Office of the Deputy Vice Chancellor (Research and Innovation)

13 January 2026

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

CREATE CHANGE

UQ Submission: Review of Human Tissue Laws - Discussion Paper

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Executive Summary

The University of Queensland (UQ) welcomes the opportunity to contribute to the Australian Law Reform Commission (ALRC) consultation on the Review of Australian Human Tissue Laws (the Review). As one of Australia's leading health and medical science research institutions, UQ strongly supports the Review, with special regard to the fact that this major review is the first in almost 50 years. We believe the Review presents a timely and much needed opportunity to enhance, update, and amend Human Tissue Acts across the country in order to create a consistent regulatory framework and to ensure best practice.

Our organisational submission is presented in two sections:

- The first section (pp 14-18, inclusive) comprises an in-depth response to the discussion paper, as prepared by **Professor Mark Midwinter and colleagues within UQ's School of Biomedical Sciences (Faculty of Health and Biomedical Sciences)**
    - Professor Midwinter outlines three perspectives within the discussion paper:
        - The School of Biomedical Sciences research perspective
        - The School of Anatomy research perspective; and
        - The legacy teaching tissue collections perspective.
- The second section outlines collated individual researcher perspectives from across the organisation to specific reform proposals and questions outlined in the discussion paper.

UQ is committed to supporting the efforts of the ALRC, and the consultation process in general. We commend the Government's initiation of this timely Review, and look forward to continued engagement with the Commission as they gather insights from stakeholders, and in advance of the release of the report to be delivered to the Attorney-General in August 2026.

Section 1: UQ School of Biomedical Sciences - In-depth Response

Submission to the Australian Law Reform Commission Review of Human Tissue Laws

Prepared by Professor Mark Midwinter

School of Biomedical Sciences

The University of Queensland

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Introduction

This submission is made by the School of Biomedical Sciences (SBMS) at the University of Queensland. SBMS is a major research and teaching organization that:

- Conducts extensive biomedical research, including studies using human tissue from living donors (blood specimens, biopsies, and other tissue samples)
- Operates research biobanks and tissue collections
- Delivers comprehensive anatomical education to science, medical, dental, and allied health students as well has continuing professional development courses
- Houses the School of Anatomy (SoA), which manages body donation programs, anatomical teaching facilities and supports research
- Delivers comprehensive pathology education to science, medical and allied health students
- Houses several legacy tissue collections used in teaching histology, pathology and anatomy, which are also available in digital form
- Engages a substantial number of community groups through tours and programs of the human pathology collection.

Scope of This Submission: This submission addresses the Discussion Paper from three interconnected perspectives:

Part A – SBMS Research Perspective: Issues relating to research using human tissue from living donors, biobanking, and tissue collections relevant to our broader research activities

Part B – School of Anatomy Perspective: Specific issues relating to body donation, anatomical education, and the operation of Schools of Anatomy within the broader regulatory framework

Part C – Legacy Teaching Tissue Collections Perspective: Issues relating to the pathology, histopathology and histology collections, their uses in education, and digitisation to a global audience.

General Comments

We welcome the Australian Law Reform Commission's comprehensive review of human tissue laws and the proposals to modernise and harmonise these important regulations. We note that Chapter 15 confirms that regulation of Schools of Anatomy is not being considered beyond the proposals directly related to the Human Tissue Acts. While this acknowledgment is noted, we would stress the need to address a wider national-level review of the regulatory framework for modernisation and harmonisation of Schools of Anatomy regulation. Additionally, in Queensland regulation of SoA is under the HTA - Transplantation an Anatomy Act, 1979. Hence changes to the HTAs (which we broadly welcome) materially impact SoA. Legacy teaching tissue collections do not currently have as extensive regulation as the SoA, and changes to HTA would also materially impact those.

PART A: SBMS Research Perspective

Research Using Human Tissue from Living Donors and Biobanking

1. Research on Blood and Tissue from Living Donors (Chapter 8)

As a major biomedical research organization, SBMS regularly conducts research using human tissue donated by living individuals, including blood specimens, biopsies, cheek swabs, and other tissue samples. We welcome the comprehensive approach taken in Chapter 8 to address these research activities. The current regulatory framework creates unnecessary barriers to important medical research while the proposed reforms would provide much-needed clarity and flexibility.

1.1. Current Problems with Tissue Type Distinctions (Sections 8.9, 6.2-6.3)

The Discussion Paper correctly identifies that current HTAs create artificial and scientifically outdated distinctions between regenerative tissue, non-regenerative tissue, and blood. Many jurisdictions only allow adults to donate non-regenerative tissue or blood specifically for research, which creates barriers that are 'out of step with contemporary research uses of tissue.'

Key Issues Affecting Our Research:

- The regenerative/non-regenerative distinction no longer correlates with actual medical risk
- Restrictions on tissue types prevent valuable research that poses minimal risk to donors
- Scientific value of tissue is unrelated to whether it regenerates
- Current restrictions create uncertainty for researchers and impede paediatric research particularly.

1.2. Support for Proposals 32-34: Adult Consent for Research Tissue

Response: We strongly support **Proposals 32-34**, which establish a modern, flexible framework for research using tissue from living donors. These proposals are essential for enabling SBMS to continue our important research activities while maintaining the highest ethical standards.

This balanced approach legitimises broad consent (essential for biobanking) while respecting participant autonomy through ongoing information access and withdrawal rights. This addresses the ethical concern that 'consent is treated as a static event achieved at a single point in time' rather than 'an ongoing process that should be maintained' (Section 8.7).

Proposal 34 provides the critical safeguard by requiring compliance with the Australian Code for the Responsible Conduct of Research and the National Statement on Ethical Conduct in Human Research (2025). This ensures that:

- Research with higher participant risk receives more scrutiny from ethics committees
- Restrictions are proportionate to actual risk rather than categorical tissue types
- The framework remains flexible and responsive to medical developments
- Ethical standards are maintained without imposing disproportionate barriers.

1.3. Support for Proposal 35: Children's Tissue for Research

Response: We support Proposal 35, which adopts the Tasmanian model [section 22B of the Human Tissue Act 1985 (Tas)] for paediatric tissue donation.

As noted in Section 8.20-8.23, paediatric research currently faces significant barriers due to inconsistent state and territory regulations regarding blood, biopsy material, cheek swabs, and tumour cells from

children. The Tasmanian model provides a nuanced approach that protects children while enabling important research by requiring:

- Ethics committee approval in accordance with the Australian Code for the Responsible Conduct of Research, 2018, and National Statement on Ethical Conduct in Human Research (2025)
- Appropriate consent/assent per the National Statement
- **And** that either: (a) research benefits the child, (b) removal occurs during beneficial procedure without health prejudice, or (c) removal involves negligible/low risk and minimal discomfort.

1.4. Question 28: Adults Without Decision-Making Capacity

Response: Yes, new human tissue legislation should contain provisions similar to Proposal 35, that allow tissue removal from adults without decision-making capacity for research, with appropriate safeguards.

In the acute clinical setting (emergency care or intensive care, for example), recognition of low risk research (as defined in National Statement, 2025, section 2.1), there should be provision for sampling (e.g. blood, tissue fluids, minimally invasive measurement) with *'agreement to continue'* participation (National Statement, 2025, section 4.5.16).

Recommended Safeguards:

- Ethics committee approval required in accordance with the Australian Code for the Responsible Conduct of Research, 2018 and National Statement on Ethical Conduct in Human Research (2025)
- Consent from appropriate substitute decision-maker per guardianship/advance care directive framework
- Assessment that research may benefit the person or their medical condition
- If removal during therapeutic procedure, medical practitioner satisfied it won't prejudice health
- If not directly beneficial, removal must involve negligible/low risk and minimal discomfort
- Respect for any known prior wishes of the person (from advance care directives or other sources)
- 'Agreement to continue participation' for acute care setting with low-risk research.

These safeguards balance the importance of research on conditions affecting adults with limited capacity (enabling research that may directly benefit similar populations) while preventing exploitation and maintaining ethical protections.

2. Regulation of Stored Tissue Collections (Chapter 10)

SBMS maintains research biobanks and tissue collections for ongoing research activities. Clear regulatory oversight of these collections is essential for maintaining public trust and ensuring ethical operations.

2.1. Question 31: Legal Rules for Research Biobanks

Response: Yes, legal rules are needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks.

Rationale: The current gap in direct legal oversight of research tissue collections creates:

- Inconsistency in governance standards
- Uncertainty about storage and disposal requirements

- Potential risks to donor interests and public trust
- Barriers to collaborative research across institutions.

2.2. Question 32: National Regulation and Oversight

Response: Yes, to both parts (a) and (b). National regulation, guidance, and oversight would be beneficial for:

a) Research tissue collections / biobanks that store and/or distribute human tissue or human bodies

b) Educational collections of human tissue (including anatomical collections within Schools of Anatomy).

Benefits of National Oversight:

- Consistent standards across jurisdictions
- Clear accountability mechanisms
- Transparency in operations
- Enhanced public trust
- Facilitation of inter-institutional collaboration
- Protection of donor interests.

2.3. Question 33: Specific Regulatory Requirements

Aspects requiring regulation:

- Consent processes and documentation
- Storage conditions and security
- Access protocols and authorization procedures
- Transfer procedures between institutions
- Disposal methods that respect cultural and ethical considerations
- Record-keeping and traceability requirements
- Quality standards for tissue preservation
- Transparent reporting of tissue sources and uses
- Regular auditing and compliance verification.

Types of collections to be regulated: All types of human tissue collections should be equally regulated, whether sourced from living persons, deceased persons, donated specifically for research, donated for educational purposes, stored in Schools of Anatomy, held in research biobanks, or maintained in pathology collections. There should be no regulatory distinction based on the source or original purpose of collection. Consistent regulation ensures ethical standards apply universally.

Collections that should not be regulated: No. We cannot identify any category of human tissue collection that should be exempt from appropriate regulation. All human tissue collections involving storage, research use, or educational use should be subject to ethical oversight and regulatory standards.

3. Prohibition of Trade in Human Tissue (Chapter 11)

3.1. Question 40a: Prohibition of Tissue Obtained Without Consent or for Profit

Response: Yes, we strongly support prohibitions on the use of human tissue where:

Tissue obtained without donor consent:

- This is fundamental to ethical practice
- Protects human dignity and autonomy
- Maintains public trust in research and medical education.

Tissue obtained in exchange for reward or profit:

- Aligns with international norms (Declaration of Istanbul, WHO Guiding Principles)
- Prevents exploitation and coercion
- Avoids commodification of human tissue.

3.2. Cost Recovery Framework

Payment for sourcing human tissue should be strictly limited to **'cost recovery' charges only**, as specified in the HTAs. This should include:

- Reasonable expenses for tissue retrieval
- Processing and storage costs
- Distribution and administrative costs
- Quality control and safety testing.

Critical Requirement - Donor Consents - All imported human tissue must be accompanied by:

- Documentation of donor consent
- Evidence of ethical procurement practices
- Verification of compliance with source country regulations
- Transparency about the tissue source and donation circumstances.

Rationale (Reference to 11.73): Given Australia's reliance on imported tissue, it is essential to ensure that imported tissue was ethically obtained with proper consent, does not involve exploitation or coercion, meets Australian ethical standards, and maintains public trust in the tissue supply chain.

Oversight and Transparency: We support proposals for:

- Clear guidance from the National Regulator on what constitutes legitimate cost recovery (Proposal 44)
- Oversight mechanisms to ensure tissue banks operate ethically
- Transparent reporting of tissue sources, costs, and distribution
- Regular auditing to prevent profiteering while ensuring sector sustainability.

PART B: School of Anatomy Perspective

Body Donation, Anatomical Education, Anatomical Research and Schools of Anatomy Operations

Given, in Queensland, regulation of SoA is under the HTA (*Transplantation and Anatomy Act, 1979*) and changes to the HTA (which we broadly welcome) will materially impact SoA, we are submitting comments where we consider this may occur.

The School of Anatomy, as a sub-organisational unit within SBMS, manages body donation programs and provides anatomical education. The following sections address specific concerns relating to the operation of Schools of Anatomy under the proposed regulatory framework.

4. Concerns Regarding the Proposed 'Authorised Decision Maker' Hierarchy

Issue: The Discussion Paper proposes adapting the definition of 'senior available next of kin' (SANOK) to an 'authorised decision maker' model that mirrors the hierarchy set out in section 13 of the Health Care Decision Making Act 2023 (NT).

While we acknowledge the intention to maintain consistency across all health decision-making contexts (for both living and deceased persons), we have significant concerns that this proposed hierarchy could unnecessarily complicate certain donation scenarios that the current SANOK hierarchy effectively protects against.

4.1. Current SANOK Hierarchy

The existing framework prioritizes decision-makers in a clear order:

1. Spouse/partner
2. Children
3. Parents
4. Siblings
5. Personal representative (friend/executor, etc.) if none of the above are available.

4.2. Concerns with the Proposed Hierarchy

The proposed hierarchy appears to rank an Enduring Power of Attorney (EPOA) or similar appointee as having superior authority. This creates several problematic scenarios for body donation acceptance:

Legal Status After Death: In Queensland (and other jurisdictions), an EPOA ceases upon death, with the Executor of Will assuming power for estate matters. If donation decisions follow this rank of authority, it could create unnecessary complexity in establishing who has consent authority.

Potential Conflict Scenarios:

- A solicitor acting as executor would have power over a spouse or child
- A child acting as EPOA/executor having authority over a spouse (particularly problematic in cases of second marriages where family politics may be sensitive)
- A friend acting as executor having authority over family members and children

Practical Implications for School of Anatomy: These scenarios could create significant difficulties in donation acceptance and potentially expose the institution to disputes or adverse publicity. The current SANOK hierarchy generally reflects natural family relationships and expectations about who should make decisions regarding body donation, reducing the potential for conflict.

Recommendation: We recommend maintaining a hierarchy that prioritises immediate family relationships (spouse, children, parents, siblings) before appointed representatives for donation decisions. Alternatively, if the proposed hierarchy is adopted, clear guidance should be provided on how to manage scenarios where appointed representatives and family members disagree, with a presumption in favour of family wishes where there is objection.

5. Institutional Risk Management and Family Objections

Principle: The School of Anatomy operates under a fundamental principle that institutional reputation and respect for family wishes must be paramount in donation decisions.

Our Position: We would never accept a body donation from an 'authorised decision maker' if we knew that a senior available next of kin or other close family member objected to the donation. We would always err on the side of caution to:

- Avoid any possibility of placing the institution at risk of adverse publicity
- Respect the wishes and grief of close family members
- Maintain public trust in the body donation program
- Prevent potential legal disputes or media scrutiny
- Maintain social licence to operate.

This conservative approach is essential for maintaining the integrity and public confidence in anatomical donation programs, which depend entirely on voluntary, altruistic donations made in an atmosphere of trust and respect.

Implication for Proposed Reforms: Any new regulatory framework should:

- Explicitly permit institutions to decline donations where there is family objection, regardless of technical legal authority
- Provide clear guidance on managing conflicting wishes between appointed decision-makers and family members
- Recognize that institutional discretion to refuse donations is a necessary safeguard.

6. Support for Harmonised Framework and the Voice of Anatomists

We strongly support **Proposals 1-4 (pp. 9-11)** establishing a nationally harmonised regulatory framework for human tissue. This harmonisation would benefit both SBMS research activities and the School of Anatomy operations.

6.1. Critical Role of Anatomists in Regulation

We particularly emphasize that anatomists' practical expertise is important for shaping functional regulations. Anatomists possess specialized knowledge about:

- The practical requirements for tissue preservation and storage.
- Educational and research needs for anatomical specimens.
- Ethical handling and respectful treatment of donated bodies.
- The balance between maximizing educational value and maintaining donor dignity.

Recommendations Related to Proposals 28 and 29 (p. 84): The proposed reforms should include:

- Formal consultation mechanisms with anatomists and Schools of Anatomy in regulatory

development.

- Representation of anatomists on any National Regulator or advisory bodies.
- Recognition that anatomical sciences education and research serve essential public interests in training healthcare professionals
- Regulatory frameworks that respect donor dignity while enabling effective anatomical education and maintain social licence for Schools of Anatomy operating under HTA.

7. Anatomical Collections: Material Provenance and Consent

Key Principle: An important opportunity exists for Schools of Anatomy within SBMS to participate in creating or contributing to tissue collections / biobanks with material of known provenance and known medical history.

Regulatory Consistency Required: There should be no regulatory difference between tissues donated to Schools of Anatomy, material obtained from research biobanks, other educational collections (e.g., pathology collections), or any other source of human tissue for research or education.

7.1. Requirements for Material

New Material:

- Consent must always be fully informed.

Documentation must be comprehensive and maintained.

- Provenance must be clearly established and recorded.

Legacy Collections:

Known Provenance Material:

- Should have accompanying consents where practicable
- Historical documentation should be maintained and updated where possible
- Clear records of donor identity and consent history.

Unknown Provenance Material:

- Must be clearly marked as such
- Should include documentation of what information is available
- May have restricted uses depending on the absence of consent documentation.

7.2. Indigenous Material - Critical Requirements

Any material that may be Indigenous or potentially Indigenous must be:

Immediately Identified and Segregated:

- Removed from general collections
- Stored separately and securely
- Kept out of public view.

Properly Reported:

- Through the Coroner's Office
- Through the Department of Women, Aboriginal and Torres Strait Islander Partnerships and Multiculturalism (DWATSIPM) or equivalent state bodies

- For assessment and cultural determination.

Repatriation Priority:

- Repatriation to appropriate communities should be pursued where possible
- Cultural protocols must be strictly observed
- Community consultation is essential.

If Repatriation Not Immediately Possible:

- Material should be kept in an appropriate 'keeping place'
- Maintained with appropriate cultural respect
- Held pending final determination on ethical disposal
- Disposal must accord with cultural sensitivities and First Nations advice.

Alignment with National Policy: These requirements align with the Australian Government's policy on Indigenous repatriation and the Declaration on the Rights of Indigenous Peoples (Article 12), recognizing the right of Indigenous peoples to repatriation of their human remains.

8. Integration: Research Regulations and Anatomical Education

The proposals regarding research tissue from living donors (Part A) have important implications for how anatomical education and Schools of Anatomy operations should be regulated under the new framework.

8.1. Clarification Needed: Definition of 'Research' in Anatomical Context

Issue: The proposals focus on research use of tissue from living donors, but it is unclear whether 'educational uses' of donated bodies at Schools of Anatomy are considered 'research' under **Proposals 32-35.**

Educational uses at Schools of Anatomy include:

- Gross anatomy teaching for medical, dental, allied health, and science students
- Surgical / medical specialties skills training and technique development
- Clinical research using anatomical specimens
- Development and testing of medical devices
- Creation of preserved specimens for ongoing educational collections.

Recommendation: The final legislation should clarify that the expanded purposes ('medical, educational, and scientific purposes') encompass all legitimate anatomical education and research activities conducted by Schools of Anatomy. The consent framework should recognize that donors who consent to body donation to a School of Anatomy understand their donation will be used for the full spectrum of anatomical education and research.

8.2. Application of Broad Consent Principles to Body Donation

The principles in **Proposal 33** regarding broad/unspecified consent are highly relevant to body donation for anatomical purposes. When individuals donate their bodies to Schools of Anatomy, they typically provide broad consent for educational and research purposes without knowing the specific uses. The Discussion Paper's approach to broad consent (Sections 8.12-8.18) recognizes this is ethically appropriate when donors are informed about general types of uses, ongoing physical risk is minimal, and compliance with ethical standards is maintained.

Recommendation: The regulatory framework should explicitly recognize that broad consent for body donation to Schools of Anatomy is ethically appropriate and legally valid, provided donors are informed about the general nature of anatomical education and research uses.

8.3. Compliance and Enforcement (Question 45)

For Schools of Anatomy:

- Licensing system with regular audits by National Regulator (or alternative)
- Enforceable undertakings appropriate for documentation or procedural deficiencies
- Graduated sanctions: warnings, improvement notices, fines, suspension of operations, license revocation
- Criminal penalties reserved for deliberate misuse, commercial exploitation, or gross disrespect for donors.

The compliance framework should be proportionate and recognize that Schools of Anatomy generally operate with high ethical standards. The focus should be on maintaining social licence and public trust through transparency and accountability rather than punitive measures for minor administrative lapses.

Part C: SBMS Legacy Teaching Tissue Collections Perspective

9. Teaching using Tissue from Humans in Stored Tissue Collections (Chapter 10)

As a core function, SBMS continuously teaches using human tissue in Legacy Teaching Tissue Collections. There are three related collections: histological and histopathological samples (microscopic) and macroscopic pathology specimens. These legacy collections have been collected and used in teaching for over a century. Currently, there is little regulatory framework that is directly applicable to these collections, or provides guidance for future tissue collections, so we welcome this discussion. An important consideration in this setting is providing and enforcing appropriate ethical standards for students relating to the use of tissue for teaching and learning, which is consistent with both the School of Anatomy, and research. We submit the following comments for the questions posed in chapter 10.

9.1. Exceptions to the need for consent (Question 27)

Response: Yes, there should be a need for consent, even for small samples, for tissues collected under new regulatory frameworks. However, there should be exceptions to this for already collected material within legacy collections.

Rationale: Even small samples contain potentially personally identifiable genetic information, and it would be difficult to justify an arbitrary division that allowed differential treatment of differently sized parts of a human body.

However, imposing a requirement for a need for consent onto already collected Legacy collections would create a significant barrier to our ability to teach students, as there are no alternative materials available, and replacing existing materials with consented and provenance newly collected materials would take significant time.

Therefore, we propose that there should be an exception to the need for consent for materials that were collected previously into Legacy Collections, with an overall aim to replace non-consented or non-provenance materials. Non-consented materials should be treated in a dignified and ethical manner, as far as possible the same as consented materials, with information about the lack of consent or provenance readily available when they are used.

There should, however, be strong support for continuing effort into establishing provenance for these collections and establishing a community of care to assist with their management.

9.2. Questions 29 and 30: Requirement to obtain consent before use for a non-consented purpose

Response: Yes, there should be a need for consent, where it is practical and possible to obtain such.

Rationale: Legacy collections may contain material that is decades or centuries old, and seeking consent for further uses may not be possible if the donors or originators of tissue are deceased.

Additionally, consent may have been sought for a broad category of activity, such as teaching, without requiring individual teaching activities to obtain new consent. Such a requirement might impose undue burdens on the donor.

If a new activity could reasonably be considered to fall under categories for which consent has already been obtained, then it could be exempted from a requirement to obtain consent specifically for that activity. However, if a new activity does not reasonably fall under an existing category for which consent has already been given, the proposed activity may lead to personally identifiable information being discovered or released (and a donor has not consented to this) and a donor is still alive and able to give informed consent, then this should

be sought use for a non-consented purpose. This legitimises broad consent (required for teaching) and also respects donor autonomy, whilst minimising potential burdens on the donor.

If a donor is deceased, or not capable of giving informed consent, then use of this tissue in non-consented activities should be handled as proposed for research setting (Section 1.4 Question 28: Adults without Decision-Making Capacity).

9.3. Question 32: Regulation of Stored Tissue Collections

Response: Yes, it would be beneficial to have national regulation, guidance and oversight for educational collections of human tissue. Storage conditions should be guided by the ten agents of deterioration which are the core components of preventive museum conservation. They include physical forces, thieves and vandals, fire, water, pests, pollutants, light, incorrect temperature, incorrect relative humidity, and dissociation (or custodial neglect).

Rationale: Increasingly, human tissue is digitised, and digital files are shared on platforms that have national (and international) access. Partly this is because not everywhere has access to human tissues for teaching. However, a current lack of national regulation means that this area does not have oversight or guidance for best ethical practice, and competing regulations between states and territories make it difficult to ascertain what should be done.

As for the physical tissue, preventive conservation measures established by museums will be applicable to such collections. These allow for a holistic understanding of the broad physical environment in which such tissue should be maintained.

9.4. Question 33: What should be regulated?

Response: All aspects of tissue collection, storage, use, transfer and disposition for tissue collected under new regulations should be regulated to create a coherent and respectful environment for the use of human tissue, regardless of use. Legacy Collections may need to be exempted from some regulations. Digital collections should be specifically included in this regulation.

Rationale: Legacy Collections would need to be exempted from some of the regulations, as they will not be able to fully adhere to the same conditions as tissue collected with consent and provenance. However, as far as possible, all human tissue should be treated similarly.

A national framework would permit more digital resource-sharing between institutions in Australia, particularly for access for students in regional and rural areas, who use digital collections, and who otherwise may not be able to access physical collections.

Digital collections also raise separate issues of collection, storage, use, transfer and disposal, and a person's tissue may continue to exist in digital form after the physical tissue has been disposed.

9.5. Question 34: Accessing stored tissue

Response: Yes, with some restrictions.

Rationale: Australia is a multi-cultural society. Cultures differ in what they consider the ethical and respectful treatment of materials that originate from persons, and this should be reflected in the regulation of tissue, rather than applying a western secular approach globally. A person may consent for the use of their tissues for teaching whilst alive but may wish for all parts of their body to be buried together at death, in which case a family, friends or a community may seek to have the tissue returned.

A person may withdraw consent for use of their tissues and may seek to have those tissues returned to them, rather than disposed.

A person may separately consent or not consent for use of the physical and digital forms of their tissue.

Tissues may also originate from communities where the donor or their next of kin is no longer alive, but the community seeks the return of the tissue.

However, the processing that occurs for human tissue stored in legacy collections often involves hazardous chemicals. Additionally, human tissue poses biological risks. These risks must be managed

appropriately if tissue is returned to a donor, or the donors family or friends, and should be made clear when a person is consenting. The option of disposition should be offered.

Digital forms of tissues are extremely difficult or impossible to recall or remove, once they have been released, and the near impossibility of recalling all images should also be made clear during consent.

Conclusion

We commend the ALRC for undertaking this comprehensive review of human tissue laws. Harmonisation and modernisation of these laws is overdue and will provide significant benefits for research, education, and public health. We welcome many of the proposals put forward.

From both the SBMS teaching research perspective (including the School of Anatomy within SBMS), we emphasize the importance of regulation of SoA under the HTA [*Transplantation and Anatomy Act, 1979 (Qld*)] and changes to this (which we broadly welcome) could materially impact SoA. Our major areas of comment in the proposals relate to:

1. Removing arbitrary tissue-type restrictions while maintaining proportionate ethical safeguards for research
2. Legitimizing broad consent for biobanking, tissue collections and body donation with appropriate donor protections
3. Establishing comprehensive regulation of all tissue collections with national oversight
4. Maintaining a donation hierarchy that reflects family relationships and minimizes conflict
5. Protecting institutional discretion to decline donations where family objections exist
6. Including the expertise of anatomists in regulatory development
7. Respecting Indigenous cultural rights and prioritizing repatriation efforts
8. Ensuring ethical procurement standards for all human tissue

We stand ready to engage in further consultation and to provide additional input as the review progresses toward final recommendations. Both SBMS and its School of Anatomy have essential expertise to contribute to creating a regulatory framework that balances innovation in research and education with respect for donors, ethical practice, and public trust. We respectfully submit this response for your consideration.

On behalf of:

School of Biomedical Sciences, The University of Queensland

Ends

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Section 2: Collated responses from individual UQ researchers

National Legislative Framework

Proposals 1–3 seek to address fragmentation in the regulation of human tissue through legislative harmonisation, and the establishment of a National Regulator with strong standard-setting and enforcement powers. This approach is appropriate insofar as the use of human tissue can be understood in terms of discrete acts of retrieval, storage, and use; and governed through obligations, prohibitions, and compliance mechanisms.

However, one of the central practical questions surrounding human tissue relates to how it is preserved, organised, and made usable for research once it is removed from the body. It is in this context that biobanks become key institutional actors. Based on empirical observation of biobanking practices in hospital-based research settings, the circulation of tissue relevant to research does not take the form of a single act of exchange, but of a sequence of technical and organisational processes that largely fall outside this regulatory framing. In Australia, as in many other countries, biobanks are embedded within hospitals and health services and function as long-term research infrastructures rather than sites of one-off tissue transfer.

The scientific value of tissue held in biobanks is therefore not realised at the moment of donation or retrieval, but through extended processes of classification, preservation, prioritisation, and controlled access over time. Tissue acquires research value only through a chain of practices: extraction under specific conditions, pathological classification, freezing and storage, and subsequent allocation to research projects. Each of these steps contributes to stabilising tissue as a scientific resource and enables its circulation within research systems.

These processes are organised through institutional and relational arrangements that shape who gains access to samples, under what conditions, and with what cumulative scientific and reputational benefits. In practice, access is typically not determined solely by formal eligibility or regulatory compliance, but by researchers' institutional positioning, existing collaborations with clinicians and pathologists, alignment with priority research agendas, and prior records of scientific productivity. Importantly, such dynamics do not readily take the form of legal entitlements, rights, or prohibitions, nor are they easily governed through licensing, codes of practice, or enforcement alone. As a result, they seem to fall largely outside the regulatory language outlined Proposals 1–3.

This is not a flaw of the proposed framework, but a structural limitation of law. Legal regulation cannot, and should not, govern the internal organisation of research or the distribution of scientific credit—that is, recognition accrued through authorship, publication output, grant success, and the consolidation of research trajectories over time. Nevertheless, in the context of biobanking, where tissue circulation is deeply embedded in research infrastructures and incentive structures, this limitation may have significant practical consequences.

A further concern relates to the audience implicitly addressed by the proposed framework. As currently articulated, the proposals rely heavily on abstract legal categories and enforcement-oriented language. While appropriate for legislative drafting, this framing risks limiting the intelligibility of the regulatory framework for those most directly involved in the day-to-day management and use of human tissue, including scientists, clinicians, and biobank personnel. Given that biobanking governance depends critically on how such stakeholders interpret and operationalise regulatory expectations, a framework that remains largely legible only within legal and regulatory domains may inadvertently widen the gap between formal regulation and practice.

The objects of human tissue laws

Question 1 - Do you agree with the objects listed in Proposal 5 for human tissue legislation?

While the objects set out in Proposal 5 address important ethical and regulatory concerns, they do not fully capture how human tissue is currently used and valued in contemporary research settings, particularly in relation to biobanking.

The objects place significant emphasis on donation as a voluntary and autonomous act, and on the prevention of exploitation at the point of tissue removal. However, a substantial body of scholarship has shown that donation often occurs in contexts of structural asymmetry, including clinical dependency, vulnerability, and unequal distributions of knowledge and power (Titmus 1970; Frow 1997; Rodriguez 2023). In such settings, the assumption of fully free and disinterested consent warrants closer scrutiny. In addition, while Proposal 5 (Object D) refers to promoting equity and reducing inequities in access to human tissue and its benefits, it does not acknowledge that access to tissue in biobanks is mediated through institutional, organisational, and professional arrangements. These arrangements shape who is able to use tissue for research, whose projects are prioritised, and how scientific benefits are accumulated over time.

As a result, the proposed objects risk remaining disconnected from the practical realities of tissue circulation and use in biobanking. Without recognising these dynamics, the legislation may continue to lag behind the practices it seeks to govern, despite its stated aim of modernisation.

Question 2 - Aside from the objects set out in Proposal 5, should new human tissue legislation include other objects?

Yes. In addition to the objects set out in Proposal 5, new human tissue legislation should include objects that explicitly recognise:

- the social, clinical, and institutional contexts in which tissue donation occurs, including patient vulnerability and power asymmetries both at the point of clinical encounter and within research settings, across disciplines and institutional hierarchies
- the role of biobanks as long-term research infrastructures through which tissue circulates and scientific value is produced over time; and
- the importance of organisational and governance arrangements in shaping access to human tissue and the distribution of benefits arising from its use.

Incorporating such objects would not require the legislation to regulate the internal organisation of research. Rather, it would provide a more accurate and transparent account of the conditions under which human tissue is used in contemporary medical and scientific practice, and would support the stated aims of equity, trust, and modernisation.

Removing barriers and promoting equitable access to human tissue

Question 3 - Is there a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use?

There is a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use. However, equitable access operates across different spheres and should not be understood solely in terms of donor participation or access to clinical benefits. Alongside population-level and cultural considerations, equitable access is also shaped by how scientific and translational research practices function in everyday institutional settings, including how access to samples is prioritised, negotiated, and sustained within research infrastructures.

While legislation cannot determine how human tissue will ultimately be used, a framework that relies primarily on abstract prescriptions about how systems ought to operate risks leaving persistent blind spots. In practice, access to human tissue is often organised through institutional arrangements and professional practices that can produce uneven access to biological samples even in the absence of formal legal barriers. If these practical dynamics are not acknowledged, commitments to equity may be difficult to realise in practice, despite being clearly articulated in law.

Question 4 - If there is a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use (Question 3), what are the specific barriers that new human tissue legislation needs to address?

In considering barriers to equitable access, it is important to distinguish between equity at the point of donation or transplantation and equity in the subsequent use of human tissue. While existing legal frameworks focus primarily on consent, representation, and fairness in donation and transplantation processes, patterns of access to human tissue for research and related purposes are shaped at a later stage, when human tissue is stored and made available for use within institutions. At this stage of implementation, access is often determined by institutional control over collections or repositories of human tissue and by reliance on established professional networks, rather than by transparent or system-wide criteria.

For example, where patients consent to the storage of human tissue within institutional repositories as part of routine clinical care, subsequent access to that tissue for research purposes may be limited to specific institutional units or research groups, even where other ethically approved research projects address the same condition. If new legislation does not take these mechanisms into account, inequities may persist at the level of use, even where equity is achieved at the level of donation and transplantation, thereby undermining the broader objectives of the legislative framework.

Reforms related to the donation of tissue by living persons

Proposal 14

This proposal is framed around consent to the removal of human tissue for specified purposes, including medical, educational, or scientific use. This formulation appears to assume that tissue removal for research typically occurs through a distinct donation process, in which consent is sought specifically and primarily for that purpose. However, in many contemporary health and research settings, human tissue later used for research is not obtained through procedures performed for research, but arises from routine clinical or surgical care that is already clinically indicated.

In these contexts, tissue is removed for diagnostic or therapeutic reasons and only subsequently enters pathways of storage and potential use for research. As a result, consent for research use often does not operate at the point of tissue removal as a discrete donation act, but is embedded within broader clinical admission, treatment, or consent processes. This may take the form of general or broad consent obtained alongside consent for clinical care, rather than consent sought through a standalone research donation procedure. Such arrangements are not exceptional, but are a common feature of hospital-based research and biobanking infrastructures in jurisdictions with integrated clinical–research systems.

In hospital settings, the timing and context in which informed consent is sought are therefore central to assessing whether consent meets the requirements articulated in Proposal 14, including voluntariness, understanding, and decision-making capacity. Where consent is obtained in circumstances involving serious illness, emotional distress, or time pressure, patients may have limited opportunity to clearly distinguish between consent required for their clinical treatment and consent relating to the storage and potential future use of human tissue for research. While consent may be formally obtained, these conditions warrant careful consideration in evaluating how the elements of valid consent are realised in practice.

Proposal 14 also, appropriately, emphasises the ability to withdraw consent. However, effective withdrawal depends not only on the existence of a legal right, but on the availability of clear, accessible, and workable mechanisms through which that right can be exercised. In hospital-based and biobanking contexts, where tissue may be stored within institutional repositories soon after removal, it is important that individuals are clearly informed, at the point of consent, about how withdrawal operates in practice and about any practical or temporal constraints that may apply once tissue has entered these systems.

Reforms relating to tissue donation for research

Proposals 32-34

These two proposals set out a detailed framework governing consent to the removal and use of human tissue for research, including circumstances in which future research uses are not yet known. The framework appropriately emphasises voluntariness, information, decision-making capacity, and the ability to withdraw consent. However, these proposals appear to rest on an implicit assumption that consent for research operates primarily at a discrete point in time, closely aligned with a specific research purpose or procedure.

In many hospital-based research environments, this assumption does not reflect how tissue is commonly used for research. Tissue that has already been removed as part of routine clinical care may enter institutional repositories or biobanks and be used across multiple research projects over extended periods of time. In such settings, consent for research use often takes the form of general or broad consent covering future, unspecified research activities, rather than consent tied to a single, well-defined research project. This mode of consent is not exceptional, but a routine feature of integrated clinical–research systems.

Where consent is provided in this way, its ethical and regulatory significance unfolds over time, as tissue is stored, shared, reused, and incorporated into ongoing research infrastructures. In this context, the effectiveness of consent cannot be assessed solely at the moment it is given, but depends on how consent-related protections are operationalised as tissue circulates within research systems. This includes how information is communicated to participants, how decisions about access and reuse are made, and how the scope of consent is interpreted in practice.

Proposal also 33 appropriately recognises the importance of withdrawal and access to information where consent is provided for future research uses. However, the meaningful exercise of these rights depends not only on their formal recognition, but on the availability of clear, accessible, and practicable mechanisms through which individuals can exercise them over time. In biobanking and institutional research contexts, participants may have limited visibility over where their tissue is stored, how it is used, or whether withdrawal remains feasible once tissue has been distributed, de-identified, or incorporated into multiple research projects.

In addition, the framing of consent for research in Proposals 32–34 appears to rely on an implicit assumption that donation of tissue for research removes that tissue from broader circuits of exchange or valuation. While donation clearly precludes direct financial transactions with donors, it does not prevent donated tissue from generating scientific value, institutional advantage, reputational benefit, or downstream economic gains within research and innovation systems. Treating donation as a sufficient safeguard risks obscuring these dynamics and the unequal distributions of benefit that may arise through research use over time.

Explicit recognition of these features of contemporary research practice would help ensure that the consent framework in Proposals 32–34 aligns more closely with how human tissue is stored, accessed, reused, and valued within hospital-based research infrastructures. Such recognition would support safeguards that are responsive to the longitudinal and institutional nature of research use, while preserving the central role of consent and ethical review under the Australian Code for the Responsible Conduct of Research and the National Statement.

Question 32 - Would it be beneficial to have national regulation, guidance and oversight for: a. research biobanks that store and/or distribute human tissue or human bodies; or b. educational collections of human tissue?

Yes. National regulation, guidance, and oversight would be beneficial for research biobanks that store and/or distribute human tissue, particularly where these collections operate within public hospitals or integrated clinical–research environments. In such settings, human tissue circulates across clinical care, research, and donation contexts, each of which is governed by distinct norms, values, and institutional expectations. Without national guidance, the governance of biobanks is left to fragmented institutional practices that may not adequately address how these different frameworks intersect in practice.

National oversight could help ensure greater consistency, transparency, and accountability in how stored tissue collections are governed over time, while still allowing flexibility for different types of collections and uses. The case for national regulation is particularly strong where collections function as shared research infrastructure and where access decisions can have system-wide implications for equity and public trust.

Question 33 - If you think it would be beneficial to have national regulation of research biobanks or educational collections of human tissue:

a. What aspects of tissue collection, storage, use, transfer or disposal need to be regulated?

Regulation should not treat tissue collection, storage, use, transfer, and disposal as discrete or sequential stages, as these processes are deeply interconnected in practice. In hospital-based research biobanks, tissue is most often obtained as part of routine clinical procedures, stored within institutional repositories, and later made available for research under conditions shaped by existing infrastructures and organisational arrangements.

At this stage, access to stored tissue is frequently determined by institutional roles, custodial control over collections, and the capacity to maintain the material conditions required for preservation, rather than by transparent or system-wide criteria. Decisions about use and transfer are therefore embedded within institutional hierarchies, professional networks, and local practices, which may include some researchers while excluding others.

Where these dynamics are not explicitly addressed, governance of stored tissue collections tends to occur informally, by default. This can result in uneven access to tissue for research purposes, even within publicly funded institutions, and may undermine broader objectives relating to equity, fairness, and the responsible use of human tissue.

New human tissue legislation should therefore consider regulating not only consent and ethical approval, but also the institutional governance of stored tissue collections. This could include clarifying custodial responsibilities, establishing transparent access and allocation criteria, and introducing accountability mechanisms for decisions about use and transfer. In institutions where research ethics or governance committees already assess the scientific and ethical merit of proposed studies, these bodies may also be well placed to have an oversight role in relation to access to stored tissue held within institutional repositories or biobanks. Such an approach would not require new evaluative structures, but would build on existing review processes to promote more equitable and transparent access to shared tissue resources. Without addressing these aspects, inequities in the use of stored tissue may persist, even where regulatory requirements are met at the point of tissue removal.

b. What types of collections should be regulated?

Regulation should focus on institutional tissue collections embedded within clinical and research settings, particularly hospital-based research biobanks and repositories that store human tissue obtained through clinical care and make it available for multiple research uses over time. These collections play a central role in mediating access to human tissue and therefore have significant implications for equity, governance, and accountability.

c. Are there types of collections that should not be regulated?

Rather than excluding particular types of collections from regulation based on size or duration, care should be taken to ensure that smaller or project-specific tissue collections are not left entirely outside regulatory oversight. While these collections may not require the same governance structures as institutional biobanks, they can raise significant concerns in relation to consent, quality control, and repeated tissue sampling from patients.

In the absence of clear institutional frameworks, small and decentralised collections may operate with limited transparency, increasing the risk of inconsistent consent practices, duplication of tissue collection from the same patients, and variable standards in storage and documentation. For these reasons, the existence of institutional biobanks may in fact provide a mechanism to consolidate collections, reduce unnecessary repetition, and support more consistent ethical and quality standards. Accordingly, the distinction should not be between collections that are regulated and those that are not, but between different levels and forms of regulatory oversight, proportionate to the scale, purpose, and institutional embeddedness of the collection.

Reforms relating to the prohibition of trade

Proposal 40, with respect specifically to Question 35 – Should the prohibition on exchanging human tissue for reward have extra-territorial effect?

Yes. The prohibition on exchanging human tissue for reward should have extra-territorial effect. Given the transnational circulation of human tissue, data, and research outputs, limiting the prohibition to domestic exchanges risks undermining its purpose and creating regulatory blind spots.

However, extending the prohibition extra-territorially should not rest on the assumption that prohibiting "reward" at the point of donation or procurement is sufficient to remove human tissue from market dynamics. Even where tissue is obtained through donation and without direct financial payment, downstream research activities may lead to commercially valuable outcomes, including patents, proprietary technologies, or marketable medical products. Donation alone does not, in practice, place human tissue entirely outside the circuits of value creation.

For this reason, the central regulatory challenge is not simply whether to prohibit trade, but how to recognise and govern the complex ways in which human tissue moves across clinical, research, and commercial domains. Treating these domains as separate risks obscuring how value is generated over time and across jurisdictions, particularly when tissue, derivatives, or associated data circulate internationally.

Accordingly, any extra-territorial prohibition should be accompanied by a regulatory approach that is adaptive rather than exhaustive or fixed. New human tissue legislation should avoid presenting the prohibition as a closed solution, and instead acknowledge the limits of what can be fully anticipated or captured through static definitions of "reward" or "exchange". Mechanisms for ongoing oversight, guidance, and review are therefore essential to ensure that emerging forms of value generation do not fall outside regulatory attention simply because they do not resemble traditional models of trade.

Whether implemented through new human tissue legislation or amendments to the Criminal Code Act 1995 (Cth), extra-territorial effect should be supported by regulatory practices that recognise the entanglement of clinical care, donation, and research, rather than assuming these spheres operate independently. Without this, the prohibition risks reproducing a formal boundary between what is regulated and what is left unexamined, rather than effectively addressing the realities of contemporary human tissue use.

General comments on Proposals 41-44 and Questions 36-37

The proposed framework for prohibiting the exchange of human tissue for reward, together with defined exceptions, exemptions, and guidance on cost recovery, reflects a serious effort to prevent exploitation and commodification. However, the most significant challenge raised by this section is not whether particular exceptions are appropriate, but the underlying assumption that legislation can exhaustively anticipate and stabilise the forms of exchange it seeks to regulate.

In practice, the circulation of human tissue does not occur through clearly bounded or static transactions. Even where tissue is donated without direct financial reward, it may later be incorporated into research, development, or clinical pathways that generate economic, institutional, or reputational value over time and across jurisdictions. The presence of exceptions, exemption mechanisms, and discretionary decision-making by a regulator already implicitly recognises that the boundary between permissible and impermissible exchange cannot be fixed once and for all.

For this reason, the key regulatory risk is not insufficient prohibition, but overconfidence in the capacity of legal definitions and enumerated exceptions to capture evolving practices. Treating clinical care, donation, research, and downstream value creation as separable domains risks obscuring how these spheres are entangled in institutional settings, particularly in hospital-based research environments. Agreements may be voided under Proposal 41, and exchanges prohibited under Proposal 40, while forms of value extraction or strategic advantage continue to operate outside the narrow concept of "reward" as currently defined.

In this context, the exemption mechanism proposed in Proposal 43 is essential, but it should be understood not as a supplementary technical tool, but as a recognition of the inherent limits of static regulation. Decisions about exemptions should therefore be guided not only by the listed factors—public interest, nexus to human tissue, source, and risk of exploitation—but also by an explicit acknowledgement of institutional and systemic effects, including how exemptions may shape patterns of access, concentration of control, and long-term sustainability of tissue infrastructures.

Similarly, guidance on cost recovery under Proposal 44 should be framed as adaptive and revisable, rather than definitive. Cost recovery practices are deeply tied to the material and organisational conditions of tissue retrieval, storage, processing, and distribution, and may evolve as infrastructures, technologies, and research models change. Treating such guidance as fixed risks reproducing the very gaps between law and practice that this reform process seeks to address.

Overall, this section would benefit from an explicit recognition that effective regulation in this area cannot be fully exhaustive or final. Rather than presenting the prohibition, exceptions, and exemptions as a closed system, the legislation should be understood as establishing a framework for ongoing regulatory judgement, revision, and learning, capable of responding to practices that will inevitably exceed the scenarios anticipated at the time of drafting.

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

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Contact details

Contact
Deputy Vice-Chancellor (Research and Innovation)
E [redacted]
W uq.edu.au

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