain the remains of a deceased person whenever the coroner has jurisdiction to hold an inquiry concerning the death of the person. This right of the Coroner has priority over any other right to possession such as a potential donation to a school of anatomy.

Once an order for disposal of the remains has been issued by the Coroner, a licence holder may proceed with the potential donation. A copy of the Coronial order for disposal of the remains should be retained with the consent paperwork.

Public Health (Disposal of Bodies) Regulation 2002 – List A and B diseases

Anatomy license holders wanting to use donated bodies and human tissue must determine that the body or tissue is not infected with a List B disease as outlined in section 3 (1) of the *Public Health (Disposal of Bodies) Regulation 2002* regarding List A and List B diseases.

2 ANATOMY LICENCES

2.1 General Information

A person in charge of the conduct of anatomical examinations at a university, college, or other tertiary educational institution can apply for a licence to lawfully possess human bodies and tissue for examination purposes at a location specified in the licence.

An anatomy licence is issued in accordance with the *Anatomy Act 1977*. A licence may be issued with additional terms and conditions.

Anatomy licences are issued by the Director-General, NSW Department of Health, or their delegate, for up to a 2 year period subject to satisfactory annual inspections. Re-application is required at the completion of the licence period. The Director-General may revoke the licence at any time.

2.1.1 Applying for an Anatomy Licence

Written applications for an anatomy licence must be submitted to the Director-General, NSW Department of Health. The information required in an application is outlined at attachment 1. Additional information can be included in the written application if desired.

2.1.2 Application inspections

An inspection of the proposed facility specified in the application, will be undertaken as part of the licence application process.

The inspection involves audit of the physical environment of the facility and a review of the policies and procedures of the facility and the register of specimens. The relevant local anatomy inspector conducts the inspection.

On receipt of a written application, NSW Department of Health will advise the inspector to contact the applicant to arrange an inspection. On completion, the inspection report is forwarded to NSW Department of Health with recommendations.

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

Applicants can refer to the anatomy licence inspection guidelines [see attachment 2] to gain a comprehensive overview of the inspection process.

2.1.3 One-off licences

A person wishing to conduct an anatomical workshop or training session as a one-off event is required to apply to NSW Department of Health for a licence for the specified time period of the event. The person must, in writing, address each criteria listed in attachment 1 with the exception of providing an ethics committee statement. Bona fide documentation of the event, such as a course program or workshop brochure, must be included with the licence application.

2.1.4 Reapplying for licences

Licence holders wishing to renew a licence are required to submit an application to the Director-General, NSW Department of Health prior to the expiration of their current licence. The written application needs to address the criteria listed in attachment 1. Licence holders should ensure that they submit their application 3 months prior to their current licence expiring.

2.1.5 Re-issue of licence to reflect changes to a licence holder

The Director-General, NSW Department of Health, must be notified in writing of any change to the designated licence holder of an institution. A re-issue of a licence can be requested at any time to accurately reflect changes to staff or duties within the anatomical facility.

A re-issue of a licence should be considered when the current licence holder will be absent from their regular duties for a period of time greater than 3 months.

3 INSPECTIONS

The local anatomy inspector conducts inspections for each local anatomy facility. The facility will be notified of the inspection and must fully cooperate with the inspection. An inspector can inspect any licensed premise at any time.

The inspection audits the physical environment of the facility and reviews the policy and procedure protocols of the facility and the register of specimens. After each inspection a report is sent to the facility that may include recommendations to ensure compliance with licence conditions or the requirements of the *Anatomy Act 1977*. The anatomy inspector will continue monitoring the facility to follow up on the progress of any recommendations.

The inspection is to consist of:

- ensuring the designated holder of the licence is still applicable
- ensuring compliance with any standard and additional licence conditions.
- reviewing the register to ensure it conforms with the requirements of the *Anatomy Act 1977* and
- reviewing the anatomy laboratory facility to ensure it conforms to required standards.

NSW Department of Health has developed Anatomy Licence Inspection Guidelines to assist inspectors in undertaking the application audit and assessment (Attachment 2).

3.1 Annual inspections

The anatomy inspector is required to establish an annual schedule for inspection of anatomy facilities within his/her jurisdiction and advise those institutions accordingly.

4 ANATOMY REGISTER

All anatomy licence holders are required to keep a register of all bodies, including human tissue, in their possession. The register must also contain particular information relating to the transfer of bodies and human tissue and the disposal of bodies. An example of a register is attached (Attachment 3). Registers may be in electronic or hard copy format.

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

The register must be retained for at least 5 years from the date of the most recent entry.

4.1 Taking possession of a body/tissue

On taking possession of a body, the following information must be entered onto the register:

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

4.2 Transfer of a body

When a body is transferred either within or outside NSW, a copy of the particulars contained on the register must also be transferred with the body. The following information must be entered onto the register:

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

4.3 Transfer of human tissue

When human tissue is transferred either within or outside NSW, the following information must be entered onto the register:

- notification and date of the transfer;
- the name, address/contact details of the person to whom the tissue was transferred;
- the location where the tissue is to be retained; and
- details of the arrangements regarding the return of the human tissue.

5 DONATION OF BODIES FOR ANATOMICAL EXAMINATION

5.1 General Information

Authorisation for a body to be used for anatomical examination is predicated on the attainment of consent. Consent can be given either via a pre-registered body donation to a licensed anatomical facility by a deceased person in their lifetime, or after death by the senior next-of-kin of the deceased.

5.1.1 Written consent: hospital or forensic institution

A Designated Officer may authorise the anatomical examination of an deceased adult's body at a hospital or forensic institution if they are satisfied, that the person (during their lifetime) had given their written consent to the anatomical examination of their body after death and that consent had not been revoked. The Designated Officer's authorisation must be in writing. The anatomy facility should ensure that a copy of the Designated Officer's written authority is received at the time the body is transferred to their program. Attachment 2 provides an example of a Designated Officers Authority for donation of a body for anatomical examination

5.1.2 No written consent: hospital or forensic institution

If there is no pre-written consent by the deceased to the anatomical examination of their body after death, or the deceased is a child, the Designated Officer may authorise the anatomical examination, providing it is:

- established that the deceased had not during their lifetime expressed an objection to an anatomical examination of their body after death;
- ascertained that a senior available next-of-kin has given their consent in writing to the anatomical examination of the deceased; and
- ascertained that there is no senior available next of kin of the same or higher order in the hierarchy of senior available next-of-kin who objects to the removal of tissue from the person's body.

The Designated Officer may authorise, in writing, the anatomical examination of the deceased in accordance with any terms or conditions placed on the consent by the deceased or the senior available next-of-kin.

5.1.3 Written consent: not at hospital or forensic institution

If the body of a deceased adult is at a place other than a hospital or forensic institution, and the person had (during their lifetime) given their consent in writing to the anatomical examination of their body after death and that consent had not been revoked, the anatomical examination of that person's body is authorised, in accordance with any terms or conditions placed on the consent.

5.1.4 No written consent: not at hospital or forensic institution

If the body of a deceased person is at a place other than the hospital or forensic institution, the senior available next-of-kin can consent to the anatomical examination of that person's body even if consent was not given in writing during the deceased person's lifetime. The senior available next-of-kin should establish that the deceased had not expressed an objection to the anatomical examination of their body during their lifetime and there is no objection from any other next-of-kin (See 8A(4)(b) *Anatomy Act 1977*).

5.1.5 Coroner consent

The Designated Officer or the senior available next-of-kin cannot authorise the anatomical examination of the body of a person in respect of whose death a coroner has jurisdiction to hold an inquest under the *Coroners Act 2009* unless a Coroner has given consent to the examination.

The Coroner may set specific conditions to his/her consent. Consent by a Coroner may be given orally and, if so, is to be confirmed in writing as soon as practicable.

5.1.6 Effect of authority

The authority of a Designated Officer or a senior available next-of-kin is sufficient for:

- a person who has lawful possession of a body to cause or permit the body to be used by a licence holder for anatomical examination; and
- for the licence holder to conduct an anatomical examination of the body, at licensed premises, in accordance with the authority, subject to the terms and conditions of the consent

5.1.7 Children in the care of the State

A person must not authorise the anatomical examination of the body of a deceased child if the child was, immediately before death, a child in the care of the State.

5.2 Taking possession of a body

Licence holders can only take possession of a body for anatomical examination (other than a body transferred from another licence holder) when they have the written authority of a Designated Officer or a senior available next-of-kin.

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

5.3 Human tissue acquisition

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

Tissue acquisition in NSW is covered by the *Anatomy Act 1977*. Applicants who source tissue from interstate or international institutions are responsible for obtaining statements from the supplying institution that demonstrate that the acquired tissue complies with the consent and other provisions of the Act. It is incumbent upon the facility to ensure that any agreements with interstate/international suppliers of imported tissue clarify the requirements of the original consent regarding the disposal of the tissue. If the tissue is for local disposal the supplier should ensure that it is accompanied by the appropriate documentation to allow disposal in NSW

If an applicant wants to use body specimens from international institutions they must also ascertain that the body specimen meets the requirements of the *Public Health (Disposal of Bodies Regulation 2002)* with regard to List B diseases.

5.4 Transfer of Human bodies or Human Tissues

5.4.1 Transfer of a Body

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

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

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

5.4.2 Transfer of human tissue

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

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

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

6 RETENTION OF BODIES OR TISSUE FOR ANATOMICAL EXAMINATION

6.1 Extension to retain bodies and human tissue

A licence holder must dispose of a body in their possession within 4 years of the date of death of the deceased.

A licence holder wishing to apply for an extension to retain bodies or human tissue in their possession can do so by writing to the local anatomy inspector. A request for an extension must include the relevant donor details.

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

An inspector may not give such an extension if it would be inconsistent with the terms of the original consent of the deceased or next of kin.

Further authorisation is not required for the retention of tissue slides or tissue blocks or museum pathology specimens in sealed containers.

In granting authorisation, an inspector should consider:

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

The holder of a licence must comply with any terms or conditions that are imposed by an inspector in granting an authorisation for the retention of a body or human tissue and must enter details of the authority in the register.

6.2 Permanent retention of human tissue

Specific provision has been made in the *Anatomy Act* for the permanent retention of tissue where written consent has been given by the deceased prior to death.

Where no consent has been given and the wishes of the deceased in this respect are unknown, the senior available next-of-kin may consent to permanent retention of tissues

No consent is required for the permanent retention of small samples of tissue in the form of tissue blocks and slides.

7 DISPOSAL OF BODIES OR TISSUE

7.1 General Requirements for disposal of bodies

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

A licence holder, where practicable, should dispose of a body in accordance with the wishes of the deceased or, the wishes of the senior available next-of-kin.

7.1.1 Register

The licence holder, following the disposal of a body, must enter onto the register the:

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

7.1.2 Disposal of permanently retained tissues

There are many circumstances that necessitate disposal of human tissue separately from the rest of the body from which the tissue originated. These circumstances include where the institution has consent to the permanent retention of tissue that is no longer in a usable state. Decisions on the usable state of such tissues should be taken on a case-by-case basis by anatomy facilities and

referred to the local anatomy inspector. If the specimens are to be disposed of the institution should ensure that records detailing the method and reason for disposal are maintained.

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

- Contact with next-of-kin to arrange collection of the tissues usually by a funeral director of their choice to make their own arrangements for cremation or burial; or
- Appropriate disposal of the tissues by the institution. Dignified treatment and separate disposal are the minimum considerations involved in disposing of human tissue. Arrangements for respectful and sensitive disposal should be made at local level.

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

7.1.3 Requirements for the disposal of anatomical waste tissue

Anatomical waste should be managed in accordance with the requirements of *PD2005_132 Waste Management Guidelines for Healthcare Facilities*.

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

8 BODY DONATION PROGRAMS

It is strongly recommended that body donation programs are overseen by a suitable human ethics committee. Cadaveric material is most commonly sourced from the willed-body donation programs of the schools of anatomy at universities within NSW and interstate. A person may decide in their lifetime to donate their body, after death, to a facility for the purpose of medical training and research. Prospective donors are provided with information about the donation program to which they are considering committing their body once they are deceased. The institution will arrange for prospective donors to complete a consent form to document this decision.

8.1 Written consent

The standard of consent for a body donation program in NSW is written consent. All body donation programs should provide clear consent forms for potential donors that include options for potential donors to specify terms and conditions to their consent [See 8.2].

A body donation program can refuse to accept a body from a deceased person who gave written consent to donate their body. The reasons for non-acceptance of a body should be outlined in the information about the body donation program and a statement as to the possibility of non – acceptance by the institution should be included on the consent form signed by potential donors.

8.1.1 No written consent by the deceased

Generally, programs will not accept body donations from the next-of-kin in the absence of a signed and witnessed consent of the deceased made in their lifetime. There is however, no legislative impediment to consent to body donation from an appropriate next-of-kin, as long as the non-objection of the deceased and other next-of-kin is established. Institutions should provide appropriate forms for next-of-kin consent.

8.2 Consent forms

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

Consent forms at a minimum should therefore allow the prospective donor to:

- consent or not consent to the use of their body for certain activities, such as sponsored research, educational research; training students or other activities .
- consent or not consent to the transfer of their body to other organisations.
- consent or not consent to the permanent retention of human tissue and allow for authorisation if specific organs are to be retained, including for museum displays; and
- consent or not consent to the release of their prior medical history and /or records to the licence holder or their delegate for the purposes of determining medical suitability of the donation or for research purposes.

In addition the form should contain:

- a statement for the Designated Officer to authorise the donation (for donations from hospital and /or forensic institutions);
- a statement as to the reasons why a facility may choose not accept a prospective body donation at the time of death; and
- a statement outlining the screening tests that the donor program may chose to undertake on a donated body and the reason for those tests.

Licence holders should review the range of activities contemplated within their licence and ensure that these activities are reflected in the consent options.

8.2.1 Revocation of consent

A person can change their consent to donation during their lifetime. Body donation programs should include the option of a form for the revocation of consent within their body donation program information.

8.3 Donor information

Information re: body donation programs should provide detail for prospective donors which explain the potential uses of donated bodies and the terms and conditions that a facility may place on the acceptance and use of the donation. It is recommended that the relevant institutional ethics committee or other appropriate governance body review the donor program and its information and materials prior to their publication.

- **Uses of donated bodies/body parts /tissues:** Donor information should contain an explanation of how bodies can have different uses, such as for teaching, research and training, and provide some detail of the meaning of 'anatomical examination' to outline the intended use of a body. Examples of this include where a facility wishes to use the body /tissues from the body for public display in anatomy museums or where other activities such as forensic experimentation may be conducted.
- **Retention:** Donor program materials should include information regarding the length of time a body can be retained, from the date of death, for medical use. Programs should provide an option for permanent retention on their consent forms

- **Disposal of bodies and tissues and anatomical wastes:** Information on the options for disposal of bodies or tissues should be outlined for prospective donors. This should include information that small amounts of tissue such as body fluids, fat, skin etc may be disposed of as anatomical waste through appropriate clinical waste guidelines. Information should also be provided on the permanent retention of tissue slides and tissue blocks.
- **Public Display:** The fundamental principle of the Anatomy Act is the requirement that consent is obtained for the donation, storage and use of relevant material which has come from a human body for certain purposes. It is mandatory that donor consent forms include an option for the potential donor to authorise the use of their body or tissue for particular activities which may be considered by the facility including public display.
- **Use of Images:** The making and displaying of images (including photographs, films and electronic images) requires that facilities put systems in place to ensure suitable practices are carried out. Where licensable activities are concerned this includes ensuring that the dignity of deceased people is maintained at all times. Therefore, facilities need to put in place procedures and systems to prevent the inappropriate use of images of deceased persons or body parts.
- **Transfer of body:** Donor programs should advise prospective donors that their body, body parts or tissues, may be transferred to other organisations for use. It should be specified that transfer can occur both within and outside Australia, and allow donors the opportunity to consent to this use.

8.4 Occupational health and safety and screening of donated bodies or human tissue.

It is recommended that licence holders take steps to ensure that donated bodies or tissue specimens are appropriately screened for blood borne viruses and other pathogens prior to their acceptance of the body/tissue. This may include the use of donor screening tools and/or medical and social history questionnaires and/or the use of specific cadaveric screening tests.

8.4.1 Notification mechanisms

(See: PD2006_014 *Notification of infectious Diseases under the Public Health Act 1991*)¹

- Laboratories must notify positive results of scheduled medical conditions in the deceased to NSW Department of Health in accordance with the current NSW *Public Health Act* therefore licence holders **are not** required to undertake notification of results of Infectious disease testing or contact tracing of body donors.
- All contact tracing will be undertaken according to the framework outlined in NSW Health Policy Directive PD2005_184 *Contact Tracing Guidelines for the Sexually Transmissible Diseases and Blood Borne Viruses*. Licence holders should however have procedures in place for informing the next of kin that the donation of either the body or tissues will not be accepted.
- Licence holders can provide the details of contacts of body donors who may be at risk of infection to the local Public Health Unit if required to do so to facilitate contact tracing. Provision of contact details in these circumstances would not be in breach of statutory confidentiality provisions.

¹ Polices will be amended subsequent to the commencement of the Public Health Act 2010.

9 LIST OF ATTACHMENTS

1. Application guidelines
2. Example of a Designated Officers Authority
3. Inspection audit checklist and guidelines
 - 3.1 Examples of Anatomy Registers.

Attachment 1: Application Guidelines.

1. Proposed Licensee(s)

Name
Position
Address
Phone number(s)
Email address

Include all relevant information for both proposed licensees if application is for a joint licence.

2. Location of anatomy facility

This can be the actual or proposed facility.

3. Access to the facility

Specify the types of students and staff who will use the facility and their approximate number per year. Outline the proposed security process for ensuring only bona fide students and staff (as specified) have access to the facility.

4. Proposed anatomical activities

This can be a general statement on the range of activities to be undertaken in the facility. For example, 'The study and practice of anatomy within the terms of the Anatomy Act and NSW Health anatomy policy guidelines using tissues for the purposes of anatomical dissection and surgical technique.'

5. Accessing cadaver material

Outline the proposed process for obtaining cadaver material, including details of the facilities where tissue may be sourced from.

6. Registering tissues/specimens

Outline the proposed process for registering all tissue and specimens.

7. Disposal of tissues/specimens

Outline the proposed process for the disposal of tissues/specimens as determined by the requirements of the *Anatomy Act 1977* and NSW Health anatomy guidelines.

8. Ethics committee statement

Where necessary, statements in support of an application from referees and institution ethics committees are to be provided. (NSW Health will advise applicants if such statements of support are required as part of their licence application.)

Lodging Applications:

All applications are to be addressed to:

Director-General of Health
NSW Health Department
Locked Mail Bag 961
North Sydney NSW 2059

Attachment 2: Example of a Designated Officers Authority for Anatomical Examination

Authority by a Designated Officer for the Anatomical Examination and Release of a Body from the Hospital to a Licensed Anatomical Facility

I

(Name of Designated Officer)

1. Hereby state that I am satisfied that [Tick where applicable]

The above mentioned deceased had given their written consent to the anatomical examination of their body after death and that consent had not been revoked or objected to by the senior available next of kin.

OR

The above mentioned deceased had not during their lifetime expressed an objection to an anatomical examination of their body after death and the senior available next of kin has given their consent in writing to the anatomical examination of the deceased. There is no senior available next of kin of the same or higher order in the hierarchy of senior available next of kin who objects to the removal of tissue from the person's body.

2. Hereby authorise anatomical examination and the release of the above mentioned deceased to the:

(Name of Licensed Anatomical Facility)

in accordance with any terms or conditions placed on the consent by the deceased or senior available next of kin.

Designated Officer signature: _____

Date: _____

Coroner consent

A Designated Officer or a senior available next of kin cannot authorise the anatomical examination of the body of a person in respect of whose death a coroner has jurisdiction to hold an inquest under the Coroners Act 2009 unless a Coroner has given consent to the examination.

Attachment 3: Inspection Audit Checklist And Guidelines

Body preparation	
Vehicle reception area screened from public view	<input type="checkbox"/>
Wash hand basin; hot and cold water; non-hand operated taps soap and disposable paper towel or air dryer	<input type="checkbox"/>
Slabs, tables, fittings and fixtures in good repair	<input type="checkbox"/>
Adequate sinks with hot and cold water for cleaning equipment and appliances	<input type="checkbox"/>
Hoses fitted with backflow prevention	<input type="checkbox"/>
Refrigerated storage area temperature 1-5°C	<input type="checkbox"/>
Containers for general and clinical waste	<input type="checkbox"/>
Waste disposal	
Different types of waste containers located appropriately	<input type="checkbox"/>
Liquid waste: water authority approval for contaminated waste	<input type="checkbox"/>
Clinical wastes: disposed in accordance with appropriate environmental guidelines	<input type="checkbox"/>
Handling bodies	
Policy for handling infectious bodies	<input type="checkbox"/>
Labelling	
Sufficient systems for permanent non-identifying labelling of bodies and specimens	<input type="checkbox"/>
Sufficient systems to track all bodies/specimens within register	<input type="checkbox"/>
Management of chemicals	
MSD sheets available for easy reference	<input type="checkbox"/>
Satisfactory storage of chemicals	<input type="checkbox"/>
Appropriate mechanical ventilation systems in place	<input type="checkbox"/>
Storage	
Sufficient refrigerated storage compartments at appropriate temperature for the number of cadavers	<input type="checkbox"/>
Adequate Storage of embalmed body parts	<input type="checkbox"/>

Anatomy rooms

Occupational health and safety policy for the activities undertaken

Appropriate attire and PPE available (e.g. gowns, gloves, masks, glasses)

First aid / Emergency assistance procedures available

Security

Access only for bona fide staff and students or authorised personnel

Construction of facility

Walls

Floors

Ceilings

Lighting

Ventilation

Toilet and Showering facilities available

Pest Control program in place

General comments on overall standards:

Action required:

Name of inspector:

Signature:

Date:

Administration management

- Discussion with head of school/institution overseeing the functions of the facility and licence holder.
- Discussion on assessment of any complaints lodged with the institution regarding the application and functions of the licence and mechanisms to address those complaints.
- Evidence of protocols and procedures to ensure all users conduct an anatomical examination in a manner that affords the deceased ongoing dignity between the time of their death and burial or cremation.
- Copies of inspection reports maintained.
- Compliance with the time period to make necessary changes identified by the inspection.
- Compliance with reasonable conditions imposed by inspector (on licence).

Audit of consent forms

- Evidence of the use of a standard comprehensive consent form that allows terms and conditions to be specified on the consent.
- Evidence that anatomical examinations are conducted with the written authority of the deceased, or if the deceased did not consent during their lifetime, the written consent of a senior available next of kin.
- Evidence of the inclusion of the wishes of the deceased or next of kin relating to the disposal of bodies and/or human tissue.
- Evidence of written consent for permanent retention of human tissue.
- Contact details of next of kin.

Audit of Register

Minimum requirements of register:

- Name and address of the person who had lawful possession of the body and who delivered the body into the holder's possession.
- Date on which the holder took possession of the body.
- Date, place and cause of death of the deceased and the sex, name, age and last place of abode of the deceased.
- Evidence of tracking of any human tissue removed from a body to ensure cross-referencing of all human tissue removed from a specific body.

Retention

- Evidence that no body is retained for more than 8 years from the date of death of the deceased.
- Evidence that no body exceeds an authorised retention period.
- Evidence that no human tissue exceeds the authorised retention period.
- Evidence of formal approval for any extension of retention period.

Transfer of bodies and human tissue

- Evidence of transfer of a body or human tissue from one institution to another providing it is not contrary to the authority given by the deceased or next of kin.
- Evidence that when bodies or human tissue are transferred, the following minimum details are entered on the register:
 1. the fact that the body or human tissue was transferred;
 2. the date on which the body or human tissue was transferred;
 3. the name and address of the person to whom the body or human tissue was transferred;
 4. the name of the licensed premises, hospital, or other place where human tissue is to be retained; and
 5. details of the arrangements made with respect to the return of the human tissue.
- Evidence that bodies are only transferred to other licence holders or, with the approval of an inspector, to a person in charge of anatomical examinations outside NSW.
- Evidence that human tissue from a body in the licence holder's possession is only transferred to other licence holders, authorised officers of State or interstate hospitals, or persons approved by the Director-General.
- Evidence of return of a body or human tissue unless it has been wholly or substantially destroyed.

Disposal

- Evidence that bodies are disposed of within 4 years from the date of death of the deceased person unless retained in accordance with an inspectors written authorisation.
- Evidence of a Cremation Certificate issued by the attending practitioner pursuant to clause 48 Public Health (Disposal of Bodies) Regulation 2002.

- Evidence that when bodies are disposed of, the following minimum details are entered on the register:
 1. the fact that the body was disposed of;
 2. the date of disposal; and
 3. the name and address of the person engaged to dispose of the body.
- Evidence that bodies are disposed of, as far as practicable, in accordance with any wishes of the deceased.
- Evidence that bodies are disposed of, as far as practicable, in accordance with any wishes of the senior available next of kin of the deceased if the deceased's wishes are not practicable, or deceased has expressed no such wishes.
- Evidence that human tissue is disposed of within 4 years from the date of death of the deceased person unless retained in accordance with an inspectors written authorisation or consented for permanent retention.

Attachment 3.1: Anatomy Register Example

NUMBER: _____

NAME OF DECEASED: _____

SEX: _____ AGE: _____

DATE BODY RECEIVED: _____

RECEIVED FROM: _____

NAME: _____

ADDRESS _____

PHONE: _____

DATE OF DEATH: _____ PLACE OF DEATH: _____

LAST PLACE OF ABODE: _____

CAUSE OF DEATH: _____

REMOVAL DATE FOR CREMATION/BURIAL: _____

REMOVED BY : _____

CONTRACTING FUNERAL DIRECTOR (Please PRINT Name, Address & Contact Number): _____
