Victorian Cancer Biobank Consortium Response to the Australian Law Reform Commission's Review of Human Tissue Laws – Issues Paper 51 May 2025

Submitted July 4, 2025

The Victorian Cancer Biobank (VCB) Consortium thank you for this opportunity to provide submission to the Australian Law Review Commission (ALRC) Review of Human Tissue Laws through this consultation of ALRC Issue Paper 51.

VCB is a collaborative consortium that provides high quality human samples to support cancer research since 2006. As a key state funded research infrastructure, the consortium membership consists of Austin Health, Eastern Health, Monash Health, Peter MacCallum Cancer Centre, Royal Melbourne Hospital and Cancer Council Victoria (CCV) as the Lead Agency. Cancer Council Victoria (CCV) is a non-profit organisation that has been leading the fight against all cancers for more than 80 years in the areas of research, patient support, cancer prevention and advocacy. Its mission is to prevent cancer, empower patients and save lives.

With long term expertise in biobanking, we have recruited over 40,000 participants through a harmonised consent model and collected a wide range of human tissues (e.g. surgical excess solid tissues, blood samples, saliva/nasal swabs) that are accessible for unspecified ethical research. To-date, our samples and services provided have supporting over 350 academic and commercial research projects.

The focus of our submission is on the use of human tissue and human tissue laws in Australia for cancer research. We acknowledge research is a diverse ecosystem and issues raised may affect other research areas. Here we are providing these key recommendations:

- Stronger **consultation with the biobanking sector and increase relevance of HTAs for biobanking and research purposes**
- The reform should aim to establish national HTA or significantly increase consistency across jurisdictional HTAs (e.g. tissue definitions, cost recovery for biobanking)
- Reform to increase equitable participation in biobanking and access to tissues for research (e.g. mandate the creation of a national biobank registry and tissue access framework, enabling researchers to locate and ethically access samples across jurisdictions)
- Reform laws that enable the increase of biobanking activities and tissue availability for research, including better definition of tissues, flexible usage of tissue for ethical research, permitting reasonable cost recovery of biobanking for better sustainability.

We recognise the importance of human tissue laws in enabling the work we do; in safeguarding the interests of Australians; and in ensuring strong public trust in healthcare and research.

We thank you for consideration of this submission and welcome further consultation and discussion during the inquiry which will shape the future Australian human tissue laws.

<u>Submission contact</u>

Dr. Wayne Ng
General Manager, Victorian Cancer Biobank
Wurundjeri, Woi Wurrung Country
Level 8, 200 Victoria Parade, East Melbourne Vic 3002 Australia
[redacted] [redacted]

Acknowledgement

The Victorian Cancer Biobank acknowledges the Traditional Owners of the land and waters throughout Victoria and pays respect to them, their culture and their Elders past and present.

Response to Issues Paper 51

1. What is your personal experience of how human tissue is obtained or used in Australia?

Key summary:

- Human tissue is critical for scientific research, and professional biobanks in Australia are research infrastructure that enable ethical collection, processing and provision of tissues for research.
- Victorian Cancer Biobank (VCB) consortium ethically collects and provides excess tissues (from surgery), blood and other samples to support at least 40 research projects each year.
- Research sector still faces significant challenges in obtaining human tissues at scale to meet their needs due to lack of coordination for accessing biobanking, inconsistent and under-considered HTAs, and a not-harmonised consent framework.

Human tissue is critical for scientific research to understand human diseases (e.g. cancers) and create new ways to prevent, detect and treat diseases. The way human tissue has been used for scientific purpose has changed frequently since Human Tissue laws came into effect and will continue to evolve to meet the expectations of donors (research participants) and researchers as technology and knowledge evolves. A biobank or tissue bank acts as a research infrastructure that ethically collects and provides human samples (including tissues) for research purposes.

In our biobank consortium, over 200,000 human tissues from the consortium have been provided for over 350 Australian and international research projects. These samples have been used for a wide range of research applications including genetic testing (including 'omics testing), cell line and organoid development, biomarker identification, medical product development (e.g. blood test kit). The VCB has enabled research using human tissues to make scientific discoveries that create significant impact towards improving human health outcomes. This is evidenced by a return of investment of $1.59 estimated for every dollar invested by the government on the health and wellbeing of Victorians[1].

Nationally, there are over 400 biobanks/collections of human tissues for research purposes in Australia (likely underreported). However, our recent consultation[2] shows the health and medical research sector still experienced significant challenges for accessing good quality and ethically obtained human tissues for research. Further, one study reports overall utilisation rate of human tissues collected for research in Australia 10-15%[3], indicating underutilisation of collected and stored material.

---

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

[2] Victorian Cancer Biobank Strategic Plan 2024-28, accessible at: Strategic Plan - Victorian Cancer Biobank

[3] Henderson MK, Goldring K, Simeon-Dubach D. Advancing Professionalization of Biobank Business Operations: Performance and Utilization. Biopreserv Biobank. 2019 Jun;17(3):213-218. DOI: 10.1089/bio.2019.0005

In the experience of the VCB, both through personal biobanking activities and extensive engagement with the biobanking community and research sector, there are several reasons are contributing to challenges with access to human tissues for research in Australia:

- lack of coordination and visibility for tissue collections/biobanks at state and national levels to increase accessibility to researchers
- inconsistent regulations and ethical governance guidelines for the use and sharing of human tissues that support research and collaboration (refer to Question 2)
- inconsistent consent and quality parameters to allow interoperability between collections for research (refer to Question 2).

Lack of national coordination - despite continual sector advocacy over decades and recognition of ethically sourcing human material in Australia as an area of National importance[4], there are persisting challenges and unmet demand for human samples. While the industry is applying various efforts to self-report human tissue banking activities in various voluntary registers[5][6], these efforts are significantly below international exemplar[7]. Further, recent advances in international quality considerations for collected and stored human material through standardisation[8] are an emerging National consideration. Stronger national regulatory oversight of biobank registration and human tissue research activities is recommended.

While the laws enable research across the Country, there are also various intricate challenges experienced within the research sector whereby inefficiencies are a key result. For example, where there are differences in interpretations of legislated definitions between States and territories for consent, or access and allowed use of collected materials, there is strong reliance on individual state-based ethical oversight, and establishing National frameworks in biobanking is difficult (expanded in response to Q5).

---

[4] National Research infrastructure roadmaps, see https://www.education.gov.au/national-research-infrastructure

[5] Melbourne Academic Centre for Health Biobank Registry, accessible at: https://machaustralia.org/resource/biobank-registry/

[6] Australasian Biospecimen Network Association list of member biobanks, accessible at: https://abna.org.au/about/member-biobanks

[7] Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC) multi-nation human tissue locator, accessible at: https://www.bbmri-eric.eu/bbmri-sample-and-data-portal/

[8] ISO 20387:2018 - Biotechnology — Biobanking — General requirements for biobanking

2. What is your personal experience of how human tissue laws work in Australia?

Key Summary:

- The HTAs **do not** sufficiently cover research use and are dated in applicability to the modern research applications (e.g. omics data and organoids).
- **The HTAs on use for research purpose are significantly inconsistent** nationally, creating challenges for collaborations and streamlining equitable access of tissue for research across jurisdictions.

As a Victorian-based biobank, we primarily comply to Victorian Human Tissue Act (HTA), Victorian Medical Treatment Planning and Decisions Act, relevant privacy legislations and NHMRC ethical guidelines. The current legislations, which are foundations of our biobank compliance and operations, are enacted on the basis to respect and protect donors (such as through informed consent) for any applications, including for research/scientific purposes.

The Human Tissue Act(s) and linked legislations provide basic framework for research use of human tissue, however, they are primarily designed for therapeutic purposes, such as organ transplantation. On a positive note, this provides flexibility on usage of tissue for research purpose through a less restrictive national ethical guideline. However, such framework also subject to interpretations which create inconsistencies on how tissues can be collected and used for research. Such circumstances are similar to other jurisdictions where the inconsistencies in how human tissue is accessed, stored, and used across jurisdictions are amplified —an issue highlighted in the ALRC Issues Paper (paragraph 13). For example, fragmented legislation and inconsistent definitions across jurisdictions create practical barriers to tissue sharing, hindering the collaborations or research at scale to address health unmet needs (e.g. rare cancers).

In addition, Within in the HTA (Vic), the older term ‘tissue bank’ is still referred to instead of the more contemporary term ‘biobank’ (noting not all jurisdictions use term ‘tissue bank’). This suggests the laws are dated and with limited relevance to the usage of tissues in biobanking and research which technology and applications have evolved rapidly over the past few decades.

In Victoria, we are privileged that the HTA explicitly allows reasonable cost-recovery to be obtained by tissue banks for the cost on collecting, processing and distributing the human tissues (not the tissue itself). This has enabled our biobank to create a transparent and fair cost recovery model to achieve financial sustainability for continuing provide human tissue and services for research.

Since the current HTAs are dated and have been inconsistently updated, none of them address the need to promote the use of tissue in research or overcome barriers aforementioned in Q1 to accessing existing collections and infrastructure across Australia. Much of our work at VCB involves coordinating and promoting the use of human samples for research and collaboration but it is challenging without a national oversight of this. Several countries have enacted human tissue for research or biobanking specific legislations and have gained successful impact in addressing the national oversight, access challenges and public health issues, e.g. Finland, Sweden, Singapore. Australia can learn from the experience of these countries to ensure our human tissue laws remain fit for purpose.

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

VCB Key Recommendations:

- Stronger **consultation with the biobanking sector and increase relevance of HTAs for biobanking and research purposes**
- The reform should aim to establish national HTA or significantly increase consistency across jurisdictional HTAs (e.g. tissue definitions, cost recovery for biobanking)
- Consider reform to increase equitable participation in biobanking and access to tissues for research (e.g. mandate the creation of a national biobank registry and tissue access framework, enabling researchers to locate and ethically access samples across jurisdictions)

We recommend the human tissue laws would aim to be an enabler for health and medical research (including technology innovation and drug discovery) while encouraging and protecting the research participation of the Australians. Enabling research (academic and commercial) that will address unmet needs and improve health outcomes is of national interest and human tissue at scale play a vital role.

From a research perspective, Laws governing Human Tissue should aim to:

- increase amount and utilisation of tissue for use in research, including for cross-jurisdictional and international application, reducing barriers (e.g. mandatory creation of national biobank registry to allow searching of available tissues for research)
- address inconsistencies in governance, ethical practices and interoperability in using tissue for research to reduce barriers for research and collaborations
- clearly define sector terminology - e.g. donor vs (research) participant; (therapeutic) tissue bank vs (research) biobank
- provide clarity between application of human tissue law for research vs therapeutic purpose
- enable people to voluntarily contribute human tissue to research ethically, equitably and safely
- be in accordance with relevant international laws, including international human rights law, and reflect global practices in terms of appropriate consent, use (including financial aspects) and engagement with donating individuals and communities

These key aims will assist to address the challenges above in response to consultation earlier questions.

Since the Issue paper mainly still focuses on topics relevant to tissue for therapeutic use, we strongly recommend a more inclusive consultations with the biobanking as well as health and medical research sector during the inquiry.

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

VCB Key Recommendations:

- The reform should reflect terminology and practices to the evolved technology and application of tissues in scientific research (e.g. 'tissue bank' to 'biobank').
- The proposed principles to have emphasis on research purposes
- Recognise the **importance of equity** (participation and access) to the collection of human tissue ***for research purpose***
- Include the role of **international sharing of tissue in research**

We largely agree with the principles proposed in the Issue Paper for human tissue laws but would like to emphasise the considerations on use of tissue for scientific/research and biobanking purposes, including the role of terminology in the laws. Indeed, as mentioned in our response in Q2, the terms 'biobank' and 'biobanking' are not present in Australia's existing human tissue laws, and application or interpretation of 'scientific purposes' is variable.

The reform should aim to address the challenges raised above in response to consultation questions 1 and 2.

We further provide some examples in the principles and reform areas that research/scientific context should be considered:

- Paragraph No. 25 - Reforms that promote increased access to stored research tissue; clarification that research systems are also considered a 'donation system'
- Paragraph No. 45/46 - There is limited public awareness of tissue use in research. Enhancing the formal national oversight (accountability structure) and establishing a framework for biobanking may advance public awareness and improve research outcomes.
- Paragraph No. 96 - extending to raised awareness of biobanking/tissue donation for research importance. Currently public knowledge of biobanking is limited, compared with examples, such as UK biobank (UK), or Moonshot biobank (USA) where research from human tissue is widely publicly recognised as health research enablers.

Further to that, considerations to the international uses of tissue should also underpin the reform, with evidence supporting the Australian communities' willingness to participate in international sample sharing[9]. It is important to ensure laws enable international interoperability to maintain (or increase) Australia's capacity to safely and ethically transfer tissue across borders (e.g. effective access to research tissue for interstate or multi-national studies). Access to human biospecimens not only

---

[9] Dive, L et al. (2020). Public Trust and global biobank networks. *BMC Medical Ethics.* 21:71 DOI: 10.1186/s12910-020-00515-0

supports human health and well-being but contributes to a research ecosystem that underpins Australia's biotechnology R&D sector (e.g. development of novel therapies and products).

Regarding importance of laws that are well-designed and effective, this requires recognition that consent *for research purpose* is an important topic[10]. Further effectiveness may be gained recognising areas of synergy between the donation systems where tissues and blood may be used for dual purpose within the laws (e.g. consent frameworks that support scenarios of donation of a tissue for therapeutics *and* research purpose under a single consent framework).

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.

VCB Key Recommendations:

- agree on priority reforms areas with context relevant to research
- Reform laws to enable increase biobanking activities and tissue availability for research, including better definition of tissues, flexible usage of tissue for ethical research, permitting reasonable cost recovery of biobanking for better sustainability.
- take into account laws internationally and **key international agreements applicable to scientific use of human tissue use** as relevant to human tissue laws in considering it's priority reform areas

We generally agree with priority reform areas relevant to use of tissue for research/scientific purposes and provide specific recommendations below:

Definition of tissue - We strongly agree review of the definition of tissue and the associated implications are essential reform priorities. This is particularly important in the research context, whereby technology advancements (e.g. omics; data sharing) now enable extensive generation/sharing of information about a person and their disease from types of tissue not currently well specified in (Vic) law. For the example in Paragraph 52, while cell lines is a form of tissue, exemptions may be considered on prohibition of sales to encourage research with ethical clearance. This is also highly relevant to tissue organoid, a form of tissue derivative that is valuable and highly in demand for precision medicine.

What tissue should be used in research? - We support proper considerations in the HTA reform for reducing barriers or complications for research, such as paragraph 56, provided consent and ethical clearance are obtained.

We strongly support secondary use of tissue (removed for clinical context), as this is the legal premise for a wide array of research. Our experience is that this area of legislation is inconsistent across

---

[10] Bromley E, and Khodyakov D. (2021): The value of consent for biobanking. *Nature – Human Behaviour*. 5(9):1125-1126. DOI: 10.1038/s41562-021-01163-z.

jurisdictions with interpretation of such law varies between and within jurisdictions, including for long-term stored clinical material and hospital autopsy material. Furthermore, in cancer, diagnostic and treatment advancement has resulted in the trend towards less 'excess available' tissue for research. Reform of Human Tissue Laws should also consider the likelihood that due to these and other shifting research methodologies[11], secondary use of tissue will play a greater role in research in the future.

In paragraph 57, as the medical/research technology evolve, genetic and other testings (e.g. proteomics) are becoming common and expected in most health and medical research. Since the public are now more receptive to genetic testing; the reform should consider enforcing the accountability on privacy protection and ethical use generated data (e.g. genetic results).

How should trade in human tissue and tissue products be regulated? – As a biobank, we support permitting cost-recovery models for research tissue banks across all jurisdictions. A reasonable and transparent cost-recovery model will support biobanking, which often receives sub-optimal core funding to operate in Australia, to achieve financial sustainability in enabling access to ethically-obtained tissues and associated services for research.

Equity and increase participation in research through biobanking - In Australia, there is ethical emphasis to consider respect and equity, however, there is currently no legal accountability for equity in research. This should be evaluated. Increased research participant diversity supports improving of equitable health outcomes for all Australians. Further, legal frameworks that enable effective cross-jurisdictional consent and access for research will increase scientific output, particularly for areas of research unmet need (e.g. accrual of tissue samples in many rare and low-survival cancers can take years, and research of these diseases require strong National and International sample-sharing capabilities)[12].

Although the ALRC's priority reform areas largely reflect the *WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks (updated 2016)*[13], the Declaration should be formally considered by the ALRC as it conducts its Inquiry given the global importance of this Declaration.

---

[11] CSIRO (2023) Non-animal models: a strategy for maturing Australia's medical product development capabilities. CSIRO, Canberra

[12] Garcia, M., et. al. (2018) Impact of biobanks on research outcomes in rare diseases: a systematic review. Orphanet J. Rare Dis. 13:202. DOI: 10.1186/s13023-018-0942-z

[13] WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks – WMA – The World Medical Association

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

VCB Key Recommendations

- Consider data associated to the tissues to enable tissue and data sharing for research and collaboration while protecting the participants privacy and welfare.

While the HTA reform primarily consider the use of the tissue, we would also like to raise issues that are associated to the human tissue for research:

Tissue-associated and -generated data – The use of tissue for research is ubiquitous with analysing clinical data and generating research data (e.g. genetic data). In recent decades, the data (e.g. omics) relating to the tissue have grown exponentially and are game changer in scientific research. While these data are valuable and shareable to advance sciences, misuse of such data may have significant implications. We recommend the HTA reform would consider the accountability and ethical use of data associated to the tissue. For example, the acquisition of *23andMe* in the USA (a company who holds DNA data of 14 million individuals globally) demonstrated a regulatory challenge when donors were concerned their DNA data may be used for other purposes if the primary company responsible for initial collection was acquired by another company due to legal gaps in jurisdiction.

Linkages for specimen and data sharing – As part of our recommendation to increase accessibility of human tissue for research, we also recommend HTA reform to consider data linkage as an allowable practice within laws (for an example, tissue-generated data shared between tissue collections and biobanks to make finding/accessing tissue easier). Currently the linking biobank and data across organisations and jurisdiction has significant administrative, privacy and ethical barriers, limiting accessibility of the tissue for research, particularly rare cohorts (e.g. rare cancers).

-End of submission-