To: The Australian Law Reform Commission

Inquiry: Review of Human Tissue Laws — Discussion Paper (2025)

Submission from: The University of Melbourne — Faculty of Medicine, Dentistry & Health Sciences (with legal support)

Date: 13 February 2026

The University of Melbourne's Faculty of Medicine, Dentistry & Health Sciences (**MDHS**) welcomes the opportunity to respond to the Australian Law Reform Commission's (**ALRC**) Discussion Paper on Human Tissue Laws. Our Faculty conducts internationally recognised education and research across biomedical, clinical, translational and public health disciplines, a substantial proportion of which depends on ethically sourced human tissue, data and images. Our submission draws on consultation across our Schools and aims to assist the ALRC to craft a nationally consistent, future-proof regime that supports ethically robust research and education while maintaining public trust.

We support the ALRC's objectives to harmonise human tissue laws, establish a coherent national framework, and improve clarity around consent and governance. We also support maintaining clear interfaces with existing regulators and instruments, including the Therapeutic Goods Administration (**TGA**), the National Statement on Ethical Conduct in Human Research (**National Statement**), the Australian Code for the Responsible Conduct of Research (**Code**), and other legislative regimes that deal with specific categories of human tissue or human remains (for example, regulation relating to Aboriginal and Torres Strait Islander ancestral remains, human embryos and human cloning).

What follows synthesises the MDHS consolidated feedback into six thematic positions. For each theme we outline the issue, our position, and practical recommendations for the ALRC to consider.

1. National Framework

Australia's existing patchwork of human tissue laws creates uncertainty, duplication and delays, particularly for interstate transfers, biobanking and multi-site research. The Discussion Paper's model for a national framework is welcome, but several proposals risk conflating transplantation/therapeutic pathways with research and education pathways, which are governed by distinct risk profiles and oversight systems (e.g., Human Research Ethics Committees (**HRECs**) under the National Statement).

We support national uniform legislation with a single National Regulator, designed and implemented to **(a)** achieve genuine harmonisation, **(b)** minimise duplication with established research ethics and integrity systems, and **(c)** adopt a risk-proportionate approach that differentiates between:

- Therapeutic/clinical products and pathways regulated by the TGA (e.g., human cells, tissues and organs for transplantation); and
- Research and education uses of human tissue/material and associated data, which are subject to research ethics, privacy and institutional governance.

The ALRC may consider proposals for:

- Distinct laws for transplantation/therapeutic supply vs research/education, with tailored obligations, definitions and licences that align with existing regulatory ecosystems.
- Provisions clarifying that where the TGA regulates a product or process for therapeutic use, the human tissue legislation should not duplicate those regulatory requirements.
- Research activities should continue to be overseen through human research ethics review bodies and institutional governance in accordance with the National Statement without duplication.

Professor Michael McGuckin
Acting Dean, Faculty of Medicine, Dentistry and Health Sciences

Faculty of Medicine, Dentistry and Health Sciences
The Universit of Melbourne, Victoria 3010 Australia
T: [redacted] | E: [redacted] | W: mdhs.unimelb.edu.au | **unimelb.edu.au**

- A streamlined, nationally standardised mechanism for interstate movement of research and education specimens/derivatives, aligned with ethics approvals and privacy laws.
- A definition of human tissue for research purposes that is nationally consistent and harmonised across regulatory instruments, including the National Statement, to ensure clarity of compliance obligations.

2. Consent

The MDHS faculty supports the removal of the 'designated officer' and 'certificate of consent' requirements in the current framework, which creates duplicative paperwork but does not offer additional protection where the donating person has provided valid consent.

Research and education commonly require consent for future, unspecified uses, obtained at the time of clinical care, research enrolment, or enrolment in a body donor program. In the research context, the National Statement already provides comprehensive guidance for broad consent and, where justified, HREC approved waivers.

The legislation should expressly recognise category-based consent (e.g., "medical research" and/or "education") as valid and sufficient where activities fall within the consented category, without requiring granular, projects or use specific detail that is impracticable, administratively burdensome and offers limited additional donor/participant protection. Any resulting laws should also preserve HREC approved waiver pathways where consent cannot practicably be obtained and the criteria in the National Statement are met (e.g., reuse of diagnostically collected tissue or archived samples).

MDHS recommends any proposals:

- Incorporate provisions expressly acknowledging broad consent for research and education as valid.
- Align consent requirements with the concept of consent waivers in the National Statement, allowing secondary use of tissue/material and associated data in certain circumstances.
- Permits an authorised person to provide consent for research and teaching uses – for example, there may be situations where an authorised person provides consent for tissue collection and use where the primary donor/participant lacks the capacity to consent (neurodegenerative disease, children).
- Make clear that collection of human tissue for derivation of cell lines requires consent under the proposed framework however downstream research use may be exempt from certain regulation (this is expanded upon below under paragraph 4).
- Authorising without the need for separate approval any pre- and post-interventions reasonably required to fulfil the donation purpose (e.g., standard infectious disease testing).

3. Avoid Duplication – National Statement and the Code

The use of human tissue in research is governed under a robust and effective ethics framework, anchored by nationally consistent, principle-based approaches described in the National Statement and Code, with compliance mandated by the National Health and Medical Research Council via funding agreements. The National Statement takes a broad definition of human tissue, ensuring that project-level usage includes appropriate participant safeguards with review, approval and compliance monitoring overseen by independent ethics decision-making bodies established by the institution. Under this ethics framework, higher risk research use of human tissue is reviewed by Human Research Ethics Committees (HRECs), which include community representatives and provide robust oversight of ethical conduct, risk management, and community expectations.

Proposals to legislate compliance with the National Statement and the Code, with a clause giving legislative primacy in case of inconsistency, risk creating two parallel and potentially conflicting regimes (a human tissue regulator and the NHMRC/ARC system), with duplicative reporting, uncertainty about breach and remediation pathways, leading to compliance inefficiency rather than enhanced protection. Embedding these instruments into statute would duplicate rather than enhance protection and could

displace ethics and integrity processes, which have been carefully developed over many years. Legislation which is inconsistent with the National Statement and the Code would result in Universities being required to breach funding arrangements in order to comply, putting current and future research funding streams at risk.

MDHS recommends any proposals:

- Include a requirement to have regard to the National Statement and the Code for research uses, while leaving ethics review and integrity enforcement to their established systems; and
- Where a matter is an ethics/integrity deviation, permit resolution within the NHMRC/ARC framework without parallel legislative breach notifications, unless there is a demonstrable public risk that warrants regulatory involvement.

4. Definition of human tissue

We support maintaining a clear definition of human tissue but emphasise the importance of establishing a consistent set of standard exclusions, determined in legislation or by the National Regulator, with a pathway for clarification when the status of a material is uncertain. These exclusions should prevent low-risk or non-sensitive materials from being unnecessarily captured by the regulatory scheme.

Standard exclusions could include:

- Inert, nonviable substances produced by the body (such as nails, hair, faeces, sweat, tears, milk, serum, urine, tendon and lens), unless intended for transplantation.
- Irreversibly altered materials used in research such as DNA, RNA, proteins, metabolites, provided their provenance is known and ethically sourced.

Consideration should be given to particular exclusions from human tissue regulation of irreversibly altered and unidentifiable long-passaged human-derived cell lines, on the basis they have undergone such fundamental alteration the sample no longer holds human tissue status. The act of collecting human tissue to derive cell lines, should remain clearly within the scope of consent and governance requirements, however downstream materials that are heavily altered may justifiably not be considered human tissue and regulated more lightly.

We acknowledge that this proposed approach is at odds with the current broad definition of human tissue in the National Statement and recommend that definitions should be consistent across regulatory instruments, therefore implementation may necessitate revision of the National Statement (and other overlapping legislation such as the assisted reproductive treatment legislation).

5. Reporting and transparency

The Discussion Paper canvasses enhanced reporting. For large universities with diverse research and teaching programs, granular level reporting of tissue use would impose significant administrative burden, may not align with donor expectations, and risks disclosure of confidential research information or regulated personal/health information, without clear evidence of commensurate public benefit. Existing governance already mandates independent ethics review (including proportionate “low-risk” pathways) and institutional oversight via mandatory project-level annual reporting.

The faculty supports targeted, high-level reporting tied to explicit policy objectives (e.g., aggregate measures of donations, transfers and complaints) that avoids line-by-line or project-level disclosures for research/education uses.

MDHS recommends any proposals:

- Limit any reporting obligation to measures demonstrably linked to a policy purpose (e.g., equity of access, safety signals).
- Where possible, rely on information already captured through HRECs or institutional governance to reduce duplication.
- Make clear that reporting should not require disclosure of commercially sensitive research information or data that could re-identify donors.

6. Stored tissue

The faculty needs clarity on how a potential collections and biobanks new regime will apply to legacy collections of human tissue (including education collections under Schools of Anatomy), tissue collected originally for diagnostic purposes, and research biobanks. It is important that any new regime has prospective application and transitional safeguards to avoid unnecessary destruction or re-consent of legacy human tissue.

MDHS recommends any proposals:

- Should ensure new requirements apply prospectively, legacy collections obtained or consented to under prior frameworks should remain usable under transitional provisions, with appropriate governance (such as the National Statement).
- Define a biobank as a collection of biospecimens stored for future research, distinguishing it from therapeutic tissue banks (TGA regulated) and educational and research collections within Schools of Anatomy, which already operate under specific statutory frameworks.
- Where donor/collection consent did not explicitly contemplate future research, allow HREC approved waivers and deidentified use, per the National Statement.
- Implement a national, proportionate licensing/accreditation approach for research biobanks (distinct from TGA oversight of therapeutic product supply), with clarity on interstate and cross border transfer.
- Provide workable definitions for identifiable/re-identifiable/anonymised samples and associated data, recognising the challenges with “reidentification” in practical circumstances. I.e. where the material has been deidentified and there has been one or more transfers of the material from the original collection.
- If a donor or participant withdraws consent for future research uses, the terms agreed at the time of consent should determine how withdrawal is managed, consistent with the requirements of the National Statement. In the absence of such agreed terms, any unused tissue that remains identifiable must no longer be used for research. This tissue should be discarded within a reasonable and practicable timeframe.
- Any request by a consenting person to re-access human tissue may be considered on a discretionary basis but should not be framed as an entitlement or automatic right.
- Confirm that cost-recovery fees for research or educational access to biobank materials and Schools of Anatomy collections are permissible and are distinct from prohibited trade in tissue.

7. Deceased donation and Schools of Anatomy

Proposals 36-39 address post-mortem donation, however there are some gaps for consideration. Proposal 36 deals only with the removal of tissue for research, overlooking that some research uses the whole, intact body. It should be broadened so donors can consent to whole-body donation for research, whether or not tissue is removed. Similarly, Proposal 38 should explicitly include whole-body donation for research, not just education, to ensure Schools of Anatomy are clearly covered.

Additionally, applying the tissue removal focused consent regime in Proposal 23 to whole-body donation is inappropriate. Anatomical teaching and some research may involve no tissue removal, and when removal does occur, its nature cannot always be predicted in advance. Because valid consent under the current model assumes a defined removal procedure, it does not align with whole-body donation scenarios. A consent framework tailored to whole-body donation is therefore needed to avoid inadvertently restricting legitimate post-mortem research and educational use.

Where tissue or a body is temporarily transferred from a School of Anatomy (e.g., to an imaging facility) for approved education/research, we propose a new regime clarify that this is permissible subject to the School of Anatomy's maintaining oversight of the movement.

The discussion paper contemplates creating a parallel "non-School of Anatomy" pathway for whole-body donation for research. If this is pursued, it would need to be accompanied by a clear, evidence-based governance and licensing regime. MDHS' preference is the retention of the School of Anatomy framework for both teaching and research, as the schools are skilled in managing the interface between donor and families and ensuring the ethical and compliant treatment of donor bodies.

The Discussion Paper considered qualifications for persons authorised to remove tissue. These requirements should not apply within a School of Anatomy, as no formal qualifications are required for post-mortem tissue removal in that context, nor should they be, given that the tissue is used primarily for educational purposes by students.

We appreciate the ALRC's collaborative approach and would welcome the opportunity to engage further as the proposals continue to evolve.

Yours sincerely,

Professor Michael McGuckin
Acting Dean, Faculty of Medicine, Dentistry and Health Sciences