



**Victorian Cancer Biobank Consortium
Response to the Australian Law Reform
Commission's Review of Human Tissue Laws –
Discussion paper 2025**

Submitted 23rd January 2026

Dear Commissioners,

The Victorian Cancer Biobank (VCB) is writing to provide a submission in response to the *Review of Human Tissue Laws: Discussion Paper (2025)* released by the Australian Law Reform Commission (ALRC). We thank you for this opportunity and appreciate the Commission's acceptance and thoughtful consideration on our previous submission to the Issues Paper.

The Victorian Cancer Biobank is a state-wide, distributed research biobanking network supporting cancer research across Victoria and nationally. VCB is a state-funded partnership with members consists of Cancer Council Victoria (Lead Agency), Royal Melbourne Hospital, Peter MacCallum Cancer Centre, Monash Health, Austin Health and Eastern Health. VCB operates in partnership to collect, store and provide high-quality biospecimens and associated data for ethically approved research aimed at improving cancer prevention, diagnosis and treatment.

VCB welcomes the considerations and acknowledges the Commission's increasing recognition of the importance of human tissue use for scientific and research purposes within the broader reform agenda.

This submission is made specifically in the context of human tissue used for scientific and research purposes, with a particular focus on research biobanking in cancer. VCB recognises that the Discussion Paper necessarily addresses a range of uses of human tissue, including clinical care, transplantation and education. However, we emphasise that clear distinction between these contexts is essential to ensure that regulatory settings remain proportionate, fit for purpose and do not unintentionally constrain ethical, high-value research.

To date, VCB has recruited over 40,000 Victorians, accruing over half a million of biospecimens accessible for research. Since inception in 2006, VCB has supported over 400 research project and clinical trials, creating significant impact towards scientific discovery for improving cancer outcomes.

We are providing our responses to relevant proposals below. In summary, VCB supports reform that delivers:

- A **nationally consistent legislative framework** for human tissue used for scientific purposes;
- A **national regulator** with appropriate expertise in research and biobanking;
- **Clear distinction** between legal compliance and ethical review;
- **Regulatory flexibility** to accommodate rapidly evolving research methodologies; and
- **Strong safeguards** to protect research donor welfare, transparency and public trust while maximising public benefit from donated research tissue.

Such reform would materially improve research efficiency, enable equitable access to tissue, reduce administrative burden, and maximise the scientific and public health value derived from donated biospecimens.

We welcome the opportunity to continue engaging with the Commission as this important reform progresses and would be pleased to provide further information or clarification if required.

Yours sincerely,



Dr Wayne Ng,
General Manager, Victorian Cancer Biobank Consortium
Cancer Council Victoria



Response to Key Proposals and Questions

National Regulatory Framework (Proposals 1–4)

VCB supports the establishment of a **uniform Commonwealth human tissue legislative framework** (Proposal 1, option b), with detailed and adaptive regulation set by a national regulator. National consistency would significantly reduce jurisdictional variation that currently impedes cross-border collaboration, tissue sharing and nationally coordinated cancer research.

With the law reform, VCB recommends the inclusion of a **dedicated legislative subsection addressing tissue used for scientific purposes**, recognising that research use differs materially from clinical and transplantation contexts. Clear differentiation would prevent the misapplication of clinically focused provisions to research biobanking and provide regulatory certainty for long-term research infrastructure.

We support regulator-led detail rather than prescriptive legislation (Proposal 2, option b), as this approach provides the agility required to respond to emerging technologies such as genomics, AI-enabled pathology, organoids and advanced data linkage.

VCB supports the establishment of a **new, well-resourced national regulator** (Proposal 3, option b) with specialist expertise in biobanking and research workflows. We emphasise the importance of a close working relationship between the regulator, NHMRC, Human Research Ethics Committees (HRECs), biobanks and the research community, with clear separation between legislative compliance and ethical review to avoid duplication and inconsistency.

Long-term national consistency (Proposal 4) is essential to support sustained investment in biobanking infrastructure, shared platforms and coordinated research initiatives.

Objects of Human Tissue Laws (Proposal 5; Questions 1–2)

VCB generally supports the proposed objects, particularly those promoting appropriate use of tissue and public trust. In the research context, we emphasise the importance of explicitly supporting:

- Accessibility and appropriate utilisation of donated tissue;
- Transparency in governance and access decision-making; and
- Maximisation of public benefit from donated biospecimens.

Low utilisation of collected tissue represents a significant loss of potential benefit for life-saving cancer research. Incorporating principles aligned with **FAIR (Findability, Accessibility, Interoperability and Reusability)** would materially improve utilisation while reinforcing donor confidence. VCB collaborative and open access model has shown a good utilisation of tissue by over

400 research projects, demonstrating a significant return of investment of \$1.59 for every dollar invested¹ through the impacts created on health and wellbeing of Victorians.

VCB also recommends explicitly including the promotion of **high-quality tissue for scientific purposes** within the objects, as quality and consistency directly affect research reproducibility and impact.

Removing Barriers and Promoting Equity (Questions 3–4)

VCB supports principles-based provisions that remove unnecessary barriers and promote equitable access to tissue for research. Key barriers include inconsistent sharing rules across jurisdictions, limited discoverability of tissue collections, and uncertainty around broad consent and secondary use. Addressing these barriers would improve equitable participation, benefit-sharing and research efficiency while maintaining donor protection.

Definition of Tissue (Proposals 7–9; Questions 5–7)

VCB supports a **broad and inclusive definition of human tissue for research purposes**, including derivatives such as DNA. This approach future-proofs legislation against scientific advances and ensures materials containing donor-linked information remain subject to appropriate oversight.

We note ongoing confusion between the terms *tissue bank* and *biobank*, particularly in Victoria where research biobanks may be described as tissue banks under existing legislation. Clear, inclusive definitions would improve regulatory clarity.

VCB supports regulating most tissue-derived materials consistently for research purposes, with recognition that some materials (e.g. cell lines) may warrant exemptions from certain provisions, such as trade prohibitions, to enable low-risk, high-value research.

Consent for Research (Proposals 32–34; Questions 29–30)

VCB supports the articulated consent principles but strongly recommends **explicit legislative recognition of broad and unspecified consent for research**, as well as ethically governed secondary use of tissue collected for other purposes.

Flexibility through ethical governance mechanisms—such as opt-out consent models, waiver of consent and deferred consent—is essential for cancer research, particularly for rare diseases, retrospective studies and high public-interest research where re-consent is impractical.

¹ Marquina, C. et al. Evaluating Health and Well-Being Returns on Investment in a Cancer Biobank. 2025; 23(1):3-10. *Biopreserv Biobank*. DOI:[10.1089/bio.2024.0014](https://doi.org/10.1089/bio.2024.0014)

VCB supports donor rights to information about tissue use (Proposal 33) but notes that aggregated, transparent communication about research impact is often more practical and ethically appropriate than individualised usage reporting.

We strongly support harmonisation between legislation and the National Statement (Proposal 34), with clear distinction between legal compliance and ethical review to reduce duplication and inconsistency.

Regulating Stored Tissue Collections (Questions 31–34)

VCB proposes a **national registry for research biobanks**, administered by the national regulator, rather than prescriptive activity-based legislation. A mandate of licencing or alternate oversight mechanism such as registration with declaration at a national or state level would create clarity and transparency in minimum standards of biobanking, particularly on ethics clearance, access governance, quality management, accountability and legacy planning. VCB notes international experience, including Finland and Singapore, could be good references for develop such framework, with Europe the current exemplar on inter-jurisdictional coordination in biobanking².

Public registration would also significantly improve the visibility and discoverability of tissue collections, increasing utilisation and public benefit. VCB has proven such visibility and discoverability have been instrumental to our success in recruiting a large participant cohort and utilisation of our tissues by research community at scale (5,000-10,000 samples provided to research programs per annum). In 2024, VCB led a panel discussion with internationally recognised biobanking and research expertise³, further demonstrating strong advocacy for national, coordinated biobanking in Australia.

VCB also supports explicit permission for the import and export of tissue for research purposes within appropriate ethical governance frameworks.

Prohibition of Trade and Cost Recovery (Proposals 42 & 44; Question 36)

VCB strongly supports explicit national recognition of **cost recovery for research biobanking activities** and inclusion of research biobanks within relevant exemptions. Cost recovery is essential for sustainability, quality systems and workforce capability, and national clarity would reduce uncertainty and inadvertent non-compliance while enhancing transparency and public trust. Victoria's HTA has specifically exempted VCB consortium biobanks from this prohibition. VCB has a robust and transparent costing model to support achieving long term financial suitability.

² BBMRI-ERIC. 14 Oct 2024. Available at: [BBMRI-ERIC launches 10-Year Roadmap: Biobanking for a Healthier World - BBMRI-ERIC](#)

³ Victorian Cancer Biobank. 11 Apr 2025. Available at: [White Paper: Advancing the Impact of Biobanking Infrastructure Through a National Approach - Victorian Cancer Biobank](#)

Information Disclosure and Data Activities (Proposals 46–48)

VCB notes that many information disclosure proposals are primarily directed toward clinical and transplantation contexts. Research-related data activities associated with tissue are largely governed by existing privacy and health records legislation.

However, VCB highlights the increasing importance of data sharing and linkage in cancer research. Current legislative and ethical frameworks for research data use are complex and fragmented, creating inefficiencies and uncertainty. Greater alignment and clarity would enhance discoverability, collaboration and the value of donated tissue.