

3 July 2025

Australian Law Reform Commission
Review of Human Tissue Laws: Issues Paper submission
Australian Government
humantissue@alrc.gov.au

Dear Commissioner

The Kids Research Institute Australia (The Kids) welcomes the opportunity to provide a submission to the Australian Law Reform Commission on the review of Human Tissue Laws.

As one of the largest and most successful medical paediatric research institutes in Australia, The Kids works with community, researchers, practitioners, policy makers and funders, as well as Federal and State Governments, to inform and improve the health and wellbeing of children through excellence in research. With the vision of happy healthy kids, empowering communities and those with lived experience through consumer and community involvement continues to be a key priority of our strategic plan.

The Kids is committed to continue working closely with all levels of Government to improve the lives and wellbeing of children and young people. We have teams of internationally regarded and highly qualified researchers in Western Australia and across the country who are examining diverse areas of work; a lot of this research is undertaken on and in relation to human tissue and involves the collection and transfer of human tissue. These matters explored through the research by The Kids inform our evidence-based advocacies.

We commend the Commission for reviewing the Human Tissue Laws and for recognising the need for reforming current laws and practices, in circumstances where the Human Tissue Acts (HTAs) are significantly outdated. The Kids would like to raise the following concerns in relation to current Human Tissue Laws, highlighting the gaps in legislation and where greater clarity could be beneficial. The Kids would also like to draw attention to areas of concern which were not featured in the Issues Paper.

- **Outdated and inconsistent legislation:** There is a real need for legislative reform as there have been significant scientific advances (e.g., in human genetic sequencing) since the HTAs were first passed. Human Tissue Laws in Australia must be updated to keep pace with the science. For example, section 34(b1) of the *Human Tissue Act 1983* (NSW) (NSW HTA) specifies that the NSW HTA does not apply to “the use, for therapeutic, medical or scientific purposes, of small samples of any tissue that is lawfully removed from the body of a person ... and retained in the form of a tissue slide or tissue block which enables microscopic examination of the tissue”. The effect is to allow unregulated storage, transfer, and use, without need for consent, of what is known as “fixed tissue” (i.e., tissue that is preserved to prevent decay). However, modern technology can now extract and sequence DNA from fixed tissue, meaning individuals’

genetic identities can be accessed without their knowledge or legal protection. It is also important that the HTAs are harmonised, for reasons including that tissue collection and research is often conducted in different states, by different entities. The collaborative nature of research means that human tissues are frequently shared and exchanged across state (and international) borders. A research organisation handling human tissue in relation to scientific research is infrequently the organisation which has collected the human tissue in the first place. Inconsistent legislation across these settings creates uncertainty amongst donors and researchers as to how human tissues may be used.

- Transfer of human research tissue: Transfers of human tissue between facilities, both domestic and international, are poorly regulated. While agreements such as Material Transfer Agreements and/or Collaborative Agreements are standard practice in research, they are not legally mandated and are frequently ignored.
- Informed consent: Current consent processes lack transparency. Donors often do not fully understand how their tissue, and data generated from analysis of their tissue, will be used, undermining trust in human research, and creating barriers to research recruitment and tissue donation for research purposes. Broad consent language, potential conflicts of interest (e.g., clinicians recruiting their own patients), and timing (e.g., recruitment occurring just before a procedure) compromise the “informed” aspect of consent.
- Paediatric samples: There is no legal requirement to re-consent a donor once they reach adulthood, even though samples can be stored for decades. Adults may unknowingly have tissue in research they never personally consented to. While there is new guidance around assent from children, it is also inconsistently applied and should be clarified in law.
- Children under state care: Children without legal guardians (e.g., under state care) cannot currently donate human tissue due to lack of an authorised consent-giver. This gap needs careful legislative consideration.
- Inconsistent definitions: The inconsistencies around the legal definition of human tissue (including modifications and derivatives such as cell lines) are unhelpful and create uncertainty. The Kids endorses the Commission’s focus on definition as a priority area for reform. Human Tissue Laws are also complicated by the fact that there is presently no defined position in Australian law on the ‘ownership’ of human tissue once it leaves the body.
- Research and commercialisation: Related to the issue of whether there is (or should be) a legally recognised right of property in human tissue extracted from the body, The Kids wishes to highlight that the results of research into human tissues may sometimes be commercialised. To improve health and medical care and drive innovation, researchers may seek to translate their findings into marketable products or services. Where commercialisation involves data and/or derivatives from human tissues, there is a need to consider how donors are engaged and involved in the commercialisation process.

The Kids recommends that the Commission explores the following measures to support the reform of Human Tissue Laws:

Uniform legislation across Australia

For the reasons outlined above, there is a compelling need for uniform legislation across states and territories.

Ensure culturally sensitive approaches and transparency

The Kids recognises a need for more culturally sensitive approaches to human tissue donation, research, management, and disposal of samples. We strongly believe that practices must ensure alignment with community expectations, cultural considerations, and to Indigenous data sovereignty principles.¹ While this will ensure that practice is consistent with community standards and protocol, our view is that this should be the minimum standards for all.

From a community engagement perspective, transparency is crucial in ensuring community involvement occurs, and individuals who may be patients or research participants are empowered to make decisions. Transparency should include the who, what, when, where, and why – why being the most important aspect for community understanding, as it is the purpose of their involvement and engagement. As part of best practice, The Kids recommends that the following practical steps are taken by organisations which collect and/or use human tissue for research purposes.

- Clear information guidelines need to be made available, which outline how and why organisations intend to use human tissue (or not use it), and any future use. Donors have the right to be fully informed of the intended use of their samples, or if/when they are not used.
- Guidelines need to be accessible across all channels and available in a variety of media, without reliance on written information alone.
- Access to interpreters, translational services, and direct contact with the organisation via a specific helpline or email address would be ideal so individual concerns or queries can be properly addressed. Consultation with communities would identify cultural needs and requirements based on specific regions.
- If research results are commercialised, donors need to be informed and must be given transparency about the process by which their human tissue has been or will be used.

Develop a process for re-consent

There is currently a lack of clarity and consistency around consent and authorisation frameworks and a need for far greater clarity and consistency where child donors are concerned. The updated *National Statement on Ethical Conduct in Human Research* has guidance on child assent and consent that is lacking specificity for human tissue. The lack of process around re-consent once a child donor reaches adulthood is also an important issue that needs addressing. We strongly believe re-consent should be determined at a specific age, for example, when a child turns 18 years of age. Similarly, we agree that very careful consideration needs to be taken for children under state care. For example, there is a need to consider what happens when a child returns to family care or ‘ages out’ of the state system.

Careful consideration of human tissue ‘ownership’ and ‘custodianship’

The Kids has identified that a need for a community-led, culturally sensitive discussion around the concept of human tissue ‘ownership’. Given the difficulties with reconciling legal definitions of property and ownership with human tissue after it has been extracted from the body, we would suggest considering the idea of ‘custodianship’, which would align more closely with community expectations, with consideration given to the rights and responsibilities of custodians of human tissue, and obligations which arise if/when custodianship is transferred. The concept of

¹ Lowitja Institute 2021, *Indigenous Data Governance and Sovereignty*, Research Pathways: Information Sheet Series. Available at: https://www.lowitja.org.au/wp-content/uploads/2023/10/328550_data-governance-and-sovereignty.pdf

'custodianship' would also allow consideration to be given to providing donors with the right to have their human tissue samples destroyed at any stage.

We would be pleased to elaborate on the comments provided here and look forward to work with you. Should you require any clarification or further information, please contact Fiona Roche, Head of Government Relations on [REDACTED].

Your sincerely

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