Australian Alliance for Indigenous Genomics (ALIGN)

Submission to the Australian Law Reform Commission's Review of Human Tissue Laws: Discussion Paper

30 January 2026

Introduction

This submission has been developed by the Australian Alliance for Indigenous Genomics (ALIGN) in response to the Australian Law Reform Commission's (ALRC) review of Human Tissue Laws: Discussion Paper. It builds upon our previous submission in July 2025 in response to the ALRC's Issues Paper.

About the Australian Alliance for Indigenous Genomics

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 further input into the Review of Human Tissue Laws in response to the Discussion Paper. We have responded to the most relevant and pertinent questions and issues raised in the Discussion Paper, and as such, 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.

[1] The Australian Alliance of Indigenous Genomics

ALIGN's Key Points in Response to the Discussion Paper's Questions and Recommendations

That all responses and key points raised within this submission are addressed, including:

- **The development of an Aboriginal and Torres Strait Islander Governance Framework/Guidelines to support the implementation of the Acts.**
- **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.**
- **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 biobank staff.**
- **Update the Acts to include appropriate reference to the proposed Framework/Guidelines for use when developed.**

Contact for further information

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ALIGN's Responses to Select Discussion Paper Questions

Question 1. Do you agree with the objects listed in Proposal 5 for human tissue legislation?

We recommend the development of an Indigenous Governance Framework or Guidelines that accompany or 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. Specific Indigenous sovereignty and governance protocols are recommended for biobanks to ensure culturally appropriate handling, management, informed consent, sharing and management of Indigenous bio-specimens. The Commission has acknowledged that there has been a lack of diverse consultation with Indigenous Communities and key stakeholders to date. Further and ongoing consultations are recommended by ALIGN, given the complexity of issues being dealt with in this process and the diversity of cultural, knowledge and practices that exists among Indigenous peoples and Communities.

Question 2. Aside from the objects set out in Proposal 5, should new human tissue legislation include other objects?

In keeping with our original submission, we seek specific objects that recognise and protect the cultural knowledges, expressions, rights and practices of Aboriginal and Torres Strait Islander Peoples, including:

- 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)

Question 3. Is there a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use?

We applaud the recognition by the Commission to embed equity within new or amended legislation, however, this essential value is not clearly articulated in the Discussion Paper, and we suggest that this

could be brought under the role of a Regulatory Authority. Broader consultations with Aboriginal and Torres Strait Islander Peoples in seeking a diverse range of opinions, priorities and recommendations should be undertaken before new legislation is drafted. Recognising and capturing the cultural, geographical and Community diversity of Aboriginal and Torres Strait Islander peoples is essential. We strongly recommend that consultations with the National Aboriginal Community Controlled Health Organisation (NACCHO) and the state/territory Aboriginal and Torres Strait Islander health peak bodies be undertaken.

Question 4. If there is a need for new human tissue legislation to include provisions designed to remove barriers and promote equitable access to human tissue donation, transplantation, and use (Question 3), what are the specific barriers that new human tissue legislation needs to address? In considering this question, please ignore:

- definitions of senior next of kin that may be outdated and unsuitable (we address these in Proposal 25); and

- disclosure of information provisions that in some jurisdictions prevent the families of deceased donors talking about their family member's experience (we address these in Proposals 46 and 48).

While existing barriers could be better identified through extensive consultations with Aboriginal and Torres Strait Islander Peoples, there are known barriers to accessing health and research environments that may impact on Indigenous Australians in the context of tissue and organ donation, biobanking specimens and research. These include: a lack of trust in government health and research services, insufficient information that is culturally relevant and understood, a lack of knowledge of decision making by multiple family members, a lack of Indigenous sovereignty, governance and management of biospecimens, data, and research. Cultural governance frameworks should be developed to guide: organ retrieval and collection, storage, use, management and research of biological tissue. Repatriation processes may need to be considered and prioritised. Developing culturally appropriate information and resources will be essential in reaching Indigenous and multicultural communities and building trust and knowledge for the spectrum of decisions and processes covered by the HTAs.

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 consequently increase 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.

Further, in focusing on the particular barriers and concerns facing Aboriginal and Torres Strait Islander people, it is likely that the principles that are developed in response to improve equitable access for these Communities may be beneficially generalised as best practice for the wider population.

Question 5. How do you think 'tissue' (or an alternative label) should be defined in order to be suitably broad? In your response, you might consider the following options:

a. tissue means material which consists of, includes, or derives from human cells (a definition based on section 54 of the Human Tissue Act 2004 (UK)); or

b. tissue means the human body or any constituent material, substance, or part removed from a human body that is, includes, or derives from

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. Many 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. 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. 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. 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. In new human tissue legislation, should the word 'tissue' be replaced with another label? In your response, you might consider alternative options such as:

a. 'substance of human origin';
b. 'human material'; or
c. 'cell, organ, and tissue'.

If 'tissue' is to be replaced with a new label in the new human tissue legislation, it should be clearly defined and capture the broad range of derivates and information that can arise from human tissues, e.g., genomic data and laboratory cell lines. In this respect, option B ("human material") could be defined to explicitly include lab-created derivatives and would be lay-person friendly. "Biologics" as defined in the Therapeutic Goods Act would be useful, but is not widely understood by the public, and "tissue" alone is insufficient to cover other human-derived materials that carry the same risks, e.g., anything with genomic material.

Question 7. Should any of the following materials be excluded from human tissue laws, or excluded from the operation of human tissue laws for particular purposes, circumstances, or provisions of the new human tissue legislation?

- Human milk, Foetal tissue, Faecal tissue, Gametes (from deceased donors), Cell lines - If you think some of the above materials should be excluded from human tissue laws (either completely or for particular purposes, circumstances, or provisions), why? Are there other types of tissue that you think should or should not be regulated by human tissue laws?

In your response, you may want to consider Proposal 5 (the objects of human tissue laws), Proposals 40–44 (reforms relating to the prohibition of domestic trade) and Proposals 32–39 (reforms relating to tissue donation for research).

If cell lines and patient derived xenograft models are included within the human tissue laws, we recommend that very clear and strict definitions be put into in place to protect the ability to conduct life-saving research. Incorporation of these clear definitions will also support ease of reference and consistent interpretation, given the genomic data inherent to these types of materials. We also recommend that 'identifiability' be clearly defined, as this is a key concept for several of the proposed reforms and ideally should not be used as a regulatory mechanism. Tissue containing DNA is always potentially identifiable.

Question 9. To maintain national consistency, which of the following statutory locations or approaches would be most appropriate for provisions relating to the determination of death, assuming that these provisions apply for all purposes?

a. A 'Uniform Death Act', adopted as national uniform legislation in each state and territory; or
b. New human tissue legislation (Proposal 1); or
c. Each state and territory decide where to locate the determination of death provisions but make an intergovernmental agreement that there be a consistent approach to future amendments to these provisions.

If agreement can be reached by all state and territory governments, then a national "*Uniform Death Act*" would be consistently understood and applied.

Question 10. Are there additional safeguards aside from those set out in Proposal 14 that should be set out in new human tissue legislation?

The Review 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. 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 make it difficult 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 Review 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?).

Question 17. Does Proposal 23 strike the right balance between the autonomy interests of individuals, the need for flexibility to accommodate unforeseen circumstances, and respect for a deceased person's next of kin? What are the advantages and disadvantages of this approach?

We recommend expanding and having a more flexible definition of "next of kin", as it would benefit many Aboriginal and Torres Strait Islander families and Communities and relieve decision-making pressure.

Question 29. Should there be a legal requirement to obtain consent from people who provide tissue samples before using their tissue for research or other purposes that they did not consent to? You may want to consider Question 27, where we ask about secondary uses of tissue samples taken during a post-mortem examination.

As a baseline expectation, consent for the use of tissue should be a requirement. As a standalone, consent itself is an insufficient protection of individual interests and should always be supported by a trustworthy regulatory system, including mechanisms for community engagement to better address group harms and benefits through participatory governance. However, the transparency and accountability effected through consent processes contributes to public trust in health systems, research as an example, and should be supported.

Question 30. If a legal requirement for consent is imposed (Question 29), should there be exceptions to it? If so, what exceptions should exist?

While in the vast majority of cases consent should be obtained for secondary use of tissue samples, clear exceptions should be included to allow laboratories to undertake quality assurance and accreditation activities. However, any exception for educational purposes would require additional community consultation to ensure that cultural considerations were appropriately integrated.

Question 34. Should new human tissue legislation provide that individuals have a right to access their stored tissue? If so, what should 'access' entail in this context and who should be granted the right?

Yes, granting individuals the right to access their stored tissue should be incorporated into the new legislation. Access should include the right to revoke consent and have samples repatriated, both by the individual and their next of kin. Further, 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 Review 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 40. Should new human tissue legislation include a mechanism to help make sure that imported tissue has been ethically sourced? If so, should the mechanism be:

a. A prohibition of the importation into Australia of human tissue that was originally obtained without the consent of the donor, or in exchange for reward or profit? or
b. A reporting mechanism similar to that contained in the Modern Slavery Act 2018 (Cth)?

If (A), the retrospective application of the laws must be considered for tissues such as HeLa cells, for example, which are widespread in research laboratories.

Question 42. We have heard there is a need for data from donation agencies, tissue banks and other tissue product manufacturers, distributors, and sponsors to better understand the demand for tissue and inform future policy development. If you agree there is a need for data, what type of data is needed?

Data should include those related to the collection and management of Indigenous data across the spectrum of activities covered in these Acts, such as organ donation, tissue collection, and use. As described, the collection and management of Indigenous data reflect the need to have appropriate data sovereignty and governance protocols in place.

Question 44. In relation to Question 43, if you support mandatory reporting, should the National Regulator (or alternative) have the power to conduct mandatory inspections of records?

Yes, however, we believe that this should be expanded to include mandatory inspections of "records, policies and processes".

Question 45. Do you have views about the best mechanisms to encourage or enforce compliance with the obligations and prohibitions that we are proposing should be included in new human tissue laws, regulations or standards? In your answer, you may wish to focus on particular obligations or prohibitions that we are proposing, and the best way of encouraging or enforcing compliance with these.

If a culturally appropriate set of regulations or principles were to be developed to accompany the revised HTAs, this framework could expand in detail the specific requirements that would better support the needs of Indigenous Australians, and the penalties where appropriate that would be applied for institutions and their employees who breach the acts and principles. We request consideration for how common terms in legislation like "*a reasonable person*" or an "*ordinary person*", when trying to determine a reasonableness test, might be Eurocentric and not hold in an Indigenous or multi-cultural Australian context. The values and norms that the majority might hold or have may not align with the values and norms that under-represented groups like Aboriginal and Torres Strait Islander people have and hold, i.e., should "reasonableness" tests be reviewed and broadened to be more representative of Indigenous and multi-cultural Australians?

Question 46. Do you have views on the timeframe/s within which the reforms set out in this Discussion Paper should be implemented, or on how the implementation of these reforms could be staged or prioritised?

Our recommendation is that the timeframe for reform and implementation must consider and incorporate the need for appropriate consultation with Aboriginal and Torres Strait Islander Communities. We recommend undertaking early engagement and consultation as a priority.

Question 47. Is there an urgent need for reform of human tissue laws that we have not addressed in this Discussion Paper?

While there is recognition for equitable processes and considerations within the draft, there is a lack of definition and a need for expansion of the specific requirements and priorities of underrepresented groups, including Indigenous Australians. Specific proposals for the culturally appropriate management of Indigenous biospecimens and data are lacking, along with mode-detailed consent processes for biospecimens and data research. 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 Review should seek to make recommendations that would create a more coherent regulatory environment that is easier for donors, families, clinicians, and researchers to navigate.