Australasian Biospecimen Network Association - Submission for Review of Human Tissue Laws: Discussion Paper (2025)

Dear Commissioners,

The Australasian Biospecimen Network Association (ABNA) thanks the Australian Law Reform Commission for the opportunity to provide a submission in response to the *Review of Human Tissue Laws: Discussion Paper (2025)*. We also appreciate the Commission's acceptance of, and engagement with, our previous submission to the Issues Paper.

ABNA acknowledges and welcomes the thoughtful consideration given to our earlier input, much of which is reflected in the scope, framing and proposals contained in the Discussion Paper. We are encouraged by the Commission's recognition of the importance of human tissue use for scientific and research purposes within the broader reform agenda.

We wish to emphasise that ABNA's responses to this Discussion Paper are provided specifically in the context of **scientific and research purposes**, with a particular focus on **research biobanking**. All comments and recommendations in our submission should be interpreted within this context. While we recognise the Discussion Paper necessarily addresses a range of uses of human tissue—including medical, transplantation and educational purposes—we note that careful distinction between these contexts is at times required to ensure regulatory settings remain proportionate and fit for purpose.

Overall, ABNA considers that the Discussion Paper reflects an increasing focus on tissue use for research. Our key feedback centres on the need for:

- a nationally consistent, principles-based legislative framework;
- a national regulator with appropriate expertise to provide guidance and oversight;
- a central registration of research biobanks;
- sufficient regulatory flexibility to avoid unnecessary barriers to ethical research; and
- strong safeguards to protect donor welfare and public trust while enabling high-quality, impactful research.

ABNA welcomes the opportunity to continue engaging with the Commission as this important reform progresses and would be pleased to provide further input or clarification as required.

Yours sincerely,

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In collaboration with ABNA member representatives:

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Dr Cassandra Griffin	Biobanking and Clinical Research Manager; Co-Deputy Director, HMRI Cancer Detection and Therapy Program; Co-chair of ABNA Indigenous Engagement in Culturally Safe Biobanking and Biospecimen Sciences Special Interest Group; Co-Chair ABNA Post-mortem Tissue Collection Special Interest Group.
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Theme	Proposal & Question No.	ABNA Positions/Feedback
National regulatory framework	P1 & P2	We support a uniform Commonwealth human tissue legislative framework (**P1, option b**), with detailed and adaptive regulation set by a national regulator, as this would significantly reduce jurisdictional inconsistency and administrative burden that currently impedes cross-border collaboration and tissue sharing for research. National consistency would directly improve research efficiency, enable multi-centre and nationally coordinated studies, and maximise the scientific and public health value derived from donated tissue - expediting improved outcomes for the patient community. We further recommend a dedicated legislative subsection addressing human tissue used for scientific purposes, recognising that research use differs materially from clinical and transplantation contexts. Clear differentiation would prevent misapplication of clinical-focused provisions to research, provide regulatory certainty to biobanks and researchers, and ensure donated tissue is utilised in ways that align with donor expectations and public interest. In addition, we support regulator-led detail rather than prescriptive legislation (**P2, option b**), as this provides the necessary agility to respond to rapidly evolving research technologies (e.g. genomics, AI-enabled pathology, organoids). Such flexibility ensures that regulatory settings remain fit for purpose over time without creating unintended barriers to innovation or access. In the context of biobanking, other than UK HTA, biobanking legislation in Finland[1] and Singapore[2] also provide established frameworks with the aim to protect the welfare of tissue donors and to enable scientific research. The uniform legislation also aligns with the significant demands[3] [4] for a national coordinated framework of biobanking in Australia.
	P3	We support the establishment of a new, well-resourced national regulator (**option b**), while acknowledging NHMRC as a potential option for regulating tissue used for scientific purposes, provided fragmentation is

[1] https://fimea.fi/en/substances-of-human-origin/biobanks
[2] https://www.moh.gov.sg/others/health-regulation/regulation-of-human-biomedical-research/
[3] https://www.education.gov.au/national-research-infrastructure/resources/2026-nri-roadmap-issues-paper
[4] https://www.csiro.au/en/work-with-us/services/consultancy-strategic-advice-services/csiro-futures/health-and-biosecurity/biobanking

		avoided. A specialist regulator with strong understanding of biobanking and research workflows would enable proportionate, purpose-fit oversight, reducing compliance duplication and uncertainty. Clear separation between legislative compliance and ethical review is also critical to streamline governance processes and avoid duplications, support consistent decision-making by HRECs, and allow researchers to focus on scientifically and ethically robust research. To allow this, we strongly advocate for a close working relationship between the regulator, NHMRC, biobanks and scientific communities. Adequate and ongoing funding for the regulator is essential to maintain consistent guidance, stakeholder engagement, and education, thereby strengthening long-term compliance and public trust.
	P4	ABNA supports a legislative framework designed for long-term national consistency, with efficient mechanisms for review and amendment at the Commonwealth level. Such a framework would provide regulatory certainty for long-term investment in biobanking infrastructure and research programs, while enabling timely updates to keep pace with scientific, ethical and technological developments. National consistency would also facilitate shared platforms, registries and coordinated research initiatives, strengthening Australia's overall research capability.
Objects of HTLs	P5; Q1–Q2	We generally support the proposed objects in Proposal 5 as they relate to scientific purposes, particularly those promoting appropriate use of tissue and public trust. We also emphasise the importance of objects that support accessibility, appropriate utilisation and transparency in the context of tissues for research purposes, as low utilisation rates of collected tissue currently represent a significant loss of potential benefit for life-saving research. Applying FAIR (Findability, Accessibility, Interoperability and Reusability) principles to research tissue access would further maximise utilisation, reduce waste, and ensure donated tissue contributes meaningfully to public benefit, thereby reinforcing public confidence in biobanking. Promoting public trust is critical (include increasing public awareness of biobanking) which would further our ability to ensure that guidelines and policy are underpinned by the interests and perspectives of those impacted by their use i.e. the general public. For Q2, we also recommend to explicitly include promotion of high-quality tissue for scientific purposes within the objects, as improved quality, consistency and interoperability of biospecimens directly enhance reproducibility, comparability and overall research impact.

Removing barriers and promote equity	Q3–Q4	We support principles-based provisions that remove unnecessary barriers and promote equitable access to human tissue for scientific purposes. A principles-based approach allows proportionate regulation aligned with research risk, reducing compliance burden while maintaining donor protection. Addressing barriers such as inconsistent tissue and data sharing rules across jurisdictions, limited discoverability of tissue, inconsistent approaches around broad consent, and constraints on secondary use would materially improve access to tissue for research. This approach would also support more equitable participation and benefit-sharing through transparent and respectful governance frameworks. We also support removing barriers and promote equity for tissue use of First nations in a culturally safe approach while acknowledging the significant gap in existing legislative and ethical frameworks. ABNA has formed a special interest group led by indigenous researchers to map a framework for cultural safety in the collection, storage and use of biological samples from first nations persons. These guidelines will be essential to ensuring equity in research outcomes and we welcome the opportunity to collaborate with the HTA as this work continue.
Definition of tissue	P7, 8 and 9; Q5	We support a broad and inclusive definition of human tissue for research purposes (Option A), including derivatives such as DNA. A broad definition future-proofs the legislation against rapid scientific and technological change, avoiding the need for frequent amendment as new tissue-derived materials and methodologies emerge. Consistent inclusion of tissue and its derivatives ensures that materials carrying sensitive donor-linked information remain subject to appropriate oversight, while enabling continued access for ethically approved research.
	Q6	From our perspectives, the term 'Tissue' is concise and sufficient for scientific/research purposes. However, we also suggest to broadly define the term on tissue handling initiatives, i.e. Tissue banks vs Biobanks as per this discussion paper. Currently tissue bank is also interchangeably used for research biobanks (e.g. members of Victorian Cancer Biobank are listed as Tissue Banks in Victorian HTAs but function as research biobanks)
	Q7	For scientific purposes, we **support not to exclude them except cell lines**. All these materials contain information/contents (e.g. DNA) that are critical for research but also still related to the donors which should be regulated similarly as other materials. Cell lines (or similar items) are resources for low-risk scientific research for years with general acceptance on it's commercial impacts towards advancing scientific research.

		We also acknowledge and support the needs of exempting these materials from certain provisions, e.g. the prohibitions of trades, for the benefits of improving research access and enabling other purposes.
Reforms related to death	P10–P13 P38-39	Post-mortem donation of tissue specifically for research purposes relies upon the current clinical definition of death and requires a Medical Certificate of Cause of Death to be issued by the relevant treating clinician. Any reforms to the definition of death are not relevant in this setting. Items 60 to 97 apply to transplantation and do not reference the use of post-mortem tissue for research where the individual donor, or a designated next of kin with appropriate legal authority such as enduring guardianship, provides explicit consent during life to the post-mortem collection and use of their tissue for research. The regulation of these research donations varies between State and Territory jurisdictions, sometimes necessitating the involvement of Designated Officers depending on where the individual dies. Non-coronial autopsy procedures, carried out by an appropriately qualified practitioner, require HREC and Institutional Governance bodies approval.
Donation of tissue by people with limited capacity	P20–P22	HREC oversight is appropriate
Consent for research	P32	We support the articulated consent principles but strongly recommend explicit recognition of broad and unspecified consent for research, as well as ethically governed (instead of consent mandate) secondary use of tissue collected for other purposes. Clear legislative recognition of such flexibility would maximise the scientific value of donated tissue, particularly for rare conditions and high public interest research where re-consent is impractical. This approach aligns with established ethical mechanisms such as waiver of consent, opt-out models and deferred consent, enabling timely and socially valuable research while maintaining respect for donor autonomy and wellbeing. Explicit clarity would also reduce uncertainty for biobanks, researchers and HRECs, supporting more consistent and efficient decision-making. We acknowledge ALRC has considered these in the discussion paper but the proposal does not clearly align with the described aims.
	P33	We support the donor rights in proposal 33 but suggest broadening the term on accessing info on how tissues are used. While transparency and communication with participants regarding research use and impact is critical, regular and aggregated communication can be more practical and ethically appropriate than providing

		individualised usage information, which may be labour-intensive and potentially harmful without a defensible ethical framework (i.e. reveal incidental research findings to patient if they are clinically verifiable and actionable).
	P34	We strongly support this proposal to ensure harmonisation while providing clear distinction between legal compliance and ethical governance, reducing inconsistency, duplication and administrative burden.
Consent relating to kids and adults with limited decision-making capacity	P35 and Q28	There should be a recognition of the psychological burden associated with paediatric consents, by providing flexible, capacity assessed pathways for consent. The HTA should support consent where appropriate to be provided by authorised decision makers on the child's behalf, where the child is unable to provide consent due to decision making limitations, while also acknowledging the child's willingness to participate.
Consent Access and repurpose of stored tissues	Q29–Q30	We support a more flexible approach on consenting the repurpose of stored tissues (secondary usage). As per our statement in P32, the proposal should articulate the flexibility with appropriate ethical governance. This allows other ethical approaches to obtain permission for secondary usage of tissue for research, e.g. op-out consent, HREC waiver etc. We suggest adding clarity that the repurpose of stored tissue collection in this section should generally cover secondary usage of tissue. For instance, the collected tissue from standard of care surgery that is immediately repurposed for research activity.
Regulating stored tissue collections	Q31-33	For tissue used for research, we propose a national registration and declaration scheme for research biobanks administered by the regulator, rather than prescriptive activity-based rules. Such scheme would enhance assurance of minimum standards in ethical approval, access governance, quality management, accountability and legacy planning, thereby improving consistency and trust in biobanking operations. Public registration of biobanks would enhance visibility and discoverability of tissue collections, directly improving access and utilisation for research. We propose such a framework and registration infrastructure could be established in collaboration with an existing biobanking agency and/or a National Collaborative Research Infrastructure Strategy (NCRIS) initiative. International experience (e.g. Singapore and Finland) indicates that such frameworks are associated with increased tissue utilisation and research output, demonstrating clear public benefit. A recent publication[5] in

[5] Tupasela A, Southerington T, *et. al.*. Estimating the use of biological samples in Finnish biobanks and hospital collections. Eur J Hum Genet. 2025 Nov;33(11):1493-1498. doi: 10.1038/s41431-025-01906-w. Epub 2025 Jul 5. PMID: 40617980; PMCID: PMC12583472.

		Finland demonstrated the impact of biobanking legislation toward higher utilisation of biospecimen, advancing scientific research. Excluding end-user researchers from licensing requirements ensures regulation remains proportionate and does not create unnecessary barriers to research. Furthermore, we also propose the regulations to include **permission to import and export of tissues for research purposes** with existing appropriate ethical governance in place.
	Q34	For research tissues, while the rationale is sensible, we have a few concerns that should be addressed: • purpose of access should align (e.g. research tissues may not be suitable for clinical testing) • accountability of tissue after transfer may be complicated If the rights are instituted, governing mechanisms should be established.
Prohibition of trade	P42, P44; Q36	We strongly support explicit national recognition of cost recovery for research biobanking activities and inclusion of research biobanks within relevant exemptions. Cost recovery is widely accepted and is essential for the financial sustainability of biobanks, enabling continued investment in quality systems, staff expertise and infrastructure. National clarity would reduce regulatory uncertainty and the risk of inadvertent non-compliance, while requirements for transparency of cost models would enhance accountability, donor confidence and public trust.
Tissue importation and ethics oversight	Q40–Q41	We support explicit permission for the import and export of human tissue for research purposes within appropriate ethical governance frameworks (as raised in Q31-33). This is critical for enabling national and international collaboration, access to rare tissues, and participation in global research consortia, thereby enhancing Australia's scientific competitiveness while maintaining donor protection and ethical standards.
Information disclosure	P46–P48	We note that proposals relating to information disclosure are primarily directed toward transplantation and other clinical contexts and have limited direct relevance to the use of human tissue for scientific research. Research-related data activities associated with human tissue are generally regulated under existing privacy and health records legislation. However, we note the increasing importance of data sharing and data linkage in research and health contexts, particularly for data collected alongside tissue samples. Such activities are

		critical to improving the visibility and discoverability of tissue collections, enabling research collaboration, and maximising the value of donated tissue through linkage with existing datasets (e.g. AIHW and other population-level data sources). At present, the combined legislative and ethical framework governing research data use, sharing and linkage is complex and fragmented, creating uncertainty and inefficiencies for biobanks and researchers.