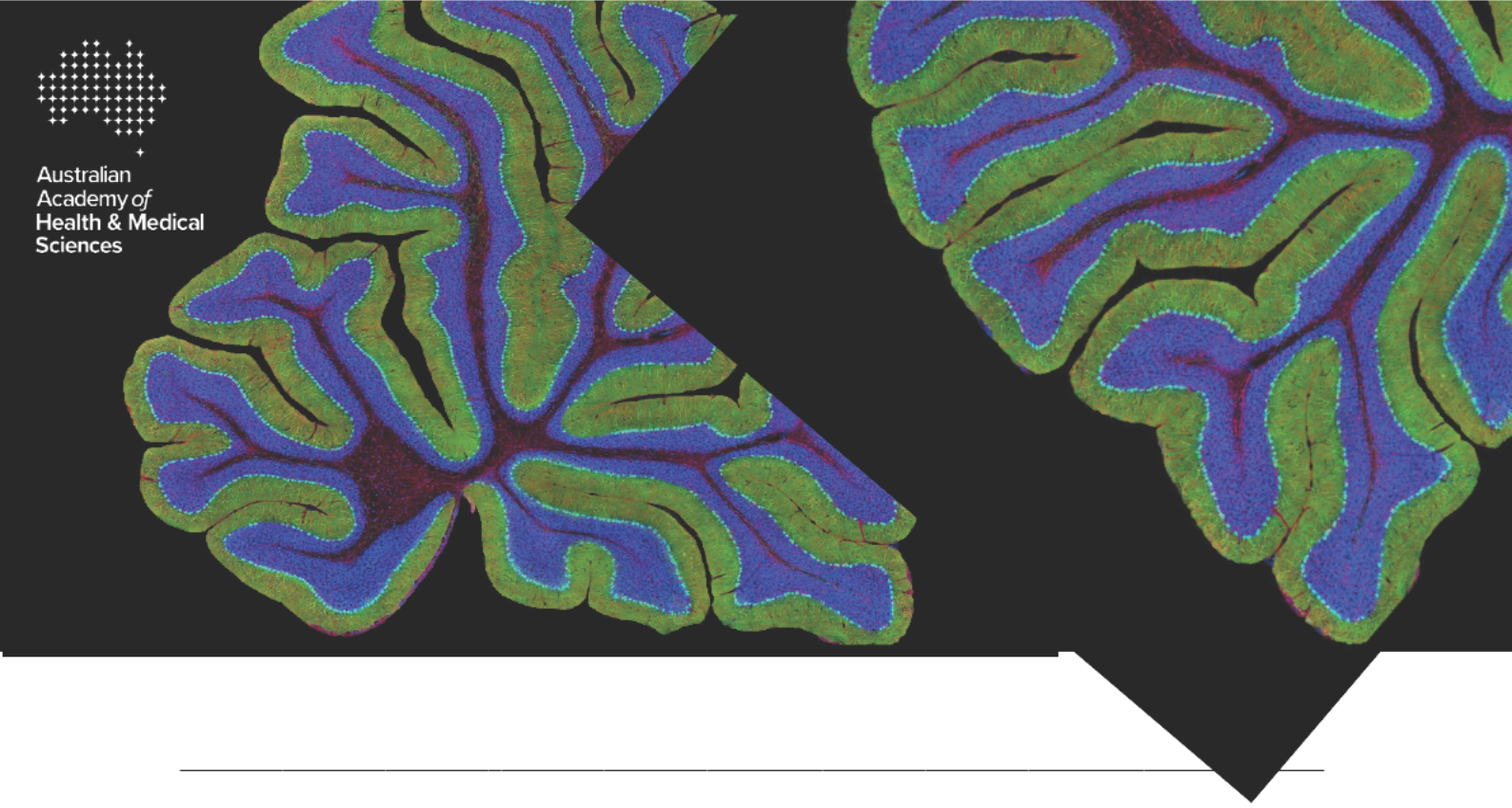

Australian Academy of Health & Medical Sciences

SUBMISSION TO THE AUSTRALIAN LAW REFORM COMMISSION REVIEW OF HUMAN TISSUE LAWS CONSIDERATIONS REGARDING RESEARCH USES OF HUMAN TISSUE

This submission from the Australian Academy of Health and Medical Sciences (AAHMS) to the Australian Law Reform Commission's (ALRC) Review of Human Tissue Laws outlines key considerations relating the use of human tissue for research purposes.

While the Review's Terms of Reference are currently focused on clinical and educational uses of human tissue, the Review presents a timely opportunity to consider the use of human tissue for research purposes – a related and increasingly significant area.

As Australia continues to innovate across the health and medical sciences – including in fields such as genomics, data linkage, and biobanking – our national human tissue laws must be future-fit and ethically robust, reflecting the Australian community's expectations around consent, privacy, and transparency. One of the biggest challenges that needs to be addressed is the lack of consistency in human tissue laws across the nation.

In this submission, the Academy presents targeted observations and guidance on how the broader Review process could also lay the groundwork for the consistent, principled regulation of human tissue research that underpins public trust and enables ethical innovation. Australia should seek to create an environment in which the safe and secure use of human tissues for legitimate research purposes is balanced with the rights and interests of individuals.

Existing legislative and regulatory framework

The use of human tissue for research is currently regulated across Australia through a complex, fragmented, and nationally inconsistent framework of oversight, guidance and legislation – including:

- **Commonwealth legislation**, including aspects of the Therapeutic Goods Act 1989, the Research Involving Human Embryos Act 2002, and the Privacy Act 1988.[2] The applicability of these laws is limited by the Commonwealth heads of power in the Constitution.
- **State and territory legislation**, including Human Tissue Acts governing the removal, use, and disposal of human tissue; Coroners Acts for post-mortem tissue; and privacy legislation. There is a lack of uniformity across the nation with regard to the obligations imposed through these and other state- and territory-based laws.
- **Primary regulatory framework** provided by the National Health and Medical Research Council's (NHMRC) ethical guidelines, which establish the fundamental principles for all human research, including tissue-based studies.[1] The NHMRC guidelines apply to all Australian research involving humans.
- **Key regulatory bodies** regulate certain aspects of human tissue research. For example, the Therapeutic Goods Administration (TGA) regulates research involving therapeutic products and certain clinical trials that involve tissue collection. The TGA's requirements apply across all states and territories.[2]
- **Human Research Ethics Committees** (HRECs) are institutional committees that review and approve research proposals, which is mandatory for all research involving human tissue. However, there are currently no mechanisms to ensure consistency in the ways in which HRECs interpret NHMRC ethical guidelines – despite HREC approval being mandatory. HREC review is the central safeguard for ensuring that research meets ethical, legal, and privacy standards.

The Academy encourages the ALRC to take their Review of human tissue laws as an opportunity to ensure that there is greater uniformity across Australia in the application of laws and other regulatory instruments in the context of human tissue.

Key areas for consideration

1) Scope and definitions of human tissue:

While all biological materials contain DNA, this alone does not justify treating all tissue types uniformly under the law. Materials such as corneal tissue, plasma, blood, gametes, and breast milk each warrant distinct ethical, cultural, and scientific considerations.

- Applying overarching principles and consent standards consistently across tissue types would provide a clear foundation and ensure baseline protections for donors, regardless of the material involved.
- Allowing for tailored regulatory sub-frameworks where necessary would account for specific sensitivity or uses. For example, the DNA in gametes is heritable, whereas the DNA in other tissues is not – hence the need for a tailored regulatory framework for gametes.

2) Consent framework for research

Using human tissue for research requires informed consent from individuals concerned, which is a very important underlying principle. Usually this consent will be specific to a particular study. However, there are instances where specific consent can impose undue burden on donors and researchers, for example, where tissues are stored in biobanks and other tissue repositories for use in future, as yet undetermined studies. Broader, more dynamic consent models could reduce this burden. However, it is crucial that consent is always sought, even if it is broad. The Academy does not support the introduction of opt-out consent frameworks in this context, because of ethical, equity and reputational risks which could undermine trust, particularly among already disadvantaged or marginalised communities.

- Specific consent should be sought wherever possible. However, there are examples where broad prospective consent is needed, since it allows donors to give permission for a range of future research uses of their tissue without requiring them to provide consent for each and every study – for instance where they consent for their tissue to be stored and used for research purposes in a biobank. However, it is important that in such cases, all uses of such tissues for individual studies should still require HREC review and approval. Such an approach would balance respect for donor autonomy with the practical needs of large-scale, long-term research, such as that often conducted using biobank resources.
- Dynamic consent methods, which enable ongoing, interactive engagement between researchers and donors, show promise in enhancing transparency and autonomy. However, their use should remain subject to HREC approval, and further evaluation is required to determine their scalability, sustainability, and potential impact on participation rates and the burdens placed on donors and researchers.

3) Legal framework

Situating the governance of human tissue for research purposes within privacy law (rather than property law) would align more closely with underlying concerns around consent, control, and personal dignity.

- Focusing on control of personal information better addresses the risks of misuse and ensures respect for donors' rights.
- A privacy-based approach would reflect the evolving nature of tissue research, where identifiable data can carry equal or greater risk than physical samples themselves.
- Integrating donor rights and complaints mechanisms into existing privacy legislation would help to avoid legislative fragmentation.

4) Commercial and international considerations

There are currently inconsistencies between domestic and international rules around human cell lines. In practice, imported materials, which are routinely used in Australian research, are generally classified as low-risk by HRECs – often because they are anonymised, commercially available, or obtained with prior ethical approval.

- Standardising provenance and consent requirements for both domestic and international human-derived materials would improve regulatory coherence and ensure that all research materials are subject to comparable oversight, regardless of their origin.
- Coordinating with existing frameworks – e.g. those from the Australian Quarantine and Inspection Service, institutional biosafety committees, and the Office of the Gene Technology Regulator – would avoid duplicative regulation.
- Historical collections should be addressed sensitively, with consideration given to measures such as sunset clauses for legacy collections and exemptions or special review processes for low-risk, long-standing materials.

5) Governance and accountability

The creation of a national oversight body, similar to the UK Human Tissue Authority, may improve coordination and provide the capability for overarching governance of complex situations such as the closure of research institutions or biobanks that hold human tissue.[3]

Any move towards harmonisation should explicitly reinforce the central role of HRECs as the independent review mechanism for all human tissue research, ensuring that variations in consent type or tissue source are ethically justified and publicly accountable.

- The Australian Commonwealth embryo research model, established under the Research Involving Human Embryos Act 2002, provides a clear example of national harmonisation through a single licensing framework. Adopting a similar approach to human tissue research could support consistent ethical frameworks and could streamline regulation, ensure consistent ethical standards, and reduce duplication while preserving state and territory roles.
- Formalising shared ethical and regulatory standards would strengthen federal-state/territory cooperation.
- A national oversight body would be well-placed to integrate transition planning and data stewardship obligations into licensing or approval processes

Authorisation

This submission was endorsed by members of the Academy's Executive on 17 July 2025 for publication by the Australian Academy of Health and Medical Sciences.

Australian Academy of Health & Medical Sciences

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