



SA Health

Standard for the
Operation, Management
and Oversight of Schools
of Anatomy in South
Australia

Version 2017.01



**Government
of South Australia**

SA Health

INTRODUCTION

Schools of Anatomy provide important undergraduate and postgraduate teaching in anatomy, advanced surgical training, clinical skills training, research and product development.

All Schools of Anatomy must comply with the requirements under the *Transplantation and Anatomy Act 1983* (the Act) and any subordinate legislation.

Schools of Anatomy are authorised under the provisions of the Act. This *Standard for the Operation, Management and Oversight of Schools of Anatomy in South Australia* (the Standard) sets out requirements for the oversight, monitoring and quality assurance of all Schools of Anatomy in South Australia.

An accompanying *Audit Checklist and Evaluation Tool* (the Audit Tool) document will be used by Inspectors of Schools of Anatomy in undertaking their duties. The Audit Tool can also be used by Schools of Anatomy for internal monitoring and review.

PURPOSE

The Standard and accompanying Audit Tool have been developed for use by both Schools of Anatomy and Ministerial appointed Inspector/s of Anatomy to assist in ensuring that agreed processes and operational requirements are being met.

The Standard and accompanying Audit Tool are intended to:

- (i) support routine internal monitoring and review of Schools of Anatomy
- (ii) establish an agreed framework for formal inspection and audit of Schools of Anatomy by SA Health
- (iii) set out requisite minimum standards for prospective Schools of Anatomy (to permit authorisation under the Act)

This Standard consists of three parts:

Part One – applies to all Schools of Anatomy

Part Two – applies to Schools of Anatomy that operate a Body Donation Program

Part Three – a listing of related professional requirements and legislation

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DEFINITIONS

Any word or phrase defined in the Act has the same meaning in this Standard.

(The) Act	<i>Transplantation and Anatomy Act 1983</i>
Anatomical Examination	Anatomical Examinations are as defined in Part Two, Section 1 of this Standard.
Biological Waste	Discreet, unidentifiable or unrecognisable waste materials necessarily removed as part of routine dissecting, surgical training or the demonstration of new and innovative surgical approaches, sectioning and specimen preparation. This may include body fluids, blood, bone, fat and fascia.
Body Donation Program	A program that operates for the acceptance of bodies donated to science under Part 5 of the <i>Transplantation and Anatomy Act 1983</i> . The initial acceptance process includes responsibility for all consent procedures.
Body Part	Any identifiable or recognisable part of a cadaver such as an organ or extremity. <i>For example an organ or identifiable part of an organ, an appendage, an external or visible body part, a joint, a muscle or identifiable part of a muscle, identifiable tissue/s, a bone or identifiable part of a bone. This does not include biological waste, slides or histology specimens.</i>
Cadaver / Cadaveric Materials	Any whole or partial body donated to a local, interstate or overseas Body Donation Program. This includes plastinated and potted materials. <i>A whole body or whole cadaver consists of the torso, with or without the head and with or without any limbs.</i>
Chain of Custody	Chain of custody refers to all processes involving the handling and managing of cadavers or cadaveric materials (from the time of delivery to a body donation program / despatch to a School of Anatomy, to the time of return of the remains and subsequent disposal). During this period the identity and location of all cadavers / cadaveric materials must always be known or able to be ascertained. A loss of the identity of cadavers / cadaveric materials or an inability to determine their location constitutes a breach in the chain of custody. The ability to maintain the chain of custody is a fundamental requirement and is a central aspect of the audit and evaluation of Schools of Anatomy in South Australia.

Inspector	A public sector contractor or employee appointed by the Minister pursuant to regulation 6 of the Regulations for the purposes of inspecting Schools of Anatomy according to the requirements set out in this Standard.
Next of kin	As defined in the <i>Transplantation and Anatomy Act 1983</i> .
Permanent collection	Materials kept for greater than 5 years, or materials retained after the donor remains have been released.
Plastinated materials	Materials that are infiltrated with silicone (or other curable polymer) and are not considered as wet materials. They are able to be retained permanently as teaching resources.
Potted materials	Wet materials mounted and encased within a perspex 'pot' and mounting solution, and used to permanently display dissected materials and delicate models.
Public Display	The organised display of donated body part/s where the general public or those not otherwise associated with the operation of the SOA or the teaching and study of anatomy are able to view cadaveric materials.
Regulations	Regulations enacted pursuant to section 34 of the <i>Transplantation and Anatomy Act 1983</i> .
Responsible Officer	The Responsible Officer is the person responsible for the School of Anatomy's compliance with the Standard. The Responsible Officer must be a senior officer within the institution that has broad governance over the operations and conduct of the School of Anatomy.
School of Anatomy	A place where anatomy is practised, and the teaching and study of anatomy are carried out pursuant to section 33 of the <i>Transplantation and Anatomy Act 1983</i> . A School of Anatomy will receive cadavers and/or cadaveric materials to support the work undertaken.
Standard	<i>Standard for the Operation, Management and Oversight of Schools of Anatomy in South Australia</i>
Supplier	A person or organisation which supplies cadavers or cadaveric materials other than by individual donation to a Body Donation Program.

Part One: Schools of Anatomy

This part contains the requirements for all existing Schools of Anatomy to maintain their licence, and for prospective schools to gain a licence.

The sections in this part cover the following:

1. Governance Arrangements and Ethical Considerations
2. Anatomical Examinations
3. Respectful Handling of Cadavers and Body Parts
4. Sourcing of Cadaveric Material
5. Identification and Tracking of Cadavers/Cadaveric Materials
6. Transportation Protocols
7. Management of Plastinated and other Permanently Retained Materials
8. Historical Materials of Uncertain Origin
9. Infection Prevention and Control Measures
10. Ensuring a School of Anatomy is Fit for Purpose
 - A. Security
 - B. Privacy
 - C. Capacity to support appropriate management of potential health risks and the implementation of infection prevention and control guidelines and procedures
 - D. Building Design
 - E. Disposal of waste other than cadavers and cadaveric material
 - F. Management of Chemicals
 - G. Workplace Health & Safety
 - H. Integration with Teaching Institutions
11. Disposal of cadavers and cadaveric materials

1. Governance Arrangements and Ethical Considerations

All Schools of Anatomy, prospective and current, must have:

- i. An established governance structure or committee within the prescribed institution that provides oversight to the School of Anatomy with respect to laboratory practice, and links to research, teaching and ethics.
- ii. A Responsible Officer, who has overall responsibility for the School of Anatomy complying with this Standard. The holder of this position will be the primary contact for the Inspector.
- iii. A Code of Conduct for all persons participating in anatomical examinations involving cadavers / cadaveric materials. The Code of Conduct must be readily accessible to relevant persons at all times.

The Code must also cover those involved in laboratory based work including research, the conduct and/ or observation of dissections or the viewing of anatomical specimens in museums or special purpose viewing room.

- iv. A guided induction process and induction manual, inclusive of the Code of Conduct, for staff new to the School of Anatomy.
- v. A guided induction process and induction manual, inclusive of the Code of Conduct, for students new to the School of Anatomy.
- vi. A process to ensure that visitors to anatomy museums are familiar with the Code of Conduct.

Documentary evidence of governance arrangements, the Code of Conduct and the induction process and manual must be made available to the Inspector when requested. The Inspector must be advised whenever there is a change in the designated Responsible Officer for the School of Anatomy.

2. Anatomical Examinations – scope of activity

Anatomical Examinations may involve the use of cadavers / cadaveric materials for the following purposes only:

- a. Teaching and study of anatomy at undergraduate and postgraduate levels, including workshops involving internal and/or external parties (eg surgeon training in surgical techniques)
- b. Research (ie the gathering of data through the conduct of specific examinations or procedures)

The following conditions apply to Anatomical Examinations:

- i. Cadavers / cadaveric materials may only be used for the above categories of Anatomical Examination.
- ii. Prospective Schools of Anatomy must specify in their application which categories are to be undertaken in the School.

- iii. Where research is specified to be undertaken in the School, it must be done in a manner consistent with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research 2007* (and subsequent updates).
- iv. Prior to the use of a cadaver / cadaveric materials, the School of Anatomy must ensure that:
 - a) the identity of the cadavers and/or cadaveric materials to be used in the anatomical examination(s) is documented. For Schools of Anatomy not operating a Body Donation Program, identity in the form of a donor number that can be linked back to identification records held in the relevant Body Donation Program or by the relevant supplier is sufficient;
 - b) the intended use of all body parts for anatomical examination(s) is documented; and
 - c) all students, researchers and staff to be involved in the anatomical examination(s) have undertaken an induction program appropriate for the relevant activity and evidence of this is available for review by the Inspector as and when required.
- v. The documentation referred to in iv(a) and iv(b) above, must be endorsed by an appropriate delegate in the institution by which the School of Anatomy is governed and be available for review by the Inspector as and when required.

3. Respectful Handling of Cadavers and Cadaveric Materials

- i. The bodies of deceased persons must at all times be handled with respect.
- ii. Cadavers / cadaveric materials must only be used in accordance with the specific consent given in the donor consent records, with particular note of any limitations.
- iii. Schools of Anatomy must ensure that there is no improper use of cadavers / cadaveric materials. For example, they must never be used for entertainment, profit, personal purposes, by unauthorised personnel, nor be the subject of unauthorised photography or unauthorised electronic imaging.
- iv. All cadavers / cadaveric materials must be stored in a secure environment, with access only available to bona fide staff and students or authorised personnel.
- v. All Schools of Anatomy must have documented security arrangements for all premises used for anatomical examinations involving cadavers / cadaveric materials.
- vi. All personnel with access rights to storage areas of cadavers / cadaveric material must have completed an induction program and be familiar with the Code of Conduct.
- vii. Cadavers / cadaveric materials used for public open-day sessions, including anatomy museums or public displays of anatomical specimens, must be

used in a respectful manner, in accordance with donor consent, and with appropriate security.

- viii. All visitors to Schools of Anatomy must be fully supervised by authorised personnel. Schools of Anatomy must have a documented protocol in place outlining the requirements for visitor access to the premises.

4. Sourcing of Cadaveric Material

- i. Cadavers / cadaveric materials sourced from a South Australian Body Donation Program must be done via a formal written application to ensure proper accountability of cadavers / cadaveric material.
- ii. Cadavers / cadaveric materials sourced from an interstate and/or an overseas supplier must be accompanied by written documentation to ensure that the requirements outlined in this Standard and the legislative requirements of the Act are being met. In particular, written documentation of the following is mandatory:
 - a) evidence of informed consent to donation;
 - b) intended use of the materials and consent to such use;
 - c) process to manage the identification and tracking of body parts;
 - d) requirements regarding the disposal of the materials in accordance with the original consent, including appropriate documentation to allow disposal in South Australia.
- iii. Authorisation to operate a School of Anatomy must be sought prior to arranging the sourcing/transport/importation of any materials.
- iv. Contracts for the sourcing of cadavers / cadaveric materials are only to be entered into by Schools of Anatomy and must be consistent with section 35 of the Act.
- v. The importation into South Australia of any overseas sourced cadavers / cadaveric materials must be done in accordance with any applicable quarantine laws, import licences and public health requirements regarding notifiable diseases, and any other laws applicable from time to time.

All documentation concerning the sourcing of cadaveric materials must be made available to the Inspector when requested.

5. Identification and Tracking of Cadavers / Cadaveric Materials

- i. All cadavers / cadaveric materials (including plastinated and potted specimens) retained for any use in a School of Anatomy must be clearly and permanently identifiable or, for Schools of Anatomy not operating a Body Donation Program, re-identifiable by the donor number assigned to them by the relevant supplier. Where the materials have been sourced from a Body Donation Program, the Register must also contain details that link it to the Register kept by that Program.

- ii. Schools of Anatomy must have in place a secure labelling and tracking system, which incorporates a Register of all cadavers / cadaveric materials stored or in use at the School of Anatomy.
- iii. Separated body parts (eg severed hands) must all be labelled in such a way that it is possible to identify the body to which the part belongs. The identity of all such separated body parts must be clearly documented in the Register and linked to the body record. This applies to both permanent and temporary removals.
- iv. Schools of Anatomy must have a comprehensive system in place to ensure that the chain of custody of all body parts located in its premises is reliably maintained and documented.

6. Transportation Protocols

- i. Procedural guidelines that facilitate the identification, tracking and monitoring of body parts to ensure the chain of custody is not broken must be in place for the secure transportation of cadavers / cadaveric materials to and from the School of Anatomy.
- ii. All cadavers / cadaveric materials must be fully labelled for transport, including a description of the materials and an identifier that is able to be linked to the source School of Anatomy or, interstate or overseas supplier.
- iii. Schools of Anatomy must ensure that any contractors or service providers adhere to the requirements for transportation, through the establishment of a Memorandum of Understanding or other written agreement.
- iv. Transportation of cadavers / cadaveric materials must be undertaken in a manner which minimises the risk of public exposure.

7. Management of Plastinated and other permanently retained Materials

- i. Procedures and documentation must be in place to ensure that the plastination of cadavers / cadaveric materials and the retention of other materials permanently (including body parts that will therefore not be cremated) is consistent with donor consent.
- ii. Appropriate procedures must be in place to permanently identify the donor (or facilitate re-identification of the donor) and to register plastinated and permanently retained body parts, including details relating to the intended use and life expectancy of the materials, as well as the intended permanent location/destination.
- iii. Mechanisms must be in place to secure the chain of custody of all materials.
- iv. Schools of Anatomy receiving materials from Body Donation Programs are to maintain the relevant Body Donation Program's identification tag, and may also apply their own specific identification tag (where appropriate).

8. Historical Materials of Uncertain Origin

- i. In dealing with historical materials of uncertain origin, Schools of Anatomy must have in place strategies to ensure that:
 - a. Materials of unknown origin are clearly identifiable as such; and
 - b. Confusion with other materials is avoided.
- ii. Historical materials of uncertain origin must be treated with the same level of respect as all other cadaveric materials.
- iii. The disposal of unidentifiable body parts must only be done after consultation with and written advice from an Inspector.
- iv. Should an identification marker be dislodged and separated from any body part in the normal operations of a School of Anatomy and the School of Anatomy cannot identify the origin of the body part, the School of Anatomy must keep a register of such occurrences and provide this, as required, to the Inspector. A new identifying marker must also be assigned and recorded on the register.

9. Infection Prevention and Control Measures

- i. Schools of Anatomy must have fully documented infection prevention and control guidelines and procedures in place which are readily accessible by staff, students and other authorised personnel as applicable. They must also be available for review by the Inspector at any time.
- ii. The infection prevention and control guidelines and procedures must ensure appropriate measures are in place for both fresh and embalmed specimens.
- iii. Staff and students of Schools of Anatomy must receive an induction program which incorporates the infection prevention and control guidelines and procedures.
- iv. All persons handling cadaveric materials must use standard infection control precautions and procedures and must use personal protective clothing and equipment in accordance with standard infection control precautions and procedures.
- v. Schools of Anatomy must operate in accordance with the *South Australian Public Health Act 2011* and the *South Australian Public Health (Notifiable and Controlled Notifiable Conditions) Regulations 2012*.

10. Ensuring a School of Anatomy is Fit for Purpose

- i. Security

Schools of Anatomy must have in place security policies and processes that require, at a minimum:

- a. Identification standards for bona fide staff and students or authorised personnel (eg photo id cards);

- b. The management and documentation of authorised access;
 - c. Physical and technological barriers (eg swipe cards) to prevent unauthorised access at all times;
 - d. The secure storage of all cadavers / cadaveric materials when not in use;
 - e. Supervision of visitors at all times.
- ii. Privacy
- a. The design of all locations (eg laboratories and dissecting rooms) must ensure restricted access to authorised persons to locations where cadavers are stored, displayed and/or used.
 - b. Areas purposely designed for public display, such as museums, must also facilitate restricted access and visitors must be supervised at all times.
- iii. Capacity to support appropriate management of potential health risks and the implementation of infection prevention and control guidelines and procedures
- a. Laboratory hardware must be appropriate and fit for purpose.
 - b. Clean gowns, gloves, masks, glasses and dissection instruments must be available at all times and worn when handling cadaveric materials.
 - c. Staff and student facilities must include change rooms and washing areas.
 - d. There must be adequate ventilation of all rooms where cadaveric materials are used and prepared. The ventilation system for the laboratory must minimise the spread of airborne pathogens by being isolated from other ventilation systems in the building.
 - e. There must be documented and appropriate cleaning procedures for all areas of the laboratory, including procedures for the cleaning and disinfection of instruments and equipment.
- iv. Building Design

The laboratory must be appropriately designed for the receipt, embalming, freezing, handling and dissection of human remains (where practiced). This includes:

- a. Adequate lighting must be available in all areas.
- b. A reticulated water supply must be available.
- c. Power supply outlets in the laboratory and body storage areas must be protected from wetting through the use of protective covers and other current best practice.
- d. An emergency back-up system for the power supply must be in place and fully operational for refrigeration, storage facilities, lighting and air handling systems.
- e. All areas must have non-slip flooring.
- f. Wet floor surfaces must be washable, sealed floors appropriately sealed at the edges, and must have adequate drainage.
- g. The operating temperatures of all body storage and freezing facilities must be continuously monitored.
- h. There must be adequate space for the accommodation of each body in body storage facilities to ensure that the integrity of the body/body part is

not compromised and that identification / chain of custody requirements are upheld.

- i. The facilities for body storage, transfer and dissection must be of sufficient size and strength to allow safe handling. This should include provision for larger and heavier bodies (eg through the use of appropriately reinforced tables or trolleys).
 - j. Work areas must be of a sufficient size to allow staff and students to work in an uncrowded space.
 - k. Instruments and other items needed must be readily accessible within the work area.
 - l. Handwashing facilities must be appropriately located for use.
 - m. Clean and contaminated areas should be assigned and clearly labelled where appropriate.
 - n. A dedicated area free from contamination must be available to review documentation and for general office use.
 - o. Ventilation systems must be appropriate.
- v. Disposal of waste other than cadavers and cadaveric materials
- a. Different containers must be provided for the disposal of general and biological (medical) waste and must be located appropriately.
 - b. Biological waste must be disposed of as medical waste by incineration only.
- vi. Management of Chemicals
- a. Appropriate facilities and protocols must be in place for the safe and secure storage, handling and disposal of embalming materials and chemicals and any other toxic chemicals and substances held at the School of Anatomy or the prescribed institution.
- vii. Workplace Health and Safety
- a. The School of Anatomy must meet the relevant health, safety and welfare standards, as prescribed by the *Work Health and Safety Act 2012* and the *Work Health and Safety Regulations 2012*, including but not limited to protocols for dealing with spills and the disposal of hazardous materials.
- viii. Integration with Research and Teaching Institutions
- a. The School of Anatomy must be in sufficient proximity to its prescribed institution's parent/central research and/or teaching facility (or one of its campuses) to ensure that it is functionally integrated into the research and teaching environment of the facility.
 - b. Any activities involving cadavers and/or cadaveric materials that are held at a different site require the separate approval of the Minister pursuant to section 33 of the Act.
 - c. Any materials that are temporarily lent to another School of Anatomy remain the full responsibility of the lending School of Anatomy.

11. Disposal of Cadavers / Cadaveric Materials

- a. The cadaver / cadaveric materials must, to the extent it is reasonably practicable to do so, be disposed of in accordance with the deceased person's wishes and/or supplier agreement or instructions.
- b. The disposal of whole identifiable cadavers and of identifiable body parts must comply with the *Burial and Cremation Act 2013* and the *Burial and Cremation Regulations 2014*.
- c. The disposal of other cadaveric materials must be by medical incineration, in line with the *Environment Protection (Waste to Resources) Policy 2010*.
- d. The cadavers/cadaveric materials must be disposed of as soon as practicable after:
 - a. the period for which the body was authorised to be retained (for time limited authorisation); or
 - b. the conclusion of the purposes for which the body was authorised to be retained.

This part does not apply to remains that are to be kept indefinitely.
- e. Where the cadaver/cadaveric materials are on temporary loan, they must be returned to the originating Body Donation Program or interstate or overseas supplier for disposal.

Part Two: Body Donation Programs

This part contains specific requirements relevant to Schools of Anatomy operating a Body Donation Program. They are additional to the requirements outlined in Part One of this Standard.

1. The School of Anatomy must have in place a procedure that ensures the donation of cadavers / cadaveric materials by members of the public operates on the basis of informed consent.

For the purposes of this requirement, prospective donors and their next of kin must be provided with detailed information in writing informing them of all relevant aspects of the Body Donation Program, including full disclosure as to the possible use/s of donor remains for anatomical teaching, study, display and research; as well as addressing the final disposal of remains.

2. The School of Anatomy must keep up-to-date copies of the information and consent forms and make them available to the Inspector, as required.
3. The School of Anatomy shall only accept bodies into a Body Donation Program with all the necessary documentation.

For the purposes of this requirement, the necessary documentation includes:

- *the signed consent form (donor and next of kin);*
- *the death certificate;*
- *the coroner's authority to dispose of human remains (where required under the Coroner's Act 2003);*
- *the designated officer consent (where required under the Act).*

4. The School of Anatomy must maintain a register of donors accepted into the Body Donation Program.
5. The School of Anatomy must have in place appropriate policies and procedures for the acceptance and management of cadavers / cadaveric materials into the Body Donation Program, which shall cover the following matters at a minimum:
 - i. The assessment and acceptance of cadavers / cadaveric materials into the program, including policies and processes for screening for infectious risk.
 - ii. The categories of staff that are authorised to receive or dispatch cadavers / cadaveric materials.
 - iii. The maintenance of the register of donors, including data entry requirements.
 - iv. The assignment of body identification / cadaver numbers and toe tags (or equivalent)
 - v. Embalming/freezing and body storage requirements.
 - vi. Disposal arrangements.
6. The School of Anatomy must have in place appropriate processes for receiving and assessing applications from other Schools of Anatomy for the transfer of / access to cadavers / cadaveric materials.

7. Cadavers / cadaveric materials may only be provided to other Schools of Anatomy, or their legally established and regulated interstate or overseas counterparts, in accordance with the intent of the Act, this Standard, and donor consents, including the intended use. The cadavers / cadaveric materials should be returned to the source School of Anatomy unless alternate arrangements have been formally requested and agreed to by the donor or the donor's representative.

8. The School of Anatomy must have an induction manual in place for contracted funeral directors, which covers the key requirements of security, transportation, maintaining the chain of custody, documentation, privacy and ethics (as outlined in Part One of this document). Authorised service providers should also have an understanding of informed consent and be familiar with the operation of the Body Donation Program and the information provided to prospective donors and their families.

Part Three: Related Professional Requirements and Legislation

Burial and Cremation Act 2013

Refer to this Act and the subordinate ***Burial and Cremation Regulations 2014*** for the legal requirements relating to the disposal of whole identifiable cadavers and of identifiable body parts (per Part One, Section 11(b) of this document).

Coroner's Act 2013

Part One, Section 3 of this document refers to the *Coroner's Act 2013* in relation to the disposal of human remains. Compliance with this is only mandatory for cases that have been investigated by the coroner.

Environment Protection Act 1993

Refer to this Act and the subordinate ***Environment Protection (Waste to Resources) Policy 2010*** for the legal requirements relating to the disposal of other cadaveric materials (per Part One, Section 11(c) of this document).

National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research 2007 (and future updates).

Compliance with this document is mandatory for any research based activities undertaken within Schools of Anatomy (per Part One, Section 2(iii) of this document).

South Australian Public Health Act 2011

Refer to this Act and the subordinate ***South Australian Public Health (Notifiable and Controlled Notifiable Conditions) Regulations 2012*** for the legal requirements around infection prevention and control measures required to be in place (per Part One, Section 9(v) of this document).

South Australian Transplantation and Anatomy Act 1983

This Act provides for the donation of cadavers / cadaveric materials for anatomical purposes and for the authorisation of Schools of Anatomy in South Australia (and for other purposes). It is from this legislation (and any subordinate legislation) that this Standard follows.

Work Health and Safety Act 2012 and the Work Health and Safety Regulations 2012

Refer to this Act and the subordinate ***Work Health and Safety Regulations 2012*** for the legal requirements around health, safety and welfare standards (per Part One, Section 10(vii)(a) of this document).

National Pathology Accreditation Advisory Council's (NPAAC) "Requirements for the Facilities and Operation of Mortuaries", Third Edition 2013.

Readers should note that this Standard has been informed, in part, by the requirements imposed by NPAAC on mortuary services in hospitals and forensic settings. However, the requirements contained within do not directly apply to Schools of Anatomy.