

Review of the Victorian Human Tissue Regulations 2015

Consultation paper – August 2025

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Background

The *Human Tissue Act 1982* (the Act) and the Human Tissue Regulations 2015 (the current Regulations) regulate human tissue including the removal of human tissue for transplantation, donations and transfusion, post-mortem examinations, and the authorisation of schools of anatomy. The Act also prohibits trading in human tissue in the absence of a relevant permit under the Act.

The Act defines tissue as an organ, or part, or a human body, or substance extracted from, or from a part of, the human body. For example, faecal specimens, breast milk, skin, bone and cadavers are all considered tissue under the Act.

Regulations were first made under the Act in 1997 and were most recently reviewed and re-made in 2015. In accordance with the *Subordinate Legislation Act 1994*, the current Regulations will expire (or 'sunset') on 22 December 2025.

The Department of Health (the department) considers that it is necessary to remake the current Regulations, in the same or similar form, to ensure the relevant parts of the Act can continue to operate as intended. To ensure continuity, it is intended that those new regulations will be made before the current Regulations expire.

The department is also proposing to include some additional provisions in the new regulations, which are not included in the current Regulations. Requirements that might be included are set out in this consultation paper for feedback.

Human Tissue Regulations 2015

The objective of the current Regulations is to prescribe matters that are authorised or required to be prescribed for carrying out or giving effect to the Act.

The current Regulations are minimal, limited to prescribing lists relating to:

- classes of persons who may remove tissue from the body of a deceased person;
- institutions within which a school of anatomy may be authorised; and
- tissue banks that may engage in reasonable cost recovery.

As set out below, the Act also provides for regulations to be made in relation to schools of anatomy, but there are no such provisions in the current Regulations.

The current Regulations can be downloaded from the [Victorian Legislation website](https://www.legislation.vic.gov.au/in-force/statutory-rules/human-tissue-regulations-2015/001) at [<https://www.legislation.vic.gov.au/in-force/statutory-rules/human-tissue-regulations-2015/001>](https://www.legislation.vic.gov.au/in-force/statutory-rules/human-tissue-regulations-2015/001).

Review

Scope

Regulations made under the Act can only deal with matters that are within the regulation-making powers that are listed under sections 37 and 46 of the Act.

Section 46 of the Act states that the Governor in Council may make regulations prescribing all matters that are authorised or required to be prescribed for carrying out or giving effect to the Act. These regulations may be of general or limited application, and may differ according to differences in time, place or circumstance.

Section 37 of the Act sets out powers for Governor in Council to make regulations relating to schools of anatomy. The regulations may make provisions for a wide range of matters including—

- the period after death within which, and the manner in which, bodies may be transported to a school of anatomy;
- the conditions subject to which anatomical examinations and the teaching and study of anatomy and the practice of anatomy may be carried out;
- the furnishing of returns and other information by the person in charge of a school of anatomy;
- the precautions to be taken in regard to the receipt and custody of bodies;
- the inspection of schools of anatomy;
- the regulation and control of schools of anatomy; and
- the disposal of bodies or any parts of bodies.

Reform proposals that go beyond these matters would require amendments to the Act. They are beyond the scope of the current reform process for updating the Regulations.

Those matters are better considered as part of the current review of Australia's human tissue laws that is being conducted by the Australian Law Reform Commission (ALRC) [Review of Human Tissue Laws: Issues Paper \(2025\) | ALRC](https://www.alrc.gov.au/publication/review-of-human-tissue-laws-issues-paper-2025/) <<https://www.alrc.gov.au/publication/review-of-human-tissue-laws-issues-paper-2025/>>. The ALRC review includes examining consent processes, ethical considerations, and regulatory inconsistencies across jurisdictions, as well as addressing emerging technologies and practices. It will also consider the regulation of schools of anatomy and the financial aspects of tissue provision.

Noting this scope, the department welcomes all feedback as part of this consultation process. Feedback on matters that cannot be addressed in regulations made under the Act may inform feedback from the department to the ALRC review or be recorded for consideration in any future review of the Act.

Process

This consultation paper sets out proposed content for the updated Regulations.

Stakeholders are encouraged to provide written feedback in response to this consultation paper. The department will consider all this feedback when developing recommendations for the content of the proposed updated Regulations. Once the updated Regulations are made, the department will circulate a summary of the feedback received in response to this consultation paper and how it has informed the updated Regulations.

Under the *Subordinate Legislation Act 1994*, a Regulatory Impact Statement (RIS) must be prepared for regulations that impose significant regulatory burden.¹ A departmental analysis found that the potential burden of the proposed regulations described in this paper would fall well below the significant burden threshold of \$2 million per year as set out in the *Victorian Guide to Regulation*, and a formal Regulatory Impact Statement is not required.

As set out below, the proposed reforms intend to continue provisions of the current Regulations – in the same or similar form – and to formalise existing guidelines, policies, procedures and tools that are used by the department and schools of anatomy to ensure the safe and ethical supply and use of human tissue for teaching and study.

¹ See sections 7(2) and 8, *Subordinate Legislation Act*, [Victorian legislation website](https://www.legislation.vic.gov.au/in-force/acts/subordinate-legislation-act-1994/042), <<https://www.legislation.vic.gov.au/in-force/acts/subordinate-legislation-act-1994/042>>.

How to make a submission

Feedback is invited on the proposed content for the updated Regulations, as set out in the following tables. The blank column on the right-hand side of each table can be used to provide comments, concerns or suggestions about the proposals. You do not need to provide comments against every item. You do not need to answer any specific questions in your response.

Some items flag that the department is particularly interested in receiving feedback on a specific aspect of a proposal.

For any item, you might consider addressing the following questions in your response:

- Do you support the proposal? Why or why not?
- Do you have suggestions for an amendment to the proposal?
- If you are responding for a school of anatomy
 - To what extent would the proposed requirement necessitate changes in your organisation?
 - How long would it take to make any required changes?
 - What information or guidance would you require from the department to do so?

In your submission, you may also raise any issues regarding the Regulations that you believe have not been addressed in the tables below. As noted above, you can also raise broader reform issues relating to the Act. While these are outside the scope of reforms to remake the Regulations, they will be noted by the department to inform input into the ALRC review or future reform opportunities.

Submissions may be sent by email or post:

Email to: Legislation and Regulation Reform [Legislation and Regulation Reform
legandregreform@health.vic.gov.au](mailto:legandregreform@health.vic.gov.au)

Post to: Regulatory Reform and Policy,
People, Operations, Legal and Regulation Division
Department of Health
50 Lonsdale Street, Melbourne, VIC 3000

Submissions are due by **midnight on 23 September 2025**.

You may choose to share personal or professional experience or knowledge, as well as qualitative and quantitative data. We ask you not to provide any identifying, or potentially identifying, information about individual people.

Please read the Privacy Collection Notice below before completing a submission.

Privacy Collection Notice

The department is committed to protecting your personal information and privacy, and any information you provide is collected and handled in accordance with the *Privacy and Data Protection Act 2014*.

The information in your submission is collected by the department to administer the consultation process for the review of the Human Tissue Regulations 2015 and to inform the development of the proposed updated Regulations.

You can choose to make an anonymous submission. However, you will need to provide your contact details if you would like the department to advise you of the outcome of the consultation.

For more information on the department's privacy collection practices, please refer to the department's [Privacy policy](https://www.health.vic.gov.au/department-of-health-privacy-policy) <<https://www.health.vic.gov.au/department-of-health-privacy-policy>>.

You may contact the Legislative and Regulatory Reform team supervising the consultation by emailing [Legislation and Regulation Reform](mailto:legandregreform@health.vic.gov.au) <legandregreform@health.vic.gov.au>.

You may contact the department's Privacy team by emailing [Privacy team](mailto:privacy@health.vic.gov.au) <privacy@health.vic.gov.au>.

You/your organisation can request access and changes to information that you provide to the department using the email contacts above.

Proposed updates to the current Regulations

This section of the paper seeks feedback on proposed updates to provisions of the current Regulations.

Please add your feedback into the column provided. You do not need to provide feedback on every item. You are not required to address any specific questions in your response.

Some items flag that the department is particularly interested in receiving feedback on a specific issue.

For any item, you may wish to address the following questions:

- Do you support the proposal? Why or why not?
- Do you have suggestions for an amendment to the proposal?

Persons authorised to remove tissue after death, prescribed institutions and prescribed tissue banks			
Regulation number	Current regulation	Proposed regulation and rationale	Stakeholder feedback
6	Classes of persons who may remove tissue (6) For the purposes of section 25(b) of the Act, the prescribed classes of persons are— (a) in relation to the removal of ocular tissue, persons who are employed by, or perform work for, the University of Melbourne or the Centre for Eye Research Australia Limited (I 076 481 984) on behalf of the Lions Eye Donation Service Melbourne, an unincorporated joint venture, as eye donor coordinators and whose duties include the removal of ocular tissue from the bodies of deceased persons; and (b) in relation to the removal of tissue of any kind, persons who are employed by, or perform work for, the Victorian Institute of Forensic Medicine or a hospital as— (i) forensic technicians (including forensic technical officers); or (ii) mortuary technicians; or (iii) scientists— and whose duties include the removal of tissue of any kind from the bodies of deceased persons.	<p>It is proposed to remake regulation 6 in substantially its current form to maintain the existing limited list of classes of person who can remove tissue after death. This assists in ensuring that human tissue is removed safely and ethically in compliance with the Act.</p> <p>The department is aware that there may be a rationale for expanding the scope of some classes of person authorised. Feedback is sought on the benefits of this, and on how any such expansion might be designed to minimise any increased risk of inappropriate handling and removal of tissue.</p>	Click or tap here to enter text.
7	Prescribed institutions (7) For the purposes of Part VII of the Act, the following are prescribed institutions— (a) La Trobe University; (b) Monash University; (c) Royal Melbourne Institute of Technology; (d) The University of Melbourne	<p>It is proposed to remake current regulation 7 in substantially its current form.</p> <p>This is considered appropriate to ensure that authorisations can be issued under section 35(2) of the Act for operation of a school of anatomy within the currently prescribed institutions.</p>	Click or tap here to enter text.

Regulation number	Current regulation	Proposed regulation and rationale	Stakeholder feedback
8	<p>Prescribed tissue banks</p> <p>(8) For the purposes of section 39A(1) of the Act, the following are prescribed tissue banks—</p> <ul style="list-style-type: none">(a) Austin Health Tissue Bank;(b) Barwon Health Bone Bank;(c) Donor Tissue Bank of Victoria;(d) KconFab (Kathleen Cunningham Consortium for Research into Familial Breast Cancer) Tissue Bank;(e) Lions Eye Donation Service Melbourne;(f) Melbourne Health Tissue Bank;(g) Monash Health Tissue Bank;(h) Peter MacCallum Cancer Centre Tissue Bank;(i) Victorian Brain Bank.	<p>For the purposes of section 39A(1) of the Act, it is proposed to remake regulation 8 in substantially its current form.</p> <p>This will continue to provide specified tissue banks with reasonably practicable flexibility to recover certain costs without contravening the trade prohibitions in sections 38 and 39 of the Act. Consideration is being given to updating the list if/as appropriate.</p>	<p>Click or tap here to enter text.</p>

Proposed new provisions for the updated Regulations – schools of anatomy

This section of the paper seeks feedback on proposals for new requirements that are not in the current Regulations.

Please add your feedback into the column provided. You do not need to provide feedback on every item. You are not required to address any specific questions in your response.

Some items flag that the department is particularly interested in receiving feedback on a specific issue.

For any item, you may wish to address the following questions in your response:

- Do you support the proposal? Why/why not?
- Do you have suggestions for an amendment to the proposal so that it better achieves the relevant objective?
- If you are responding for a school of anatomy
 - To what extent would the proposed requirement necessitate changes in your organisation?
 - How long would it take to make any required changes?
 - What information or guidance would you require from the department to do so?

Governance of schools of anatomy		
A well-defined governance framework provides oversight, accountability and consistency across all activities, while policies and procedures translate principles into practice. Together, they help guide decision-making, clarify roles and responsibilities, and ensure compliance with legal and ethical standards. Embedding strong governance structures and operational protocols supports compliance with best practice and regulatory requirements, facilitates transparency, protects donor dignity, and promotes public confidence in tissue-related practices.		
Objective	Proposed regulation	Stakeholder Feedback
Governance practice is robust	<p>(1) A requirement for schools of anatomy to:</p> <ul style="list-style-type: none">(a) establish, document and implement governance arrangements and policies and procedures as set out in (2) below;(b) make copies of the relevant documents available to an inspector appointed under the Act on request;	<p>Click or tap here to enter text.</p>

Objective	Proposed regulation	Stakeholder Feedback
	<ul style="list-style-type: none"> (c) review the governance arrangements, policies and procedures at least every three years and update them as necessary following such review – or sooner after an adverse event in relation to the policies and procedures relevant to that adverse event; and (d) document the results of such a review and make them available to an inspector appointed under the Act on request. 	
Governance structure is robust	<p>(2) A requirement that the documented governance arrangements (referred to in (1) above) must include:</p> <ul style="list-style-type: none"> (a) the name and position title of the person in charge of the school of anatomy – that is, the person responsible for day-to-day operation of the school of anatomy, including the safe and ethical treatment of all human tissue in the possession or control of the school of anatomy, and compliance with the Act and Regulations. (b) membership, terms of reference and meeting frequency of a committee that is responsible for oversight of the safe and ethical treatment of all human tissue in the possession or control of the school of anatomy, and compliance with the Act and Regulations. 	Click or tap here to enter text.
Scope of legal authority is established and adhered to	<p>(3) A requirement for each school of anatomy to have policies and procedures for:</p> <ul style="list-style-type: none"> (a) documenting the scope of the authority issued under section 35 of the Act (b) identifying and documenting the personnel at the school of anatomy who are involved in the activities authorised under section 35 of the Act (including staff, students and support staff) and (c) communicating same to all relevant school of anatomy personnel (d) ensuring that those personnel operate within the scope of the authorisation. 	Click or tap here to enter text.
Handling of human tissue in possession or control of the school of anatomy is safe and ethical	<p>(4) A requirement for each school of anatomy to have policies and procedures for:</p> <ul style="list-style-type: none"> (a) the safe and ethical handling of human tissue in its possession or control, including recording and use of digital images of human tissue (still or video, including for the purposes of 3D printing). (b) compliance with relevant consents and authorisations (c) sourcing or receipt (d) storage (e) transportation (f) infection control (g) disposal. 	Click or tap here to enter text.
Use of human tissue in possession or control of the school of anatomy is consistent with law	<p>(5) A requirement for each school of anatomy to have policies and procedures for the use of human tissue in its possession or control, being use for the purposes authorised under section 35 of the Act. It would be intended that this should cover policies and procedures for ensuring that such use is consistent with the law, including</p> <ul style="list-style-type: none"> (a) the authorisation under section 35 in relation to the operation of the school of anatomy (b) where applicable section 32 (c) where applicable section 33 	Click or tap here to enter text.

Objective	Proposed regulation	Stakeholder Feedback
	<ul style="list-style-type: none"> (d) any other legal authorisation applicable to the bringing of the tissue into Australia or Victoria, and/or to the premises of the school of anatomy (e) any permit issued to the school of anatomy under section 39 of the Act (f) the consent provided by and (to the extent reasonably known by the school of anatomy) the wishes expressed by the person to whom the tissue belonged. 	
Other relevant policies and procedures are in place to support safe and ethical operation of the school of anatomy and regulatory oversight by the department	<p>(6) A requirement for each school of anatomy to have policies and procedures for the following:</p> <ul style="list-style-type: none"> (a) record keeping – including the keeping of records necessary for the identification of tissue and its location, storage and transport, while also maintaining the privacy of donors and other individuals (b) reporting information to the department (c) fitness for purpose of the premises (building) and equipment of the school of anatomy (d) managing access to the following, including supervision or restrictions, to ensure ethical and safe handling of human tissue and associated records in the possession or control of the school of anatomy (also see below regarding a proposed standalone obligation): <ul style="list-style-type: none"> (i) the premises of the school of anatomy, or parts thereof (ii) records kept by the school of anatomy containing information identifying tissue donors (iii) human tissue that is in the possession or control of the school of anatomy (e) assessment and management of human tissue (including skeletal materials) of unknown provenance (f) compliance with applicable workplace health and safety laws and regulations (g) receipt and handling of complaints about the operation of the school of anatomy (h) training and induction of school of anatomy personnel in all of the above (having regard to their role/participation in the operation of the school of anatomy) (i) monitoring compliance by those personnel with the above and responding to non-compliance. 	<p>Note: these proposed governance requirements are supplemented by additional proposed requirements about some of these matters, as set out in the following sections of this paper.</p> <p>Click or tap here to enter text.</p>
Insurance coverage is in place for the operation of the school of anatomy, to prompt identification and management of relevant risks	<p>(7) A requirement for each school of anatomy to have and document insurance coverage for its operations.</p>	Click or tap here to enter text.

Record keeping for schools of anatomy

Consistent and regulated record keeping is essential to ensuring transparency, accountability, and ethical standards in the handling of human tissue. Accurate documentation supports traceability across all stages of tissue collection, storage, use, and disposal and helps to ensure compliance with donor consent, uphold public trust, and facilitate compliance with legal and ethical obligations.

Objective	Proposed regulations	Feedback
<p>Schools of anatomy keep complete and accurate records, to support</p> <ul style="list-style-type: none"> • traceability • compliance with scope of authority and consent • safety 	<p>(1) A requirement for each school of anatomy to keep the following information on record, in relation to any tissue received and held by the school of anatomy:</p> <ul style="list-style-type: none"> (a) a unique identifier to be used for tracking and privacy purposes (b) description of the tissue (e.g. Whole body, knee joint, heart valve. Also, whether embalmed or fresh or plastinated) (c) copy or evidence of the consent to donation – permitted use, any conditions and, where available, disposal preferences (d) copy or evidence of all relevant legal authority under which the tissue has been accepted by the school of anatomy including, where applicable, quarantine and import permits and assessments, and the authority under section 32 or 33 of the Act (e) results of infection screening conducted in relation to the tissue (where applicable/available) (f) date on which tissue came into possession or control of the school of anatomy (g) date on which the tissue leaves possession or control of the of the school of anatomy (where relevant). 	<p>Click or tap here to enter text.</p>
<p>Schools of anatomy keep accurate and complete records of activity relating to use of human tissue, to support traceability and compliance with scope of authority and consent</p>	<p>(2) A requirement for each school of anatomy to keep an activity log relating to the use of all human tissue in its possession or control, to track the following, linked to the unique identifier(s) allocated to the tissue:</p> <ul style="list-style-type: none"> (a) time and date of each occasion the tissue was removed from storage (b) purpose of use or handling on each occasion (if teaching or study, include subject code; if research, include ethics committee approval number) (c) specific location where each instance of use or handling is predominately occurring (note that this may include use within the scope of the authorisation under section 35 but not on the specific premises nominated in the notice issued under section 35 and it is proposed that this would be captured in the activity log) (d) name and contact details of person physically responsible for body or tissue while being used or handled, on each occasion (e) time and date when use or handling was concluded and tissue was returned to storage (f) where tissue is transported, the details of the party commissioned to undertake that transport. 	<p>Click or tap here to enter text.</p>
<p>Schools of anatomy keep accurate and complete records relating to disposal of human tissue to support traceability and compliance with legal requirements</p>	<p>(3) For any human tissue disposed of by the school of anatomy, a requirement for the following information to be kept, linked to the identifier allocated to the tissue:</p> <ul style="list-style-type: none"> (a) the method of disposal (b) location of disposal (address of crematorium or other) and location after disposal (for example designated memorial site) (c) the date of disposal (d) the authorisation for the disposal, where relevant, including a copy of relevant documentation (e) details of the party who removed the tissue from the premises of the school of anatomy. 	<p>Click or tap here to enter text.</p>

Objective	Proposed regulations	Feedback
<p>Schools of anatomy keep complete and accurate records relating to the donation of human tissue, to support compliance with scope of consent, traceability, and management of safety</p>	<p>(4) A requirement for each school of anatomy that directly manages the consent and donation process – as opposed to sourcing tissue from a body donor program or third party (e.g. a local or overseas tissue bank) – to keep the following records in relation to each donation:</p> <ul style="list-style-type: none"> (a) death certificate of the donor including the cause of death (b) written authority for the taking of the donated tissue to a school of anatomy (e.g. under section 32 or 33 of the Act) (c) written donor consent for the intended use of the tissue, any donor terms or conditions to said consent, and any donor requests regarding disposal at the end of the permitted use (d) date on which the school of anatomy took possession of the tissue (e) unique identification number assigned to the tissue by the school of anatomy on receipt (f) infectious disease screening results relating to the tissue and (g) any quarantine or biohazard assessment and permit documentation issued by relevant Australian authorities in relation to the tissue. 	<p>Click or tap here to enter text.</p>
<p>Schools of anatomy keep complete and accurate records of tissue that moves between schools, to support traceability and compliance with scope of consent and authority</p> <p>Note this is intended to cover ‘lending’ and ‘borrowing’ activity, such as currently occurs principally through the body donor program operated by the University of Melbourne, as well as any other transfer of tissue between schools of anatomy. It is not intended that the Regulations will be prescriptive about which schools of anatomy can ‘lend’ and ‘borrow’</p>	<p>(5) A requirement for any school of anatomy that transfers tissue to another school of anatomy to keep the following information on record in relation to the tissue that is transferred:</p> <ul style="list-style-type: none"> (a) the name of the receiving school of anatomy (b) the unique identifier assigned by the transferring school of anatomy to the tissue transferred (c) a copy of the relevant permit held by the receiving school of anatomy under section 39 of the Act (if applicable) (d) date and time the tissue was removed from the premises of the transferring school of anatomy (e) date and time the tissue was received at the receiving school of anatomy (f) length of time tissue is to be kept at the receiving school of anatomy (if applicable) (g) date and time the tissue was returned to the transferring school of anatomy (if applicable). 	<p>Click or tap here to enter text.</p>
<p>Where tissue is transferred between schools of anatomy, relevant information is exchanged to support safety, traceability and compliance with scope of consent and authority. Privacy of donors is maintained to the extent possible through use of unique identifiers and de-identified information</p> <p>Note this is intended to cover ‘lending’ and ‘borrowing’ activity, such as currently occurs principally through the Body Donor Program operated by the University of Melbourne, as well as any other transfer of tissue between schools of anatomy. It is</p>	<p>(6) Where tissue is transferred from one school of anatomy to another, a requirement for transferring school to provide the receiving school with:</p> <ul style="list-style-type: none"> (a) de-identified copies of the relevant death certificate, written authority and donor consent documents (b) a unique identifier used by the transferring school in relation to that tissue (c) description of the tissue (e.g. Whole body, knee joint, heart valve. Also, whether embalmed or fresh or plastinated) (d) copy or evidence of the consent to donation – permitted use, any conditions and, where available, disposal preferences (e) results of infection screening conducted in relation to the tissue (where applicable/available) 	<p>Click or tap here to enter text.</p>

Objective	Proposed regulations	Feedback
not intended that the Regulations will be prescriptive about which schools of anatomy can 'lend' and 'borrow'	<p>(7) Where the transferring school of anatomy managed the consent and donation process directly, the documents referred to at paragraph 6(a) above would include:</p> <ul style="list-style-type: none"> (a) death certificate of the donor including the cause of death (b) written authority for the taking of the donated tissue to a school of anatomy (e.g. under section 32 or 33 of the Act) (c) written donor consent for the intended use of the tissue, any donor terms or conditions to said consent, and any donor requests regarding disposal at the end of the permitted use. <p>(8) It is intended that where necessary for the receiving school to manage disposal of the tissue in accordance with authorisations and donor consent, the information provided to the transferring school may include personal information and contact details of relevant individuals (for example the next of kin of the donor, who may be involved in disposal per the donor's consent and wishes), where disclosure is allowed under applicable privacy laws.</p>	
Unique identifiers are used by schools of anatomy to support traceability and operations while protecting privacy	<p>(9) A requirement for each school of anatomy to use unique identifiers as follows:</p> <ul style="list-style-type: none"> (a) when a body is received, a unique identifier is applied to the body as soon as practicable after physical receipt (b) when a body is divided into body parts, or tissue is removed from the body, each of those parts and each piece of tissue is assigned a unique identifier that is then linked in required records to the identifier for the body from which it is derived (c) when tissue received is not connected to a whole body also received, a unique identifier is applied <p>(10) For the avoidance of doubt, it is intended that in line with general privacy laws, storage, use and disclosure of personal information is limited to circumstances where it is reasonably necessary for the purpose of the operation of the school of anatomy and unique identifiers are otherwise used for the purposes of identifying and tracing and managing human tissue in the possession and control of the school of anatomy.</p>	Click or tap here to enter text.
Schools of anatomy records are kept secure from unauthorised access and deterioration, to protect privacy while allowing appropriate access for the purposes of managing traceability and compliance with other requirements	<p>(11) A requirement that the records kept by a school of anatomy must be physically and digitally secure, and that information collected in the course of the operation of the school of anatomy should be kept only in the physical and digital infrastructure of the school of anatomy (as opposed to in/at the physical or digital property of its personnel).</p> <p>(12) The department is considering whether to include a requirement for retention of records for a specified minimum period. Feedback is sought through this consultation process on the benefits and challenges of such a requirement and any suggestions on the minimum retention period.</p>	<p>Additional prompt question for schools of anatomy: How long do you currently keep records for and why?</p> <p>Click or tap here to enter text.</p>

Consent requirements – when donation is managed directly by a school of anatomy

Informed consent is the foundation for ethical treatment and use of donated human tissue. To support this, department considers there is an opportunity for the updated Regulations to include specific requirements for the consent obtained by schools of anatomy, where they manage the donation process directly. A prime example of the direct management of consent processes is the current body donor program operated by the University of Melbourne. It is not intended that the Regulations will be prescriptive about which schools of anatomy may manage consent directly and the requirements for consent that are set out below would apply to any school of anatomy that does manage the consent process directly.

Objective	Proposed regulations	Feedback
Donated human tissue is used in schools of anatomy only with free and informed consent and in accordance with the scope of that consent	<p>(1) A requirement that, where a school of anatomy directly manages the consent process for donation, any written consent obtained must include the following information:</p> <ul style="list-style-type: none"> (a) the purpose(s) for which the donor consents to their tissue being used (b) who can use the tissue (including if it can be transferred to other schools of anatomy) (c) any restriction or conditions on use (for example unrestricted, plastination, cultural or religious restriction, use within Victoria only, 3D print etc) (d) agreed period of use (time limited or otherwise, relates to uses above) (e) how (and where and by whom, where relevant) the body can be disposed of. <p>(2) Further examples of conditions, limitations or requests that a donor might include in their consent are as follows. Feedback is sought in this consultation process on how the Regulations might best support robust consent processes that reflect and record donor wishes on these and other relevant matters:</p> <ul style="list-style-type: none"> (a) consent to their bodies/tissue only being used for a limited time (b) consent to permanent display, but not at Open Days (c) request for final remains to be cremated and returned to family (d) request for person's name to be known by those using the body/tissues for study (e) limitation of body parts to be donated, for example exclusion of reproductive organs. 	<p>The department has heard in informal consultation that a standard form of consent would be valuable. Are there elements you think should be included in such a form that are not listed here?</p> <p>Click or tap here to enter text.</p>

Safe and respectful use of human tissue in schools of anatomy

In the absence of formal regulations about the operation and regulation of schools of anatomy, the department issued [Guidelines](#)² in 2015. These Guidelines have not been updated for some time and a recent anonymous survey of schools of anatomy highlighted a desire for clearer overall guidance that reduced the workload of trying to interpret the outdated Guidelines.

In any case, the absence of formal regulatory requirements has led to variation in practice in schools of anatomy which has allowed potential for schools of anatomy to operate unsafely, or have systems and practices that do not appropriately manage use of human tissue in line with the consent granted at point of donation, and otherwise in line with community expectations about respectful and ethical treatment of human tissue. In this regard the department notes that some communities may have particular experiences, expectations and practices relevant to donation and posthumous treatment of human tissue and human remains and is seeking to consider that diversity in developing the updated Regulations.

² The *Guidelines for the governance of schools of anatomy in Victoria* can be accessed on the department's website at: <<https://www.health.vic.gov.au/publications/guidelines-for-the-governance-of-schools-of-anatomy-in-victoria-october-2014>>.

Objective	Proposed regulations	Feedback
Use, handling and disposal of human tissue used in schools of anatomy is ethical and respectful, in line with legal requirements and community expectations.	<p>(1) A requirement that tissue in possession or control of the school of anatomy must be used, handled or disposed of in accordance with:</p> <ul style="list-style-type: none"> (a) authorisation under section 35 of the Act (b) donor consent and (to the extent known) wishes (c) any other applicable legal requirements. <p>(2) A requirement that tissue in possession or control of the school of anatomy must not be used for improper purposes such as:</p> <ul style="list-style-type: none"> (a) entertainment, (b) profit, (c) personal use, or (d) by unauthorised individuals. <p>(3) It is proposed that the requirement for respectful handling would apply whenever the tissue is in possession or control of the school of anatomy including when not on the premises specified in the notice issued under section 35 of the Act to authorise the operation of the school of anatomy.</p> <p>(4) It is intended that the requirements for respectful handling would apply to all use and handling of human tissue, including during:</p> <ul style="list-style-type: none"> (a) any public displays (b) open-day sessions and (c) arrangements for transport. 	Click or tap here to enter text.
Digital recording and social media are used ethically and respectfully in, and by, schools of anatomy.	<p>(5) A stipulation that use of digital recording devices (such as phones, cameras or videos) or social media within anatomy laboratories where bodies or tissue are present is not permitted unless authorised by the person in charge of the school of anatomy.</p> <p>(6) A further stipulation that if authorisation is granted by the person in charge of the school of anatomy, there must be conditions that the authorised person will not do any of the following with any images or representations they take/produce:</p> <ul style="list-style-type: none"> (a) include any identifying features of the deceased (b) transfer them into the public domain under any circumstances (c) reproduce or show them to non-current personnel (d) reproduce them in printing (2 or 3D) beyond the authorisation given (e) retain them beyond the term and purpose for which the authorisation was given or otherwise as permitted in the authorisation. 	<p>Additional prompt question: Given the rapid changes in technology, is there anything else you would suggest is included to try to future-proof the regulation? If yes, what?</p> <p>Click or tap here to enter text.</p>
Infection control and other biohazards are safely managed in, and by, schools of anatomy	<p>(7) A requirement that each school of anatomy must assess and document the infection control and biohazard risk associated with any human tissue in its possession or control (or coming into its possession or control). It is intended that this will include, as/when appropriate, reviewing quarantine assessments and permits and reviewing other screening results and medical history.</p> <p>(8) A requirement that upon first receipt, all bodies or human tissue must be securely stored in quarantine and must not be used or have any tissue removed until it is confirmed that it has passed screening.</p>	Click or tap here to enter text.
Privacy of donors is appropriately protected through use of unique identifiers, including after secondary prosecution	(9) As noted above in the record keeping section, it is proposed that where tissue is removed from a body in the course of the operation of the school of anatomy (secondary prosecution) the Regulations will require that school of anatomy to	Click or tap here to enter text.

Objective	Proposed regulations	Feedback
	assign a unique identifier to the tissue linked to the unique identifier for the body and track use of the tissue in its activity log, and ensure that use and disposal of the tissue is in accordance with applicable consents and authorisations etc.	
Schools of anatomy are supported to ethically and legally manage human tissue of unknown provenance	<p>(10) Requirements to assist schools of anatomy manage human tissue of unknown provenance, namely:</p> <ul style="list-style-type: none"> (a) Before accepting any human tissue (including skeletal) of an unknown or undocumented provenance, a school of anatomy must satisfy itself that it is acting consistently with the requirements of relevant legislation including the Cemeteries and Crematoria Act 2003, Coroners Act 2008, Aboriginal Heritage Act 2006 and Heritage Act 2017. This should include consultation with local police (or a forensic anthropologist directly) to have the remains cleared (for Aboriginality, heritage status or coronial interest) prior to acceptance by a school of anatomy for the purpose of teaching or study. (b) If accepting of human tissue of an unknown or undocumented provenance the school of anatomy must consider and document how the remains will be used for teaching or study. (c) Before accepting possession of human tissue of an unknown or undocumented provenance a school of anatomy must ensure it is accompanied by a statutory declaration made by the person donating the tissue that includes the following information: <ul style="list-style-type: none"> (iv) name and contact details of person making the donation (v) details on how, when and where they obtained the tissue (vi) any known history of the tissue 	Click or tap here to enter text.
Transport of human tissue to and from schools of anatomy is safe and respectful	<p>(11) A requirement that any school of anatomy undertaking or commissioning transportation of human tissue must ensure the transportation is done in a manner that:</p> <ul style="list-style-type: none"> (a) is safe, secure and reduces risk to public health or wellbeing including any requirements for medical waste and management of biohazard risk (b) allows for traceability of the tissues before, during or after transport (c) is in accordance with applicable quarantine laws, import licences and public health requirements regarding notifiable diseases, and any other laws applicable at the time of transport (d) is undertaken only by approved personnel or service providers acting under a written agreement that imposes terms and conditions consistent with the Act and Regulations. 	Click or tap here to enter text.
Transfer of tissue between schools of anatomy is safe and ethical	<p>(12) A requirement that before transferring the tissue the transferring school of anatomy must be satisfied that:</p> <ul style="list-style-type: none"> (a) the receiving school of anatomy has a permit to buy (if applicable) (b) the receiving school of anatomy is authorised under section 35 of the Act (c) transfer of the tissue to the receiving school of anatomy is consistent with the consent obtained. <p>(13) A requirement that before accepting the tissue, the receiving school of anatomy:</p> <ul style="list-style-type: none"> (a) must provide the transferring school of anatomy with a copy of a relevant permit to buy (if applicable) (b) must be satisfied that the proposed transfer and use of the tissue are consistent with the Act, the Regulations, the authorisation issued to the 	Click or tap here to enter text.

Objective	Proposed regulations	Feedback
	receiving school of anatomy under section 35 and any relevant permit issued to the receiving school of anatomy under section 39 of the Act.	
Offsite use and handling of human tissue is safe and ethical and consistent with the Act and Regulations	(14) For the avoidance of doubt, in relation to use of tissue that is within scope of an authorisation under section 35 of the Act but occurs outside the premises specified in the notice issued under section 35, it is proposed that the school of anatomy remain responsible for this tissue during such use. This includes that the record keeping requirements and respectful use and all other requirements in the Regulations apply in respect of that tissue while it is offsite and in the possession or control of the school of anatomy. Conversely, the requirements referred to in this document in relation to 'transfer' of tissue between schools of anatomy are not intended to proscribe offsite use where that is otherwise authorised and legal. Those transfer requirements relate to specific arrangements and activities where tissue is transferred between schools (e.g. 'borrowed' and 'lent' as part of a body donor program.)	Click or tap here to enter text.

Premises and equipment of schools of anatomy

The integrity and safety of practices involving human tissue rely heavily on the suitability of the physical environment and equipment used. Premises and equipment that are fit for purpose help ensure that tissue is handled, stored, and processed in ways that uphold ethical standards, minimise risk, and maintain quality. Inadequate infrastructure can compromise the dignity of donors, the reliability of outcomes, and the safety of personnel. Regulating the suitability of premises and equipment is therefore essential to support respectful, compliant, and high-quality practices across clinical, research, and educational settings

Objective	Proposed regulations	Feedback
School of anatomy premises and equipment are fit for purpose to support safe and ethical use of human tissue	<p>(1) The department is considering a requirement for the premises and equipment of each school of anatomy to be safe and fit for purpose and be maintained as such.</p> <p>(2) The requirement may refer to specific industry standards and guidelines, for example:</p> <ul style="list-style-type: none"> (a) AS/NZS 2982:2010 Australian and New Zealand Standard: Laboratory design and construction (b) AS/NZS 2243:3:2010 Australian and New Zealand Standard: Safety in laboratories (Section 5.3) (c) Requirements for the Facilities and Operation of Mortuaries (Third Edition 2013) National Pathology Accreditation Advisory Council (d) Safe Work Australia: Workplace Exposure Standards for Airborne Contaminants (2019) (e) NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia (2019) 	<p>Do you have feedback on applicability of the standards and guidelines listed, or others that are not listed</p> <p>Click or tap here to enter text.</p>

Reporting by schools of anatomy

Regulatory reporting requirements prompt schools of anatomy to review activities, manage risk, assess compliance and drive continuous improvement. In addition, notifications and reports submitted to the department support regulatory oversight and enforcement. By providing structured data and intelligence, such reporting enables the department to monitor compliance, investigate breaches, and uphold public trust.

Objective	Proposed regulations	Feedback
The department has up to date information on the person in charge of each school of anatomy, to support regulatory oversight	(1) A requirement for each school of anatomy to notify the department of any change in the person in charge of the school, no later than five business days after the change occurs, including the name and title of the new person in charge.	Click or tap here to enter text.
Schools of anatomy are promoted to record and manage adverse events proactively and consistently to mitigate and reduce impact and risk. The department receives notification of adverse events occurring in schools of anatomy to prompt engagement with reporting schools on risks and mitigation, and to inform regulatory monitoring and enforcement	<p>(2) A requirement to report each adverse event that occurs in a school of anatomy within five business days of the incident being known to the person in charge of the school. It is intended that the report include a description of:</p> <ul style="list-style-type: none"> (a) the incident and its impact (b) the action taken in response to the incident (c) actions implemented (or to be implemented) to prevent future recurrence of incidents of the same or similar nature. <p>(3) For the purpose of this reporting requirement the department is considering the following to be reportable events. Feedback is sought in this consultation process on the description and scope:</p> <ul style="list-style-type: none"> (a) matters that would constitute a breach of key regulatory and legal requirements, namely: <ul style="list-style-type: none"> (i) use of tissue other than in accordance with the applicable consent, authorisations or permits (ii) unauthorised access to or disclosure of information/records (iii) unauthorised access to tissue (iv) unauthorised access to secure areas on the premises. (b) any incident which is or is likely to be harmful to the health or wellbeing of the school of anatomy staff, students, personnel (c) loss or theft of human tissue that was in the possession or control of the school of anatomy (d) inconsistencies between recorded information held by the school of anatomy and the actual human tissue in the possession or control of the school of anatomy (e) conduct on the part of any school of anatomy personnel (including staff or students) that could reasonably be expected to be inconsistent with community expectations regarding ethical treatment of human tissue. 	Click or tap here to enter text.
Schools of anatomy are prompted to review and document key elements of their operations annually. The department has appropriate visibility of the operation of schools of anatomy, to inform regulatory monitoring and risk assessment	<p>(4) A requirement for annual reporting by each school of anatomy, to be submitted on or before 31 August of each year, covering the period 1 July of the previous year to 30 June of the reporting year.</p> <p>(5) The proposed content of the required annual report is as follows. Feedback is sought in this consultation process on the benefits and challenges associated with reporting this content.</p> <ul style="list-style-type: none"> (a) Information on human tissue received, stored, used, and disposed of by the school of anatomy during the reporting period including the following: <ul style="list-style-type: none"> (i) tissue received by the school, including description of tissue, source and date of receipt (note it is intended that in practice whole bodies and other tissue will be distinguished in some of this reporting but both will be covered) (ii) tissue transferred to another school of anatomy including description of tissue, name of other school of anatomy and date of transfer (iii) tissue received from another school of anatomy including description of tissue, name of other school of anatomy and date of receipt 	<p>Additional prompt question: Is 31 August each year a suitable reporting deadline for you, or do you foresee any issues?</p> <p>Click or tap here to enter text.</p>

Objective	Proposed regulations	Feedback
	<ul style="list-style-type: none"> (iv) ways in which tissue was used including removal of tissue from bodies or division of bodies, including purposes for which tissue was removed/divided (v) tissue disposed of including description of tissue, method and date of disposal (vi) details of any use authorised under the Act but occurring outside the premises of the school of anatomy (vii) details of human tissue received from interstate or overseas, including source, details of the tissue (e.g. whole body or part thereof, and whether fresh or embalmed), intended use, details of the cost recovery arrangement in place in relation to the import if any, and (intended) pathway of disposal (b) details of human tissue (including skeletal remains) of unknown or undocumented provenance that were offered to or accepted by the school of anatomy, including actions taken in response (c) a summary of complaints received by the school of anatomy – number, subject matter and status/outcome (note it is not intended that this requires reporting of any personal information) (d) any changes to membership or terms of reference of the governance committee for the school of anatomy (being the committee referred to in the Governance section above) (e) summary of any changes or updates to any of the policies and procedures that are required under the Regulations (f) details of any funds received or disbursed in recovery of reasonable costs associated with donation, handling and use of human tissue in the operation of the school of anatomy – source, date received, amount received, nature of the costs being covered. 	

Inspections of schools of anatomy

Inspections are a critical mechanism for ensuring that practices involving human tissue are conducted in accordance with established ethical, legal, and operational standards and requirements. Inspections provide an opportunity to assess compliance, identify areas for improvement, and reinforce accountability across institutions and facilities.

By systematically reviewing procedures, premises, equipment, and documentation, inspections help safeguard the dignity of donors, protect public confidence, and support continuous quality improvement. Embedding inspections within regulatory frameworks ensures that compliance can be effectively monitored, to help drive best practice in respectful and safe practices.

Objective	Proposed regulations	Feedback
Inspectors of schools of anatomy appointed under the Act are able to inspect school of anatomy premises and records and equipment, to provide regulatory oversight.	<ul style="list-style-type: none"> (1) A stipulation that an inspector appointed under section 36 of the Act may enter the premises of a school of anatomy at any time during ordinary hours of operation with the consent of the person in charge of the school of anatomy. (2) A requirement that the person in charge of the school of anatomy and the personnel (staff and students) of the school must provide reasonable assistance to the inspector in carrying out the inspection, including providing the inspector with access to any record that is required to be kept under the Regulations. 	Click or tap here to enter text.

Additional comments

Feedback

Do you have any other suggestions, comments or feedback on the current Regulations, proposed Regulations or broader reform issues?

Click or tap here to enter text.

To receive this document in another format, phone 03 9456 3838, using the National Relay Service 13 36 77 if required, or [email the Department of Health’s Legislative and Regulatory Reform Team](mailto:legandregreform@health.vic.gov.au) at <legandregreform@health.vic.gov.au>.

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In this document, ‘Aboriginal’ refers to both Aboriginal and Torres Strait Islander people.