Professor Mark Scott AO
Vice Chancellor and President

13 February 2026

Dr Maeghan Toews
Commissioner
Australian Law Reform Commission
By email: humantissue@alrc.gov.au

Review of Human Tissue Laws – Discussion Paper 90 (November 2025)

Dear Dr Toews,

The University of Sydney welcomes the opportunity to provide further input into the Australian Law Reform Commission's Review of Human Tissue Laws, following our earlier submission in response to Issues Paper 51 (May 2025).

We enclose comments prepared for your consideration that are targeted at issues relating to education and the scientific use of human tissue. This submission focuses on issues including national harmonisation, consent frameworks for research and secondary uses of human tissue, regulation of research biobanks and educational collections, cost-recovery and trade prohibitions, and the treatment of existing and legacy collections.

It reflects the University's practical experience operating at scale across multiple jurisdictions, and the importance of ensuring that any reform supports ethically sound research and education while maintaining public trust and regulatory proportionality.

In this context, and informed by the University's long-standing operation of biobanks, tissue collections and educational programs, the submission highlights the importance of: formally recognising research and education as legitimate purposes for the collection, retention and use of human tissue; embedding contemporary consent models endorsed by HRECs; providing statutory authority for secondary use and legacy material; recognising HREC approval as a core decision-making mechanism; and modernising and harmonising statutory definitions of tissue.

The University reiterates its strong support for the ALRC review and for the development of a contemporary, coherent and nationally consistent legal framework for the regulation of human tissue.

We would welcome the opportunity to engage further with the Commission as the review progresses, including to clarify or expand on any matters raised in this supplementary paper. Should the Commission wish to discuss any aspect of the enclosed material, please do not hesitate to contact Ms Anita Kelly, Senior Lawyer, IP, Research and Commercial Law, Office of General Counsel, in the first instance at anita.kelly@sydney.edu.au or (02) 9036 5435.

Yours sincerely,

(signature removed)

Professor Mark Scott AO
Vice-Chancellor and President

Attachment: The University of Sydney submission to the Australian Law Reform Commission's Review of Human Tissue Laws – Discussion Paper 90 (November 2025)

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The University of Sydney submission to the Australian Law Reform Commission's Review of Human Tissue Laws – Discussion Paper 90 (November 2025)

This submission does not seek to address all of the questions and proposals raised in the Discussion Paper – only those that are of relevance to the University of Sydney and its key research and educational activities.

Section 1 – A nationally harmonised regulatory framework

Proposals 1 & 2

The Australian Law Reform Commission (ALRC) proposes two alternative models for national consistency in human tissue regulation: harmonised state and territory legislation, or centralised Commonwealth legislation.

Either option is beneficial if it results in harmonisation. The centralised Commonwealth legislative model provides greater legal certainty, national consistency, and long-term stability for institutions operating across jurisdictions. However, this requires the states to forgo their legislative powers in this area, making it harder to achieve.

The second-best approach is harmonisation across the state's existing legislation.

Proposal 3 – National Regulator

The ALRC presents three options for national regulation: (a) expand the powers and functions of the existing Organ and Tissue Authority (OTA); (b) establish a new statutory regulator that incorporates the Organ and Tissue Authority; or (c) establish a new statutory regulator that operates alongside and supports the OTA.

Option (b) offers the best-balanced approach. It leverages OTA expertise and infrastructure (operational knowledge, stakeholder relationships) and can provide unified and consistent regulation and standards through a single statutory body, reducing fragmentation and regulatory gaps across transplantation, research and education.

Section 2 – The objects of human tissue laws

Proposal 5 – Objects of new human tissue legislation

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

The University supports the proposed objects stated on page 15 and suggests explicit recognition of research, education, innovation and regulatory proportionality.

Section 4 – Reforms relating to the definition of tissue

Proposal 7 – Definition of human 'tissue'

Question 6 - In new human tissue legislation, should the word 'tissue' be replaced with another label?

The ALRC proposes adoption of one legal definition of 'tissue' and sets out several options (see Question 6). The University has considered these and recommends a broad New Zealand-style definition as set out on page 33 should be used. This provides a no-gaps approach to the regulation of tissue and permits bespoke rules to apply to special categories of tissue (e.g. blood, reproductive tissue and other).

Section 8 – Reforms relating to tissue donation for research

Proposal 32 – Consent and authorisation for tissue removal for research – living persons

The University supports the ALRC’s recommendation for uniform and modern consent provisions across Australia.

The University notes the conditions for valid consent set out in section 2 are consistent with the consent requirements set out in the National Statement on Ethical Conduct in Human Research (2025) (**National Statement**).

However, the focus of subsection 2(c) on the material risks of “removal” alone does not address the risks associated with the intended research (known and unknown). For example, emerging genomic technologies mean that de-identification can no longer be viewed as an absolute safeguard for donors. Even where names and identifiers are removed, genomic sequencing of tissue results in data that may allow matching across datasets or disclosure of biological characteristics such as sex, relatedness or rare variants. This trend is already recognised internationally; for example, US tissue banks now routinely inform donors that genomic identifiability is possible, and that donated tissue may be used in research undertaken by commercial entities.

Incorporating these realities into future regulatory settings will enhance transparency, support participant understanding, and ensure long-term public trust. This reinforces the importance of valid consent (specific, extended or unspecified) and of clear participant information about the limits of de-identification.

Proposal 33 provides important clarity regarding consent for unspecified future research use of human tissue. Confirming the legal validity of broad and unspecified consent would give researchers certainty and enable ethically robust tissue collection and banking, consistent with the National Statement, which recognises specific, extended and unspecified consent as valid forms of consent for future use. Where valid unspecified consent has been obtained, secondary use can proceed without re-consenting subject to Human Research Ethics Committee (HREC) approval being in place for the planned use.

Overall, legislating the validity of broad or unspecified consent would harmonise the statutory framework with the National Statement and strengthen the governance, feasibility and ethical transparency of future research.

The regulatory framework should also remain adaptable to emerging technologies that may support enhanced donor agency and tracking. For example, blockchain-based consent tools are being explored internationally as mechanisms enabling donors to specify, record and update authorised uses of their tissue across its lifecycle. While such tools may have limited applicability to deceased-donor tissue collections – particularly where coronial or statutory next-of-kin (SNOK) arrangements apply – they illustrate the direction of technological development and the need for regulation that supports innovation while maintaining strong ethical oversight. Any national framework should therefore accommodate evolving digital consent models, provided they are consistent with the National Statement and HREC governance.

Proposal 36 – Consent and authorisation to remove tissue for research after death

The University supports the ALRC’s recommendation that an alternative consent framework be applied when tissue is collected from deceased persons.

Like proposal 32, proposal 36 sets out the requirements for valid consent for persons who have died, or persons near death with reduced decision-making capacity (at p.97). The proposal also sets up a mechanism of consent for children who are close to death or have died.

Like proposal 33, proposal 37 addresses consent for unspecified future research.

The University supports a clear legislative model for consent and authorisation to remove tissue after death and asks the ALRC to consider the comments above under Proposal 33 as relevant to this section too.

Section 10 – Reforms relating to stored tissue collections

Question 30 - Exceptions to consent requirements

The University's answer is "yes", there should be exceptions and that these exceptions need to align with the National Statement as set out above under Proposal 33. It is important these exceptions apply for existing or legacy tissue collections where consent was lawfully obtained under earlier frameworks, or where no consent exists, provided use is subject to HREC approval and oversight.

This allows legacy material to remain available for research and teaching where re-consent is impractical or impossible and avoids retrospectively invalidating previously valid consents.

Question 31 - Are legal rules needed to regulate the storage, access, transfer, and disposal of human tissue used in research biobanks? (see below)

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? (see below)

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?
  b. what types of collections should be regulated?
  c. are there types of collections that should not be regulated?

Research biobanks would benefit from a national framework and clear legal rules for consent and trade in tissue but not general and prescriptive regulation. The University recommends a framework-based approach to research biobank and tissue collection governance that preserves the legitimacy, safeguards and public trust associated with national regulatory regimes (e.g. OECD framework). Although regulation provides legal certainty, it is often administratively burdensome and slow to adapt to technological change.

On the other hand, a principles-based national framework grounded in best-practice guidance, proportional and risk-based governance, and strong ethical stewardship can operate to provide flexibility and accountability. This approach would support high-quality, trusted research without unduly constraining innovation or imposing unnecessary administrative or additional regulatory burden.

If Australia adopts a national regulator for all biobank activities, we strongly support exemptions for biobanks and tissue collections (including legacy collections) that are research focused where HREC oversight governs the collection and use of human tissue.

Section 11 – Reforms relating to the prohibition of trade

Proposal 42 advocates a general prohibition on trade in human tissue for financial gain, while creating a limited exception for certain regulated medical products (such as devices or blood products). However, research tissue banks and collections do **not** fall within this exception and therefore remain subject to the prohibition on trading tissue for reward. This may continue the existing uncertainty many collections experience and does not add clarity.

New regulations should ensure that tissue used for educational or scientific (research) purposes may be used or distributed for a fee or other benefit (including grants, commercial fees and philanthropic donations) provided it is limited to reasonable cost-recovery, infrastructure support or other commercial benefit and provided the tissue is not traded as a commodity. "Commercial benefit" may include industry funded research or fee for access models where access to tissue has commercial outcomes or research that can lead to commercial benefits by enabling the development of new drugs, diagnostic tests, medical devices or cell lines used in industry, or AI diagnostic tools trained on tissue data.

This approach considers the substantial financial and operational burden borne by bona fide research tissue banks and tissue collections (including legacy collections). Cost-recovery fees typically meet only a small fraction of operating costs (in some cases, approximately 10 per cent), and many Australian tissue banks rely heavily on short-term funding streams. To maintain viability and ensure continued access to high-quality tissue for Australian researchers, the regulatory framework should permit differentiated cost-recovery models, including the ability to charge higher fees to commercial entities, provided the tissue itself is not commodified. This approach is analogous to fee structures used by accredited model organism facilities and supports sustainability without undermining ethical principles.

For clarity, any such prohibitions should not interfere with the lawful purchase of ethically sourced human tissue for research and education. Tissue such as cell lines, tissue microarrays and blood should be permitted “trade” for non-therapeutic scientific and education purposes.

Reforms relating to advertising the trade of human tissue

Proposal 45 – Prohibited advertising

The University does not consider that Proposal 45 will adversely affect clinical trials, including industry-sponsored studies, or the operation of tissue banks. However, to avoid unintended impacts on legitimate research activity, it should be made clear that the proposed advertising restrictions do not apply to HREC-approved communications to prospective donors being recruited for clinical trials or research involving the collection and use of human tissue.

The principle being, that any advertising restrictions or guidelines should not impede legitimate donor outreach communication or fund-raising activities undertaken by research tissue banks and tissue collections. For example, tissue donation programs supporting research into Alcohol Use Disorder and other neurological conditions often require targeted outreach through social media and community channels. These activities are undertaken with HREC approval and form a critical component of public awareness, equity of access and research feasibility. The legislation should therefore clarify that HREC-approved donor recruitment or legitimate fundraising communications are not captured by advertising prohibitions.

Reforms relating to data transparency

Question 43 – how should data be reported?

The University supports transparency and suggests a voluntary approach to data reporting and information disclosure. Research institutions already operate within a robust reporting framework including ethics, contractual obligations and research / institutional governance that provide appropriate transparency and accountability.

Any move towards mandatory reporting must avoid unnecessary duplication of existing reporting obligations. Excessive auditing risks diverting resources from research and education and may disproportionately burden collections. A voluntary, proportionate approach aligned to existing HREC and funder reporting would promote transparency without imposing additional administrative overhead.

Care should also be taken to ensure that enhanced governance expectations do not inadvertently disadvantage smaller or emerging collections while allowing research tissue collections to demonstrate high standards that support arguments for sustainable funding and infrastructure investment.

Section 13 – Compliance

Question 45 - Do you have views about the best mechanisms to encourage or enforce compliance with the obligations and prohibitions that we are proposing should be included in new human tissue laws, regulations or standards?

Criminal penalties should appropriately be applied to intentional trafficking in human tissue. Any reform should avoid expanding criminal liability into areas more appropriately regulated through ethics and research integrity frameworks.

Research integrity, ethics and governance frameworks already provide proportionate and effective mechanisms for addressing non-compliance and should not be replaced or duplicated by Human Tissue Laws.

Section 14 – The timeframe for implementing our reform proposals

Implementation and Transition

Question 46 - Do you have views on the timeframe/s within which the reforms set out in this Discussion Paper should be implemented, or on how the implementation of these reforms could be staged or prioritised?

We suggest any new legislation should contain grandfathering provisions for legacy collections and statutory protections for lawful practices of existing collections – any new laws should not retrofit.