Professor Annamarie Jagose
Acting Vice-Chancellor, and Senior Deputy Vice-Chancellor and Provost

4 July 2025

Dr Maeghan Toews
Commissioner
Australian Law Reform Commission
info@alrc.gov.au; humantissue@alrc.gov.au

Dear Dr Toews,

Re: Issues Paper – Review of Human Tissue Laws – Issues Paper 51 (May 2025)

The University of Sydney welcomes the opportunity to contribute to the Australian Law Reform Commission's review of the human tissue laws and related legislation. We commend the ALRC for initiating this important inquiry, which comes at a critical time as advances in biotechnology, regenerative medicine, and tissue engineering, challenge the adequacy of existing legal frameworks.

Our **attached** submission draws on the University's multidisciplinary expertise in health law, bioethics, medical research, anatomy, collections, clinical education and practice.

Human tissue plays a critical role in teaching, research and clinical practice at the University of Sydney. Access to donated tissue is essential for training future health professionals and advancing scientific knowledge and innovation. The University is deeply respectful in its use and storage of human tissue, ensuring that all activities are conducted in accordance with ethical and legal standards.

We would welcome the opportunity to engage further with the ALRC to explore how the University can support the development of a contemporary and coherent national legal framework for human tissue use.

Please do not hesitate to contact Anita Kelly, Senior Lawyer, IP, Research and Commercial Law, in our Office of General Counsel, in the first instance, if the ALRC would like to discuss any aspect of our submission: anita.kelly@sydney.edu.au, 02 9036 5435.

We look forward to supporting this critical review as it progresses.

Yours sincerely,

[redacted]

Professor Annamarie Jagose
Acting Vice-Chancellor

Attachment The University of Sydney submission to the ALRC's Review of Human Tissue Laws – Issues Paper 51 (May 2025)

The University of Sydney submission to the Australian Law Reform Commission's Review of Human Tissue Laws – Issues Paper 51 (May 2025)

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Responses to the Issues Paper's consultation questions

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The University's responses to the Issues Paper's consultation questions

1. What is your personal experience of how human tissue is obtained or used in Australia?

At the University of Sydney (**University**), human tissue is obtained and used in several key activities:

a. **Biobanking for research**: The University hosts a diverse and sophisticated network of over 40 biobanks that support cutting-edge medical and translational research. Human tissue is collected during surgeries, biopsies and post-mortems depending on the bank's research focus. Some examples include:

i. The **Sydney Heart Bank** was established at the University in 1989 by Professor Cris dos Remedios in collaboration with the late Dr. Victor Chang AO. It was created to collect and store explanted human hearts for research purposes. It has since grown into one of the largest and most comprehensive cardiac tissue biobanks in the world.

ii. The **NSW Brain Tissue Resource Centre (BTRC)**, established in 1994, collects post-mortem brain tissue from donors with Alcohol Use Disorder and neurologically normal individuals. It has been continuously funded for over 30 years by the US National Institute on Alcohol Abuse and Alcoholism and has supported over 700 research publications. Despite strong community support for brain donation, public understanding of deceased versus living donation remains limited.

For further information and responses, we refer the ALRC to the separate submission made by the BTRC.

iii. The **Australian Arthritis & Autoimmune Biobank Collaborative (A3BC)** is a national initiative led by the University that integrates biospecimen collection with large-scale data analytics to advance research into arthritis and autoimmune diseases. It connects over 60 sites and 70 researchers, collecting genetic, microbiome, clinical, and patient-reported data

and samples to improve diagnosis and treatment, and ultimately find cures to arthritis and autoimmune conditions.

iv. The **Australian Breast Cancer Tissue Bank (ABCTB)**, established in 2006, is a not-for-profit, open-access biobank that collects and stores breast cancer tissue, blood, and clinical data from consenting patients across Australia to support national and international research. It has provided over 10,000 biospecimens to researchers and operates under a hub-and-spoke model with a central management hub at the Westmead Institute for Medical Research, University of Sydney.

b. **Anatomy education**: The University's Body Donor Program provides essential material for teaching anatomy to medical, dental, and allied health students. It also supports postgraduate education and clinical training, contributing to high-quality healthcare education.

c. **Clinical research (including clinical trials)**: Human tissue is routinely collected during ethically approved clinical research, including clinical trials conducted by the University, contributing to advancements in medical science and patient care.

   At the University, there are over 500 clinical trials in progress at any one time, with around 100 new trials starting each year. Most University clinical trials take place in medicine and health sciences, including cancer research, medicinal cannabis therapy, mental health services, research into neurodegenerative disease, healthy ageing and biomedical engineering applications.

   Clinical trials using human tissue are conducted frequently by researchers employed by or affiliated formally with the University, particularly in areas such as regenerative medicine, tissue engineering, and experimental cancer therapies.

   Researchers at the University have pioneered 3D bioprinting technologies using human materials to fabricate functional human tissues, including skin and organ-like structures, for use in clinical trials.

   The University also supports trials using resected tumour tissue to study the effects of immunotherapy.

   The Cell & Molecular Therapies group at Royal Prince Alfred Hospital, affiliated with the University, is actively involved in clinical trials using human cells for cancer therapies. Their work includes CAR-T cell therapy, gene therapy for haematological malignancies, and reprogrammed iPSC-derived cells. They operate a state-of-the-art facility for manufacturing and evaluating cell and gene therapies, supporting both academic and industry-led trials.

   Currently at pre-clinical trial phase, BIENCO, a pioneering Australian consortium, is transforming corneal transplant technology by using donated corneas from deceased individuals to create advanced bioengineered materials. Through innovative techniques, BIENCO extracts cells from a single donor cornea and uses them to produce up to 30 synthetic grafts.

d. **Archives and museums**. The University of Sydney's Anatomy Department houses human tissue in its collections, specifically within its two key museums:

   i. the J.L. Shellshear Museum of Physical Anthropology and Comparative Anatomy; and

   ii. the J.T. Wilson Museum of Human Anatomy.

   These collections are used for education, research, and public exhibitions.

2. What is your personal experience of how human tissue laws work in Australia?

The legal and ethical landscape surrounding the use of human tissue in Australia is highly complex, involving overlapping frameworks such as the human tissue laws, privacy laws, work health and safety (**WHS**) obligations and the *Anatomy Act 1977* (NSW) (***Anatomy Act***), all of which must be navigated in tandem with the *National Statement on Ethical Conduct in Human Research* (together, **HT Laws**).

At the University, this complexity is reflected in a multi-layered compliance structure that requires coordinated oversight and action from researchers, ethics committees, governance bodies, legal

advisors, and infrastructure teams to ensure lawful, ethical, and sustainable use of human tissue across research, teaching, and display contexts.

The University's compliance with the human tissue and related laws is a shared responsibility involving multiple stakeholders including:

a. **Individual researchers** – Chief investigators are responsible for ensuring that research involving human tissue complies with ethical standards and HT Laws, including securing Human Research Ethics Committee (**HREC**) approval before commencing any activity. They must also uphold research integrity by adhering to national codes and university policies, maintaining participant welfare, and ensuring proper handling, storage, and documentation of human tissue throughout the research lifecycle.

b. **Education and training** – The University uses human tissue, including cadavers and histological slides, in anatomy teaching, with human tissue also used in scientific and health professional education and training.

c. **The Research Integrity and Ethics Administration team** provides governance, training, and support to researchers and educators to ensure compliance with HT Laws where required.

d. **HREC** – This committee reviews research involving human tissue to ensure it aligns with the *National Statement on Ethical Conduct in Human Research*, focusing on participant welfare, ethical standards, and legal compliance.

e. **Governance** – Heads of Schools and Centres and Deans oversee and approve the research programs and biobanks that use human tissue in research by ensuring alignment with the University's legal obligations and sustainability goals. This oversight includes evaluating long-term resource use, infrastructure demands, and alignment with institutional sustainability strategies to support responsible and enduring research practices.

f. **Post-Award Research and Clinical Trial Contract Teams** – When contracting with funding bodies, research collaborators, collection sites, clinical trial sponsors and others, the role of these teams includes verifying that research proposals meet legal and institutional requirements, appropriate ethics approvals are obtained and documented, and the arrangements comply with HT Laws.

g. **University infrastructure** – The University supports the legal retention of human tissue for research and teaching through robust infrastructure, including Core Research Facilities equipped with secure storage systems and advanced technologies that ensure compliance with ethical and legal standards. This is reinforced by the University's Research Data Management Policy 2014, which mandates the retention of primary materials—such as human tissue—when needed to validate research outcomes, and outlines responsibilities for secure and compliant data and material handling.

h. **Office of General Counsel (OGC)** – The OGC at the University provides expert legal advice to a wide range of stakeholders—including researchers, ethics committees, and governance teams—on the interpretation and application of HT Laws and is frequently called upon to provide advice in relation to HREC training, commercial use of human tissue and lawful consent and donation. Through this advisory role, the OGC helps ensure the University's activities remain compliant with complex legal frameworks, including HT Laws, and institutional policies.

   In addition, the OGC oversees the University 's compliance framework to ensure that all institutional activities—academic, research, administrative, and operational—adhere to legal, ethical, and policy standards. It is governed centrally through the Policy Management Unit and supported by a comprehensive Policy Register, which houses binding policies, procedures, and guidelines including those for the *Human Tissue Act 1983* (NSW) (***Human Tissue Act***), privacy laws and the *Anatomy Act*.

i. **Museums and archives, curators and collection managers** must also adhere to the HT Laws, particularly regarding consent, provenance, and respectful display. This also gives rise to historical issues for collections that pre-date the HT Laws in Australia creating challenges for further use and research.

The University's most common challenges

The following are among the most common and pressing challenges the University faces with respect to the human tissue laws:

A) Consent complexities

Legal compliance with human tissue laws in Australia is often complicated by nuanced consent requirements. Consent requirements vary depending on the date of collection as illustrated by the NSW Health Guideline "Use of Human Tissue for Research" which sets out the changes to the *Human Tissue Act* (NSW) prior to 1 November 2003 and after and the differences between general and specific consent.

Samples collected before HT Laws were enacted often lack sufficient documentation regarding consent and use for research, meaning there is reluctance to use these for research purposes. Additionally, current frameworks may not align with Indigenous concepts of consent and custodianship, creating further ethical and legal challenges.

B) Commercial use limitations

There are varying interpretations of what constitutes "trade" in human tissue. While direct sale of human tissue is prohibited under state laws and ethical guidelines, the transformation of tissue into products—such as cell lines, diagnostic tools, or cosmetic materials—can blur legal boundaries, raising ethical concerns about commodification, privacy, and donor expectations. These complexities and grey areas demand careful navigation by institutions like the University, where multiple stakeholders must ensure that consent processes are robust and that any commercialisation aligns with legal and ethical standards.

Restrictions on "trade" in human tissue, unclear cost recovery provisions, and inconsistent exceptions hinder lawful and ethical research involving human tissue. Institutions require clear guidance to facilitate permissible cost recovery and commercialisation.

C) Multi-jurisdictional inconsistencies

Differing requirements under state and territory HT Laws complicate compliance for multi-site and national research projects. This fragmentation increases administrative burden and creates uncertainty for researchers and ethics committees.

D) Emerging technologies

Current HT laws do not adequately address novel uses of human tissue, such as regenerative medicine, bioprinting, and gene editing. These technologies raise new ethical and legal questions that are not fully captured by existing legislation.

E) HREC-related challenges

HRECs face obstacles in interpreting and applying HT Laws, particularly in areas involving commercial use, cell lines, privacy risks, and multi-jurisdictional research. The lack of clear regulatory guidance increases the complexity of ethics review and may delay important research initiatives.

F) Commercially available tissue and cell-lines

When tissue or cell-lines are purchased lawfully through a valid vendor there is uncertainty regarding the application of Australian HT Laws and those of the country of origin. This may impede valuable research and commercial developments.

3. What are good aims or objectives for laws governing how human tissue is obtained and used?

A) Increase availability

Support ethically sound research and transplantation by considering an 'opt-out' donation model. This would align with international best practices and help address shortages in tissue availability for scientific and clinical use.

B) Transparency

Establish clear, accessible donation systems supported by legally binding documentation. This would reduce ambiguity in consent processes and improve public trust in tissue donation programs.

C) Respect

Uphold the dignity of donors and maintain professional standards in the handling, use, and display of human tissue. This includes clarifying the interface between the *Anatomy Act* and *Human Tissue Act* to ensure respectful treatment of remains.

D) Equity

Ensure that consent processes and institutional practices are inclusive and sensitive to diverse communities.

E) Innovation

Enable the use of emerging technologies—such as gene therapies and diagnostics—through appropriate legal and ethical safeguards.

4. What principles should guide reform of human tissue laws?

- Respect for persons and the human body;
- equity;
- public trust, reinforced through transparency and awareness; and
- well-designed and effective laws, which are harmonised across jurisdictions, with clarity and consistency on consent and privacy standards.

5. Do you agree that the issues set out in the section 'Priority reform areas' should be focus for our Inquiry?

Yes. Reform should focus on:

- national consistency and clarity in laws;
- broad and harmonised definition of "tissue";
- clear post-mortem donation authorisation;
- emphasis on research use of post-mortem tissue;
- addressing advertising and cost recovery limitations; and
- inclusion of commercial research under "scientific purposes".

6. What, if any, other issues should we be focusing on in this inquiry?

A) Emerging technologies: Gene editing, 3D printing, and regenerative medicine

HT Laws should accommodate emerging technologies such as gene editing, 3D printing, and regenerative medicine. These technologies are increasingly used in research and education, including the 3D printing of soft tissue and the use of robotics in anatomical studies. There is concern that current legislation may not clearly address these innovations, creating uncertainty about consent, classification, and lawful use. Reform should ensure appropriate safeguards without creating unnecessary legal barriers to innovation.

B) Artificial intelligence (AI), anonymity and data sharing

There are emerging concerns about the intersection of privacy law and human tissue regulation, particularly in the context of genetic and genomic data. The potential for re-identification through AI and data analytics underscores the need for robust privacy protection. The nexus between privacy laws and human tissue laws is critical, especially where deidentified tissue may still carry obligations for disclosure of significant findings to donors or their families

C) Custodianship and long-term responsibility

It is unclear who holds custodianship once tissue is lawfully collected. To address this, it is suggested that legal responsibility for the tissue should transfer from the donor to the institution or researcher, who must then ensure that the tissue is used within the scope of the law and ethical standards. Establishing clearer definitions of long-term custodianship would help support the lawful and ethical management of human tissue across its lifecycle.

D) Community values and contemporary expectations

There is some concern that current HT Laws may not reflect contemporary community values, particularly in relation to consent, commercial use, and benefit-sharing. University stakeholders support updating legislation to align with modern ethical standards, public trust, and culturally sensitive practices. Reform should ensure that legal frameworks are inclusive, transparent, and responsive to evolving societal expectations.

E) Unclear scope of “scientific purposes” and commercial research

The term “scientific purposes” under current HT Laws lacks clear definition, leading to confusion and inconsistent application across research and commercial contexts. For example, whether activities such as the development of commercial products—e.g. gene therapies, diagnostics, or cell lines—fall within the scope of “scientific purposes”, and how this affects consent requirements and ethics review obligations.

Further ambiguity arises in downstream research, where human tissue initially collected for clinical use may later be repurposed for research or commercialisation. The lack of clarity around what constitutes a “scientific purpose” complicates legal compliance, particularly given evolving technologies and research practices.

F) Advertising and cost recovery limitations

Several issues arise relating to advertising, donor recruitment and cost recovery in the context of human tissue and body donation programs. One concern involves public sensitivity around financial implications of donation, as illustrated by a query to the Body Donor Program regarding whether funeral costs would be covered. This highlights the need for clear communication to avoid perceptions of financial incentives, which may conflict with legal prohibitions on trading in human tissue.

Additionally, the increasing relevance of commercial use of donated tissue—such as in gene therapy or diagnostic development—raises questions about the boundaries between lawful cost recovery and restrictions on “trade” in human tissue. To maintain public trust and legal compliance, institutions must distinguish between recovering legitimate operational costs (e.g. processing, storage) and generating profit from donated materials.

7. Are there inconsistencies between the HTAs that we have not identified in this Issues Paper that are causing problems and should be a reform focus for us?

Yes. Notable inconsistencies include:

A) Ambiguity in definitions and scope between the *Human Tissue Act* (NSW) and the *Anatomy Act*

There is significant uncertainty regarding when a human body or its parts transition from being governed under the *Anatomy Act* to being regulated under the *Human Tissue Act*. For example, questions arise about whether embalmed or dissected remains—particularly those retained for extended periods (e.g. over four years) for use in teaching anatomy—continue to be treated as a "body" or become "human tissue" under the law. This ambiguity creates compliance challenges for anatomy programs and museums.

The *Anatomy Act* and *Human Tissue Act* often operate in parallel, particularly in educational and research contexts. However, the lack of clear delineation between the two frameworks can result in inconsistent application and confusion among staff and regulatory officers. Clarifying the legal status of body parts post-dissection and the appropriate regulatory pathway would help clarify this situation.

Feedback from University stakeholders indicates that even local health inspectors may be uncertain about how to interpret and apply the *Anatomy Act* in practice. This lack of clarity can delay or complicate lawful educational and research activities involving human remains. A harmonised and modernised framework would reduce administrative burden and improve compliance confidence across institutions.

B) Inconsistent definitions across jurisdictions

The University notes that state and territory HT Laws are not harmonised, particularly in how they define and regulate "tissue". This creates significant compliance challenges for researchers conducting multi-jurisdictional studies or biobanks, who must navigate differing legal requirements and interpretations across states.

C) Fragmented national and international standards

University researchers working with international partners face difficulties ensuring that Australian legal requirements are met while also complying with foreign regulations. Australian laws should aim to be interoperable with international ethical and legal norms to enable responsible global research partnerships and uphold donor rights and protections.

D) Unclear boundaries around commercial use

The commercial use of human tissue and its derivatives (e.g. DNA, RNA, cell lines) is a growing area of research, yet current legislation does not clearly address the boundaries of lawful commercialisation. This includes uncertainty around consent for future commercial use, ownership of materials, and benefit-sharing with donors. Institutions like the University would benefit from clearer legal guidance and safeguards to support ethically sound commercial research.

E) Inconsistent authorisation and removal rules

The University wishes to highlight several issues arising from inconsistent authorisation and removal rules under current human tissue laws:

a) Next-of-kin veto power

Despite individuals clearly expressing their intent to donate tissue post-mortem, current practice often defers to the senior available next of kin (SNK), who may veto the donation. This practice lacks explicit legislative support and may create ethical or administrative barriers to fulfilling donor wishes.

b) Restrictions on who can remove tissue

The *Human Tissue Act* restricts post-mortem tissue collection to authorised personnel such as coroners or hospital staff. This limitation reduces opportunities for lawful retrieval, particularly for biobanks, and is exacerbated by the declining number of post-mortem inspections.

8. Do you think it is important that we consider any of the issues in the section 'Issues we are unlikely to focus on in this Inquiry'?

Yes, please consider:

- transplant tourism (rare but relevant); and
- impact of voluntary assisted dying legislation on deceased donation.