

The Commissioner
Review of Human Tissue Laws
Australian Law Reform Commission

Dear Dr.Toews,

Re: Facilitating the Ethical Retention and recognition of “Legacy Specimens” and
Transfer of Human Anatomical and Pathology Specimens for Education and
Research

Further to our recent submission we would like to draw the commissions attention to a pressing and unresolved issue facing Australian medical schools, teaching hospitals, anatomy and pathology museums: the lawful retention and transfer of existing human anatomical and pathological specimens for which no formal donation documentation exists.

These legacy collections, many of which were obtained prior to the introduction of modern consent and tissue legislation, represent an irreplaceable national educational and scientific resource.

Current interpretations of the Human Tissue Acts have left institutions uncertain about the legality of retaining, displaying, or transferring such specimens, resulting in the loss of access to critical teaching materials, especially for new, rural, and remote medical programs.

This submission proposes a structured, ethically sound approach to enable the continued use and lawful transfer of these materials between accredited educational and medical institutions under appropriate governance.

Australia’s Human Tissue Acts, enacted across states and territories during the 1980s, were designed to regulate the donation, removal, and use of human tissue for transplantation, research, and education. However, these laws did not anticipate the status of pre-existing anatomical or pathological collections, many of which were established decades earlier when consent documentation was not systematically recorded. Consequently, institutions now face legal and ethical uncertainty when

- The original consent records are missing or incomplete.
- The provenance of specimens is known and legitimate, but individual donor documentation is unavailable.
- Institutions with declining teaching needs (or limited storage resources) are unable to transfer specimens to those that could use them for education and research.

This dilemma is compounded by the modern decline in autopsy rates, the widespread use of minimally invasive diagnostic and surgical techniques, and the limitations of imaging and virtual teaching in demonstrating authentic pathological change.

For generations of Australian medical students and clinicians, direct exposure to human specimens has been essential for understanding disease morphology and surgical anatomy. The preservation of these specimens often through meticulous preparation over many decades—constitutes a national archive of both educational and historical significance.

Without legislative reform, many institutions are compelled to restrict access, maintain redundant holdings, or dispose of material that could otherwise serve as critical educational resources.

This issue is increasingly important and particularly acute for:

- New medical schools seeking to build anatomy and pathology resources.
- Rural and regional clinical schools, where access to cadaveric or pathological material is limited or non-existent; and
- Specialist pathology collections that could be shared between universities or hospitals if lawful mechanisms of transfer or exchange were established.

To resolve these impasses, we would like to propose that the ALRC recommend the following measures for inclusion in a revised Human Tissue framework:

1. Recognition of “Legacy Specimens”

Establish a specific legal category for specimens acquired before the enactment of modern consent provisions, recognising their ethical and educational value.

2. Institutional Licensing Framework

Permit continued retention, educational use, and limited public display of legacy collections under institutional licence, with governance by recognised ethics or compliance committees.

3. Authorised Inter-Institutional Transfer Mechanism

Develop a national protocol allowing accredited medical, scientific, or educational institutions to transfer specimens through formal agreements, ensuring proper provenance records, security, specimen care and preservation, and ongoing educational oversight.

4. Centralised Registry of Educational Collections

Create a national or state-based register of declared legacy specimens held by authorised institutions, ensuring transparency and accountability while allowing continued educational use.

5. Public and Donor Transparency

Encourage institutions to display ethical statements acknowledging the provenance and educational purpose of their collections, maintaining community trust and respect for donors.

There is international precedents for the adoption of such legislature. Several countries have already implemented practical and ethical frameworks for legacy human tissue collections:

- New Zealand's Human Tissue Act 2008 recognises "*existing holdings of human tissue*" and allows ongoing educational and research use under ethical management and institutional review frameworks [1][2].
- The United Kingdom's Human Tissue Act 2004 established the *Human Tissue Authority (HTA)*, which licenses the use, retention, and display of

human material for “*scheduled purposes*” such as anatomical examination, research, and public display [4][6][10]. The HTA explicitly provides for the lawful use of “*existing holdings*” under controlled conditions [10].

- Scotland’s Human Tissue Act 2006 similarly authorises the retention and transfer of tissue for education and research with appropriate institutional authorisation [7].
- The European Union Directive 2004/23/EC and its proposed 2022 *SoHO Regulation* establish harmonised standards for the ethical handling, storage, and exchange of human tissues across member states [8][9].

These precedents provide valuable models for Australia, demonstrating that it is possible to balance respect for donor intent with the pressing educational and scientific need to preserve and share human specimens for legitimate teaching and research purposes.

The lack of clear legislative provision for historical anatomical and pathological specimen’s places Australian educational institutions in an untenable position. Without reform, invaluable materials risk being lost to medical education and research, depriving future generations of the opportunity to study real examples of human disease and anatomy.

The Australian Law Reform Commission’s review offers a timely opportunity to provide a nationally consistent, ethically sound, and practically workable solution. This submission respectfully urges the Commission to:

- Recognise the unique status and value of legacy collections, and
- Establish lawful pathways for their retention, transfer, and educational use among accredited institutions.

Thank you for considering our submission.

Yours sincerely,

Denis Wakefield AO
MBBS (Hons 1) MD DSc FRACP FRCPA FFSc
Emeritus Professor of Medicine
Sydney, Australia

Nicholas Hawkins
MBBS (Hons 1) PhD, FRCPA
Emeritus Professor of Medicine
Sydney, Australia

A/Prof John Turchini BMedSc, MBBS, FRCPA, PhD
Clinical Discipline Head of Pathology
Year 2 Lead, Pathology Discipline Lead, MD Program
Faculty of Medicine, Health and Human Sciences
Macquarie University, NSW 2109, Australia

Professor Andrew S. Field
MB BS(Hons) FRCPA FIAC DipCytopath(RCPA)
Conjoint Professor University of New South Wales, Sydney, Clinical Medical School
Adjunct Professor University of Notre Dame, Sydney, Medical School
Director of Division of Anatomical Pathology
St Vincents Hospital, Sydney, NSW.

Prof. Nicodemus Tedla
MD, PhD.
Professor in Pathology, School of Biomedical Sciences
UNSW Medicine & Health
UNSW Sydney

Professor Anthony J Gill AM
MBBS FRCPA MD
Professor of Surgical Pathology
University of Sydney
Sydney NSW 2006 Australia

Prof Gary Velan
MBBS, DipHEd, PhD, FANZAHPE
UNSW Scientia Education Fellow
Deputy Dean Education
Professor in Pathology, School of Biomedical Sciences
UNSW Medicine & Health
UNSW Sydney

Prof. Jake Baum
MA BA MSc PHD FRSB
Professor of Infectious Diseases & Head of School
School of Biomedical Sciences
UNSW SYDNEY 2052

Assoc. Prof. A.R. (Sandy) McColl
BSc-PT (Hons), MD, CCFP, FACP, FRACGP
Clinical Director – Research Collaboration
School of Clinical Medicine, UNSW Medicine & Health
Rural Clinical Campus, Port Macquarie
PORT MACQUARIE NSW

Assoc. Prof. Cristan Herbert
BMedChem (Hons), PhD (Pathology), GCULT, SFHEA
Head of Teaching, Department of Pathology
Faculty of Medicine & Health
UNSW SYDNEY 2052

Assoc. Prof. Shane Thomas
Head, Department of Pathology
School of Biomedical Sciences
Faculty of Medicine & Health
UNSW Australia
UNSW SYDNEY NSW 2052

Professor Tara Mackenzie
Associate Dean and Head of School of Clinical Medicine (Rural)
School of Clinical Medicine, UNSW Medicine & Health
Rural Clinical Campuses
250 Edward Street, Wagga Wagga
UNSW SYDNEY

References

1. *Human Tissue Act 1983 (NSW)*. NSW Government.
<https://legislation.nsw.gov.au/view/html/inforce/current/act-1983-164>
2. *Human Tissue Act 2008 (New Zealand)*. Parliamentary Counsel Office.
<https://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1154318.html>
3. Health Research Council of New Zealand. *Collection and Use of Human Materials* (2022). <https://www.hrc.govt.nz>
4. *Human Tissue Act 2004 (UK)*. Human Tissue Authority (HTA).
<https://www.hta.gov.uk>
5. HTA. *Code of Practice C: Anatomical Examination* (UK).
6. HTA. *Code of Practice D: Public Display* (2021).
https://www.hta.gov.uk/sites/default/files/2021-07/HTA%20Code%20of%20Practice%20D%20Public%20Display_1.pdf
7. *Human Tissue (Scotland) Act 2006*. Scottish Parliament.
<https://www.legislation.gov.uk/asp/2006/4/contents>
8. *EU Directive 2004/23/EC*. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004L0023>
9. *European Commission SoHO Regulation Proposal* (2022).
https://health.ec.europa.eu/blood-tissues-cells-and-organs/revision-eu-legislation_en

HTA Guidance. *Consent Exemptions and Existing Holdings under the Human Tissue Act 2004*. <https://www.hta.gov.uk/guidance-professionals/guidance-sector/anatomy/consent-exemptions-under-human-tissue-act-2004>