The Australian Alliance for Indigenous Genomics (ALIGN)

Submission to the Australian Law Reform Commission – Review of Human Tissue Laws

4 July 2025

Introduction

This submission has been developed by the Australian Alliance for Indigenous Genomics (ALIGN) in response to the Australian Law Reform Commission's Review of Human Tissue Laws. It is comprised of three parts: Part 1 - Recommendations, Part 2 - Considerations for Aboriginal and Torres Strait Islander Peoples, Part 3 - Responses to select Review questions.

About the Australian Alliance for Indigenous Genomics (ALIGN)

ALIGN[1] is a national consortium, led by the Indigenous Genomics Group at The Kids Research Institute Australia (The Kids) and the Australian National University (ANU), in partnership with Aboriginal and Torres Strait Islander stakeholders, peak bodies and Communities, as well as research, clinical, industry and institutional partners from across Australia. It focuses on advancing the rights and interests of Aboriginal and Torres Strait Islander Peoples in genomics. ALIGN seeks to build and extend Indigenous leadership and involvement in genomic science, research, precision health care, data sciences, ethics, and Indigenous knowledge systems to reduce health inequality among Australia's First Peoples. Aboriginal and Torres Strait Islander governance both underpins and leads ALIGN's work, and is instrumental in bringing forward the voices, values, and priorities of Aboriginal and Torres Strait Islander Peoples, locally and nationally.

ALIGN's Response and Context

ALIGN welcomes the opportunity to provide input into the Review of Human Tissue Laws. This submission has been informed by members within our network who have experience across Indigenous genomic research and biobanking, Indigenous data and bio-sample sovereignty and governance, and relevant legal issues.

The limitations of the existing Human Tissue Acts (HTAs) in protecting the rights and interests of Aboriginal and Torres Strait Islander Peoples are frequently revealed across the range of activities undertaken by ALIGN. Given the recent rapid technological advances across health and medical research, and particularly in genetic and genomic health and research, there is a need to ensure that Australia's HTAs are modernised and harmonised to not only reflect these rapid changes but to ensure the principles of sovereignty, equity, benefit, access, ethical oversight and harm prevention are recognised, addressed and implemented. It is also crucial that the updated HTAs are informed by, and appropriately reflect, the unique cultural beliefs, values, and protocols held by Aboriginal and Torres Strait Islander communities, as well as the unique cultural beliefs, values and protocols held by the many culturally and linguistically diverse groups across Australia.

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[1] The Australian Alliance for Indigenous Genomics

In a series of articles recently published in *The Lancet Journal,*[2][3][4] the authors explored the importance of emerging genomic technologies (precision health) for increasing the successful long term transplantation health outcomes of the recipient and reducing organ rejection rates. Two of these papers also highlighted the importance of addressing public trust and the existing inequities for accessing donated organs by people living in low- and medium-income countries, and minority or marginalised populations living in high income countries like Australia. The policy-based article noted that even in high income countries including Australia, there were still significant system-based issues, including: variable access to specialty care, inadequate coordination between referring clinicians and transplant programmes, and variable insurance coverage and funding requirements for patients. The authors called for policies that reduce financial barriers for patients, incentives for hospitals to increase transplantation rates and improve care coordination, and quality measures that assess equity along entire transplantation pathway.

Cultural considerations must also be recognised to successfully increase Australia's organ donation rates. In a recent study in Alice Springs that sought to explore perceived barriers and enablers for Aboriginal and Torres Strait Islander Peoples around organ donation, focus groups held with Aboriginal Liaison Officers identified the importance of trust in the healthcare system, and that organ donation is still a new, confronting, and culturally taboo topic, despite being recognised as important[5]. Education was identified as a key enabler for organ donation for both Aboriginal and Torres Strait Islander Peoples (where education should be place-based, informed by local knowledge, delivered in community, and importantly, delivered before a family member is admitted to ICU) and for clinicians, which includes cultural education and trainings for the delivery of culturally safe communication around organ donation with Aboriginal and Torres Strait Islander patients.

Part 1: ALIGN's Recommendations

1. **That all key issues presented in this submission are addressed, including:**

2. **The development of an Aboriginal and Torres Strait Islander Governance Framework/Guidelines to support the implementation of the Acts.**

3. **Ensure there are broad and deep Aboriginal and Torres Strait Islander Community consultations to inform the changes to the Acts and the development of a co-designed Governance Framework/Guidelines.**

4. **The development of national culturally appropriate resources for use by Aboriginal and Torres Strait Islander Peoples and health services, non-Indigenous health services, researchers, forensics/coronial and bio-bank staff.**

5. **Update the Acts to include appropriate reference to the proposed Framework/Guidelines for use when developed.**

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[2] Advancing patient monitoring, diagnostics, and treatment strategies for transplant precision medicine - The Lancet

[3] Scientific advances in the assessment, modification, and generation of transplantable organs for patients with end-stage organ diseases - The Lancet

[4] Policy innovations to advance equity in solid organ transplantation - The Lancet

[5] Aboriginal and Torres Strait Islander attitudes to organ donation in Central Australia: a qualitative pilot study

Aboriginal and Torres Strait Islander Governance Framework/Guidelines

Developing an accompanying Aboriginal and Torres Strait Islander Governance Framework/set of Guidelines to support the implementation of the updated Acts will provide operational consistency and clarity across all jurisdictions that is grounded in cultural safety, and reflects the customary practices, LORE and values of local Aboriginal and Torres Strait Islander Peoples. These will also be essential to upholding Community trust, ethical standards, and national consistency. The Framework/Guidelines should underpin the Acts, providing strong recommendations and practical guidance for the collection, use, storage and re-use (for example secondary research use) of Indigenous tissues, remains and repatriation processes, and related and derived data. Broad and deep Aboriginal and Torres Strait Islander Community consultations should be undertaken to inform Framework/Guideline development to ensure that the voices, cultural values, and priorities of Aboriginal and Torres Strait Islander Communities are appropriately embedded.

As a national consortium underpinned by Aboriginal and Torres Strait Islander governance, and with considerable member expertise across its network, ALIGN should be engaged as a stakeholder in the proposed Framework/Guideline development process and in the review of the updated Acts.

Aboriginal and Torres Strait Islander Governance Framework/Guidelines: Essential Principles and Considerations

The Framework/Guidelines should be grounded in cultural values and informed through deep and broad Community consultations.

ALIGN recommends that the proposed Framework/Guidelines should include, but not be limited to, the following elements:

- Indigenous introduction and context
    - Including Indigenous ways of knowing, being and doing
- Community engagement and consultation processes
    - Including when changes to the HTAs are proposed
- Governance mechanisms
- Sample and data sovereignty
    - Collection, use, re-use and storage and repatriation processes if required
- Cultural safety
    - Co-designed Indigenous governance frameworks
- Informed consent
    - Including dynamic and enduring consent, with clear opt-out processes
- Secondary use of tissue samples and data derived from their analysis
- Respect, Equity (including cultural context), Transparency, Trust, Safeguards, Sovereignty, Benefit, Self-determination (and more as identified by different Communities and groups)
- Definitions (ownership, kinship terms, tissue types)

Part 2: Issues Paper Feedback

Considerations for Aboriginal and Torres Strait Islander Peoples

ALIGN has identified key issues for consideration for Aboriginal and Torres Strait Islander Peoples in the Review. These are presented as a high-level summary below and are further elaborated upon in Part 3 where relevant:

- The need for consistent and culturally appropriate guidance and regulation on secondary use of tissues
- Culturally safe participation and informed consent for Aboriginal and Torres Strait Islander Peoples
- Improving consent processes for research use beyond clinical collection
- Strengthening national guidance on Indigenous sample sovereignty
- Recognising cultural norms and values within the HTAs
- Identifying and addressing systemic barriers to equity
- Supporting culturally safe storage, repatriation, and disposal of tissue
- Clarification of definitions (Kinship, ownership and classification of tissues)
- Strengthening regulation of international export and use of tissue
- Strengthening governance and redress mechanisms
- Improving alignment across legislative frameworks (Privacy, Heritage, etc)

Part 3: ALIGN's Responses to the Inquiry Questions

Question 3. When we think about the laws governing how human tissue is obtained and used, what are good aims or objectives for these laws?

There are presently few options for Aboriginal and Torres Strait Islander tissue donors to exercise control over the full use of their tissues, particularly for secondary research purposes without the safeguard of additional consent requirements, and irrespective of whether the sample was collected for clinical or research purposes. The current laws should be updated to provide more detailed guidance **on appropriate processes for secondary uses of tissue**. Much of this work is currently delegated to research ethics processes. However, these are front-end only and do not provide oversight or **meaningful complaint mechanisms, with few (if any) opportunities for redress** when the use of these tissues results in harms to individuals and/or Communities. Equity is a useful aim, but only if operationalised with appropriate consideration of both the burdens and benefits, and assessed in the relevant social contexts.

In this context, the laws should aim to ensure that all Australians understand what is involved in donating tissue for transplant purposes, and how their tissue will be used (i.e., **informed consent processes)**. There are very few culturally appropriate resources available to help Aboriginal and Torres Strait Islander Peoples understand these issues, which results in a lack of donors, and consequent barriers and delays for transplant recipients. The proposed laws should aim to address these inequities, and to **increase trust** in tissue donation among Aboriginal and Torres Strait Islander communities. There is also a lack of understanding within Aboriginal and Torres Strait Islander Communities, and in the general public, of the downstream uses of donated tissue in medical research.

Within the Issues Paper (Pg 7) it is evident that the review, harmonisation and reforms are aimed at supporting increased access to human tissue in Australia. However, there are inherent tensions that exist between measures that increase access to human tissue and the existing issue of inequity for many Australians, particularly Aboriginal and Torres Strait Islander Peoples. Balancing culturally appropriate informed consent and acknowledging cultural practices and beliefs can often be overlooked or dismissed in favour of the wishes of mainstream popular opinion and as such their power to dominate the narrative and influence policy and law makers.

Question 4. When we think about reforming human tissue laws, what principles should guide reform?

Awareness and understanding **of Indigenous data sovereignty** and governance is increasing, particularly relating to genomic data and cancer research. Many studies and guidelines, including those by ALIGN, seek to ascribe best practice in dealing with genomic data from Aboriginal and Torres Strait Islander Peoples. However, there has been much less focus on the human tissue these data are derived from. The majority of recent advances in cancer research have come from preclinical studies and clinical trials involving the use of human samples. Despite this, there are currently no national guidelines for **"sample sovereignty**", i.e. the use of human tissue samples from Aboriginal and Torres Strait Islander Peoples in biobanks and medical research. We recommend that a clear set of national guidelines be co-developed to govern the use of human tissue from Aboriginal and Torres Strait Islander Peoples for clinical and research purposes.

In addressing equity in the context of human tissue laws, consideration should be given to defining to the issue of not only access but the ethical and cultural considerations. For example, if HTAs are amended to include the potential for removing reproductive tissue (sperm and ova) for use by a legal partner, spouse, or third party, within an Aboriginal and Torres Strait Islander context, consideration should be given to the future cultural identity of any offspring born to non-Indigenous parents. Inequitable access to organ donation for Aboriginal and Torres Strait Islander Peoples has been well established in the literature[6][7][8][9], and requires significant redress within the new HTAs and related clinical processes and practices, and should be monitored to ensure Indigenous Peoples are given and experience the same opportunities for accessing organ donation as non-Indigenous Australians. Ensuring consent for research beyond the original clinical test should be clearly articulated in the revised HTAs and monitored for compliance. In addition, we recommend that additional protections for Aboriginal and Torres Strait Islander Peoples are considered and included. If an Indigenous governance framework/set of guidelines is co-developed and underpins the HTAs, consent processes could be included within these, along with guidance for the collection, use, storage and re-use (for example research) of Indigenous tissue, remains and related data.

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[6] Renal transplantation for Indigenous Australians: identifying the barriers to equitable access

[7] Barriers to access by Indigenous Australians to kidney transplantation: the IMPAKT study

[8] If you can't comply with dialysis, how do you expect me to trust you with transplantation? Australian nephrologists' views on Indigenous Australians' 'non-compliance' and their suitability for kidney transplantation

[9] Indigenous transplant outcomes in Australia: what the ANZDATA Registry tells us

Question 5. Do you agree that the issues set out in the section ‘Priority Reform Areas’ should be a focus for our inquiry? Please tell us about why you think these issues should or should not be a focus.

The Inquiry should consider clarifying the issue of **ownership of tissue samples, for all people** (which ideally should not contribute to existing incoherence in the law). Part of this would require definitional clarity. ALIGN suggests that any definition of tissue would need to consider whether the sample contained human genomic material (and thus substances like human milk, which may contain cells from the mother may well be captured, as would some bioprinting applications and products like cell lines) in order to facilitate a risk-based approach to regulation.

The **long-term storage of tissue and blood samples in a pathology setting** should be considered. These samples are for the most part not stored in ways that consider cultural safety, and there are minimal provisions for repatriation or culturally sensitive destruction. As stated in point 57 of the Issues Paper, this has implications **that tissue can be reused for research or other purposes without consent**, including in ways that are culturally unsafe for the donor. Regulations to prohibit the international transfer of tissue from Aboriginal and Torres Strait Islander Peoples without explicit consent should also be considered. In Issue paper point 58 (and 66), **the definitions of child, parent, and family may not consider Aboriginal and Torres Strait Islander kinship structures** and **decision-making authority.** This may complicate the ability of children and their extended families to participate in important and culturally safe medical research.

Question 6. What, if any, other issues should we be focusing on in this inquiry?

Consideration for how the HTAs operate in relation to the Privacy Acts would be helpful. For example, a tissue sample is easily converted to personal information, but different regulatory processes muddy the waters for clinicians and researchers. Evaluation of the role of the OTA and whether it should have a broader regulatory role should be considered, including providing a mechanism for complaints and redress for tissue donors. ALIGN also suggests that the Inquiry consider empowering the NHMRC to make **guidelines under the Act to provide more explicit guidance on the use of existing tissue collections**, including processes for notifying the public, facilitating opt-out mechanisms, requirements for re-consent (etc.), and considering international models such as the UK's Confidentiality Advisory Group. If ownership of tissue is considered, guidance on when tissue can be traded (e.g., whether the collection can be sold if a repository becomes insolvent) and when a sample becomes a product should be addressed (e.g., what is the difference between a standard tissue sample and a stem cell line, from a risk perspective? and is the application of work or skill test still appropriate given technological advancements?).

The current NHMRC "*Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia*" state that cultural safety should be considered in the donation of tissues. However, these guidelines do not currently provide information or examples around what these considerations are or should be, or potential solutions, and do not address repatriation or return to families of unused or excess tissue (distinct from ancestral remains). While these are useful ethical principles, it is recommended that the inquiry consider **binding guidelines for repatriation of tissues from Aboriginal and Torres Strait Islander Peoples**. It is also recommended that **controls over international export of**

tissues from Aboriginal and Torres Strait Islander Peoples (for transplantation or research) are developed.

Question 8. Do you think it is important that we consider any of the issues in this section 'Issues we are unlikely to focus on in this inquiry'? If so, why?

We believe that the inconsistencies between the HTAs are exacerbated by inconsistencies with other legislative regimes, particularly relating to privacy and cultural heritage, and that the Inquiry should seek to make recommendations that would create a more coherent regulatory environment that is easier for donors, families, clinicians and researchers to navigate.

Conclusion

The Australian Alliance for Indigenous Genomics (ALIGN) is pleased to provide input into the Australian Law Reform Commission's Review of Human Tissue Laws. To support the practical translation of the updated Human Tissue Acts into consistent, effective, and equitable practice, ALIGN's primary recommendation is that an accompanying Aboriginal and Torres Strait Islander Governance Framework/Guideline is developed. This should be appropriately referenced within the updated Acts, co-designed through robust consultations with Aboriginal and Torres Strait Islander Communities, and further supported by the development of culturally appropriate Aboriginal and Torres Strait Islander resources for national use.

ALIGN would be pleased to meet with the Inquiry team to discuss issues of relevance to Aboriginal and Torres Strait Islander Communities at the appropriate Inquiry stage.

Contact for further information

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