

The Commissioner  
Review of Human Tissue Laws  
Australian Law Reform Commission

Dear Dr. Toews,

## **Re: Submission to the ALC Review of Human Tissue Laws (2025)**

### **Response to ALC Review questions and proposals**

This submission supports reform of the human tissue legislation but expresses concerns that several proposals, as currently framed, risk unintended harm to medical education, diagnostic quality, and scientific progress.

Our concerns particularly relate to pathology teaching collections, as they currently exist in many universities and hospitals in Australia. Most of these specimens are historical/legacy specimens collected long before the advent of relevant legislature. Related to such legacy specimens are problems with transfer of pathology specimens between institutions. Currently legal advice from NSW Health indicates such legacy specimens cannot be transferred to other approved institutions because the donors did not explicitly agree to such a transfer. If it was agreed that legacy specimen transfer between "licensed facilities" was permitted, then this issue would be resolved, and it would be possible to ensure the ongoing retention of these valuable specimens for educational and research purposes.

Accordingly, our submission recommends that new legislation should:

- a. explicitly permit indefinite retention of pathology specimens where ethically and professionally justified.
- b. enable controlled transfer of specimens between accredited hospitals, universities, and research institutions.
- c. adopt broad, future-oriented consent models, consistent with international standards.
- d. avoid mandatory destruction of tissue following withdrawal of consent.
- e. distinguish clearly between commercial trade (which should be prohibited) and legitimate cost recovery and academic collaboration.

It should be noted that these principles align closely with the regulatory frameworks of the United Kingdom, European Union, and United States.

### **International Comparator Frameworks**

#### **United Kingdom – Human Tissue Act 2004 (HTA)**

The UK framework is particularly relevant and instructive, whose key features include:

- a. Broad consent for research, education, and training is explicitly recognised.
- b. Ethical approval by a Research Ethics Committee may substitute for individual consent in defined circumstances, particularly where tissue is anonymised.
- c. Indefinite retention of tissue is permitted for diagnosis and audit; education and training; quality assurance; ethically approved research.
- d. Withdrawal of consent does not mandate destruction of existing samples; it prevents future use.
- e. Licensed transfer of tissue between institutions is explicitly permitted and routine.

## **European Union – GDPR and Biobank Governance**

Under the EU General Data Protection Regulation (GDPR):

- Human tissue is regulated primarily through data protection, not physical destruction.
- Scientific research is recognised as a public interest activity, with lawful bases beyond explicit consent.
- Broad consent for future unspecified research is explicitly permitted (Recital 33).
- Long-term storage and secondary use are allowed where:
  - a. governance safeguards exist.
  - b. proportionality is maintained.
  - c. ethics approval is obtained.

Mandatory destruction of samples upon withdrawal of consent is **not required** and is generally discouraged where it would undermine scientific integrity.

## **United States – Common Rule (45 CFR 46)**

The US Common Rule provides the following guidance:

- a. Research using de-identified specimens may proceed without consent.
- b. Broad consent for future unspecified research is permitted.
- c. Pathology archives are treated as institutional resources, not personal property.
- d. Withdrawal of consent prevents further use but does not require destruction of stored specimens.
- e. Long-standing recognition that pathology archives are essential for:
  - a. quality assurance.
  - b. retrospective diagnosis.
  - c. development of new diagnostic techniques.

## **Response to Specific Proposals and Questions**

## **Proposals 36 and 37 – Consent to Remove Tissue for Research After Death**

This proposal is supported in principle, but **modification is essential** to align with international best practice.

### **Our key concerns are:**

- a. The requirement to specify intended research uses at the time of consent is incompatible with pathology and future scientific discovery.
- b. Proposal 37(4), which mandates disposal of unused tissue following withdrawal of consent, is inconsistent with UK, EU, and US frameworks.

### **Our Recommendation is that legislation should explicitly provide that:**

- a. consent should be broad and future oriented.
- b. withdrawal of consent applies only to future active research use.
- c. tissue may continue to be retained indefinitely for:
  - a. diagnostic reference.
  - b. education and training.
  - c. quality assurance and audit.
  - d. public-interest research approved by ethics committees.

Mandatory disposal should be expressly excluded.

## **Proposals 38 and 39 – Body Donation and Research on the Recently Deceased**

This proposal is strongly supported.

### **Our recommendation is to clarify that tissues and derived specimens from body donation:**

- a. may be retained indefinitely.
- b. may be transferred between licensed hospitals, universities, and research institutions.
- c. may be used across education, audit, and research, subject to governance.

This aligns directly with UK anatomy and pathology integration models.

## **Question 29 – Consent for Secondary Uses of Tissue**

**We recommend that** consent should be required, but structured as **broad consent**, We recommend the use of a tiered consent framework, permitting secondary use for:

- a. education.
- b. quality assurance.
- c. ethically approved research.

- d. AI and digital pathology development.

De-identified secondary use should be presumptively lawful where ethics approval is in place.

### **Question 30 – Exceptions to Consent Requirements**

#### **The Exceptions to consent are strongly supported**

Consistent with UK and US frameworks, exceptions should apply to:

- a. de-identified tissue.
- b. public health surveillance.
- c. quality assurance and audit.
- d. legacy collections where re-consent is impracticable.

### **Questions 31–33 – Regulation of Stored Tissue Collections**

National regulation and guidance are desirable, provided they are **enabling rather than restrictive**.

#### **We recommend that regulation should address:**

- a. governance and custodianship.
- b. ethical oversight.
- c. security and traceability.
- d. lawful inter-institutional transfer.

Pathology diagnostic archives and teaching collections should **not be over-regulated** or subjected to retrospective consent requirements.

### **Question 34 – Access to Stored Tissue**

**There should be no unrestricted right to reclaim or remove stored tissue.**

#### **We recommend that access should be limited to:**

- a. information about use.
- b. access to results where clinically relevant.

Custodial control must remain with institutions to protect diagnostic integrity and public trust.

## **Proposal 40 and Question 35 – Prohibition on Exchange for Reward**

This proposal is supported, with clarification.

### **Legislation must explicitly permit:**

- a. cost recovery.
- b. inter-institutional transfer agreements.
- c. international academic collaboration.

Extra-territorial application should be confined to **commercial exploitation**, not academic or public-sector research.

### **Conclusion**

Our recommendations and comments are strongly aligned with international experience that human Pathology specimens are enduring public-interest assets whose value increases over time.

Effective human tissue legislation must:

- a. permit indefinite retention.
- b. facilitate inter-institutional transfer.
- c. support broad, future-proofed consent.
- d. avoid mandatory destruction of irreplaceable material.

Failure to embed these principles would place Australia at a disadvantage and out of step with leading international jurisdictions and risk irreversible loss of educational, and scientific capacity.

Yours sincerely

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