Submission to the Review of Human Tissue Laws: Issues Paper 51 (2025)
Australasian Biospecimen Network Association (ABNA)

Informed by a survey distributed across our full membership to encourage broad input and contribution, the following responses to *Issues Paper 51* have been developed by a group of representatives from The Australasian Biospecimen Network Association (ABNA) members. We appreciate the opportunity to participate in this important review and thank the ALRC for considering our submission. ABNA welcomes ongoing consultation and engagement to support this inquiry and contribute meaningfully to the reform of human tissue laws in Australia.

ABNA is the leading professional peak organisation dedicated to supporting excellence in biobanking and biospecimen science across Australasia (1). Our membership includes over 60 biobanks from Australia, New Zealand, and the Asian Pacific region. ABNA fosters a collaborative network of multidisciplinary researchers working in fields including human disease, veterinary science, environmental conservation, and museum collections biobanking. The majority of ABNA members are from human tissue biobanks with extensive expertise in the ethical collection and use of human tissue for research.

Currently, there are over 200 registered biobanks/specimen cohorts in Australia (2), with at least 53 housing collections from over 1,000 tissue donors. However, this figure likely underrepresents the true scale, as many research groups maintain internal collections for cohort studies and clinical trials. Economic analyses have shown that biobanks and clinical trials yield significant returns on investment—estimated at $1.59 and $5.80 respectively (3, 4).

Over the past two decades, ABNA has been dedicated to supporting Australasian biobanking organisations by promoting ethical collection of high-quality biospecimens for research. We advocate for the value of biobanking, including human tissue, in advancing research that benefits the Australasian community and globally. ABNA also facilitates knowledge exchange through its website, annual conference, online seminars and monthly newsletter.

ABNA members from human tissue biobanks acquire their specimens through various methods, including excess tissue from routine clinical procedures (surgical and non-surgical), non-invasive sampling (e.g. buccal swabs and liquid biopsies) and post-mortem organ donation. These specimens are essential for advancing health and medical research. As the distinction between diagnostic and research blurs, especially in rare disease genomics and pharmacogenomics, a unified governance model is required to manage tissue governance without duplicative ethics pathways.

Australia's human tissue legislation was developed by individual states and territories between 1978 and 1985 (5). Since then, biobanking has evolved into a recognised professional discipline, underpinning modern health and medical research (6). Advances in genomics and personalised medicine have further highlighted the importance of human tissue across the health and medical research pipeline, especially since ethical and economic shifts have reduced reliance on animal models (7). Together these factors have reinforced the need for human tissue across the health and medical research pipeline, from basic laboratory research to population studies and large-scale drug validation studies (8).

Despite their value, biobanks in Australia face challenges in providing high-quality human tissue at scale. These is partly due to inconsistent Human Tissue Acts (HTAs) across jurisdictions, insufficient strategic oversight and regulatory mechanisms to enhance tissue accessibility and sharing for research purposes and limited funding. To address these issues, many biobanks have formed collaborative networks (9) and virtual platforms (10) to enable researchers to access specimens and data across geographic boundaries. This can be particularly helpful, for example, in rare disease research. However, interstate collaboration is hindered by discrepancies in HTAs and outdated biobanking guidance within the NHMRC National Statement (11). These inconsistencies require interpretation by state policymakers, adding complexity and reducing efficiency.

Australian human biobanks comply with state and territory Human Tissue Acts, as well as Commonwealth and state privacy legislation, while operating under the ethical guidelines set by the NHMRC. The HTAs include provisions for third-party consent, such as in specialist paediatric biobanks, with considerations around re-consenting individuals who were originally enrolled as minors by parents or guardians and have since reached adulthood. While the HTAs do cover the use of tissue for scientific purposes, their primary focus remains on therapeutic applications, such as organ donation and transplantation. **There is a need for these laws to more clearly recognise the critical role of human tissue in research and to support increased accessibility for ethical research use.**

A balanced, participant-centric approach should be the foundation of any reform. Human tissue laws in Australia should be designed to protect donors while enabling ethically sound and impactful medical research. However, laws should not impose undue burdens on researchers or institutions, especially when compliance becomes unnecessarily complex or time-consuming.

These laws must:

- **Safeguard Donors**: Ensure that individuals who donate tissue, whether living or deceased, are fully informed, educated and provide valid consent, and have their privacy respected.
- **Support Research**: Facilitate access to tissue for research purposes through clear, consistent, and flexible legal frameworks across all states and territories, especially when donors have agreed to future use.

The absence of a national biobanking framework together with inconsistencies across state HTAs present significant challenges to the effective and equitable use of tissue for research across Australia. Below are a few specific challenges and recommendations related to these issues.

For these reasons, ABNA strongly supports the scope of this Inquiry to:

i. **Improve clarity and consistency across HTAs, and**

ii. **Remove unnecessary legislative barriers and ambiguous definitions.**

iii. **Recognise the critical role of human tissue in research.**

Specific Reform Recommendations

1. Clarifying Definitions of Tissue

- Current NSW legislation contains ambiguous clauses regarding "small pieces of tissue" or "blocks" (12) , often stored in paraffin or on slides for clinical use. These samples are valuable for research but difficult to access without explicit consent. Stakeholders interpret these clauses inconsistently, creating confusion and limiting research potential. Greater clarity is needed on:
  - What constitutes "small tissue"?
  - Whether “microscopic examination” refers to the method or the size of the sample?
  - How stored clinical samples of any type/size can be ethically repurposed for research?
- The ambiguity around whether substances such as DNA, RNA and immortalised cell lines fall within the definition of “human tissue” once separated from tissue/blood requires resolution. Given the widespread use of genetic material in contemporary research, recommendation is to include nucleic acids and blood fractions explicitly in future legal revision as its exclusion could result in gaps in consent, interpretation, oversight and international harmonization.

2. Broaden definitions of Tissues

- To facilitate health and medical research, **ABNA therefore also supports adopting the broadest possible definition of human tissue in legislative reform.** This should explicitly include human milk, sperm, and egg cells (13-16), alongside regenerative and non-regenerative tissues such as solid tissue, blood, whole organs, bodily fluids, post-mortem tissue and organs, and derivatives like plasma, serum, cell lines, and organoids as well as genetic derivatives such as DNA and RNA once separated from tissues/blood. All types of human tissue have the potential to contribute meaningfully to research, both now and as technologies and scientific priorities evolve. However, current HTAs in some jurisdictions preclude the secondary research use of regenerative tissue originally collected for clinical purposes. This includes blood, a critical reagent in biomedical, omics, rare disease genomics and pharmacogenomics research.
- **ABNA also encourages greater legal consideration of cell lines, particularly immortalised cell lines (17, 18) and organoids, which are derived from human tissue but possess unique properties.** These materials can be propagated indefinitely and shared widely, offering immense value to research. While ethical guidelines often address their use. ABNA believes their distinct characteristics warrant further legal clarity, especially regarding consent, ownership and long-term governance. The reform should also consider consistent provision of exception to allow commercialisation of such tissue derivatives nationally (currently only few HTAs) to enable more research while complying to consent principles.
- Biobanks that focus on human embryonic stem cell lines already exist (19). To streamline the legislation for biobanks to comply with, **consideration should**

be given to the inclusion of embryo and gamete donors in the issues considered for reform.

3. **Removing Barriers for Children in Non-Regenerative Tissue Donation**
   Children face unique challenges in tissue donation, including in post-mortem contexts. Legal reforms should address these barriers to ensure flexible participation and equitable access, while maintaining rigorous ethical standards.

4. **Post-Mortem Consent and Tissue Access**
   Post-mortem tissue, such as brain or heart samples, is critical for research into neurodegenerative and other diseases. However, current laws, including anatomy Acts, govern this process inconsistently. Many individuals mistakenly believe that indicating donation intent on their driver's licence suffices for post-mortem brain donation consent (20). A stronger legal framework clarifying consent pathways to support biobanks in accessing deceased tissue ethically for research is needed to reduce consumer misunderstandings.

5. **ABNA supports the principles of respect for individuals and the human body, and advocates for a tissue donation system that is safe, equitable, and fosters public trust.** Many biobanks have actively sought accreditation or certification as part of their ongoing commitment to meeting legal and ethical standards (21, 22). A key example is the nationally available NSW Health Biobank Certification Program, which includes dedicated modules on ethics, privacy and security, and informed consent (21).

6. **ABNA recommends that HTA reform explicitly consider both prospective and retrospective implications, ensuring that biobanks can operate under a consistent and practical legal framework that supports long-term research continuity.**
   Unlike transplantation or educational uses of human tissue, which typically involve a single event, biobanking often entails the longitudinal collection of multiple samples for research from the same individual or disease cohort over extended periods. For example, the Busselton Health Study (23) has stored samples collected from as many as 13 different timepoints over the course of 60 years from the same individuals. If such legislative changes are not applied retrospectively, biobanks may face significant challenges managing a cohort under multiple legal frameworks. As an example, the NSW HTA amendment on 1 November 2003, which introduced a requirement for written consent for research use of tissue. Prior to this date, no such consent was required. This creates a legal divide, potentially complicating governance and compliance.

7. **ABNA recommends that HTA reform to consider F.A.I.R principles to increase equitable access and availability of tissue to research nationally.**
   The research sector often faces challenges in acquiring tissue at scale to make meaning discoveries due to lack of coordination and searchability of biobanks/tissue collections in the country. Efforts on implementing F.A.I.R. principles such as mandating a national register will ensure that biospecimens and associated data are Findable, Accessible, Interoperable, and Reusable. International models offer valuable guidance includes:

- Finland's Biobank Act - mandates the registration of biobanks and provides a clear legal framework for the use of biological samples in research, even when future research purposes are not yet known
- Singapore's Human Biomedical Research Act - requires tissue banks to register with the Ministry of Health, ensuring oversight and accountability in tissue banking activities

8. **ABNA welcomes the inclusion of provisions in the reform that formally and consistently recognise the need to permit reasonable cost-recovery for services provided by biobanks across Australia**. While cost-recovery is already a common and necessary practice in the sector, the current HTAs only explicitly allow for it in Victoria, Western Australia and Queensland. The absence of such provisions in other jurisdictions creates inconsistencies that may hinder equitable access to biospecimens and threaten the long-term financial sustainability of biobanks as essential enablers of health and medical research.

   ABNA remains firmly committed to minimising risks to tissue donors and upholding ethical standards. However, cost-recovery plays a vital role in maintaining the operational viability of biobanks, particularly as they scale to meet growing research demands.

Summary

The Australasian Biospecimen Network Association (ABNA) strongly supports greater consultation with the biobanking sector as part of the ongoing reform of human tissue laws in Australia. ABNA advocates for a streamlined and harmonised national approach that upholds ethical principles while enhancing access to human tissue for health and medical research by removing unnecessary legislative barriers and clarifying ambiguous definitions.

Reform should strike a careful balance to protect the rights and dignity of donors while enabling ethically sound and scientifically valuable research. Laws must therefore be:

- **Clear and consistent** across all Australian jurisdictions.
- Supportive of **informed consent** and **privacy protections.**
- Flexible enough to allow **responsible future use** of tissue, where donors have agreed.

Reform should also be designed to meet the needs and expectations of a wide range of stakeholders, including potential tissue donors, surgeons, phlebotomists, pathologists, coroners, researchers, and research governance professionals.

In addition, ABNA encourages reform to consider the inclusion of clear legal and ethical frameworks addressing the commercialisation of intellectual property arising from human tissue-based research, provided it is conducted transparently and ethically. While this may align more closely with broader intellectual property and commercialisation regulations, it is still worth referencing here as it could further support innovation and reinvestment into biobanking infrastructure. Australia's reform

process should draw on international models to create a cohesive, future-ready legal environment that supports innovation, ethical integrity and public trust.

Finally, Australia's human tissue laws must evolve to keep pace with rapid advancements in biomedical science, including molecular pathology, AI-assisted diagnostics and genome sequencing. A future-ready system must anticipate emerging technologies and provide clear, consistent guidance across jurisdictions to facilitate responsible research and public trust. To ensure ethical and effective use of human tissues in research, the legal framework should promote transparency and be nationally aligned, supporting rigorous standards while enabling innovation.

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