



VICTORIAN INSTITUTE OF FORENSIC MEDICINE

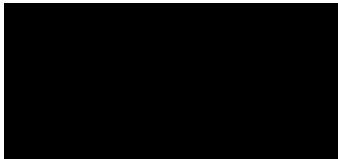
7 July 2025

Australian Law Reform Commission
Review of Human Tissue Laws

Thank you for an opportunity to comment on the Issues Paper: Review of Human Tissue Laws (the Issues Paper).

This letter flags human tissue law issues relevant to the Victorian Institute of Forensic Medicine (VIFM), which incorporates the Donor Tissue Bank of Victoria (DTBV). The VIFM looks forward to providing a more fulsome submission to the subsequent Discussion Paper.

Yours sincerely



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Acting CEO
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1. About the VIFM and the DTBV

- 1.1. The VIFM is a statutory agency established under the *Victorian Institute of Forensic Medicine Act 2024*.
- 1.2. The VIFM exists to provide quality-driven, ethically grounded, independent forensic medical and scientific services for the justice system; to expand and share our knowledge locally and globally; and to make a positive contribution to the health and safety of our community.
- 1.3. Our statutory responsibilities are to provide independent forensic medical and scientific expertise to the justice system, tissue for transplantation, and to both teach and undertake research that will benefit the community.
- 1.4. Donor tissue banking at the VIFM is undertaken by the DTBV. The DTBV is a multi-tissue bank, operating from a purpose-built Therapeutic Goods Administration (TGA) licensed facility in Southbank with specialised human tissue processing and storage facilities.
- 1.5. The DTBV screens, processes, stores, tests and distributes heart valves, skin and musculoskeletal tissue (bones and tendons) to Australian hospitals and surgeons. The DTBV's human tissue products are known as "allografts".
- 1.6. Since its establishment, the DTBV has provided over 40,000 high-quality allografts retrieved from over 4,000 donors and transplanted to approximately 18,000 recipients in the community.
- 1.7. The DTBV allografts are life-enhancing and, in the case of cardiac and skin tissue, life-saving. Human tissue is used in a wide range of reconstructive surgeries:
 - skin and cardiac allografts are used for burns and cardiac patients
 - bone can be manufactured to be a 'biological scaffold' and even a 'stimulant' to enable growth of a patient's own tissue in the recovery process from orthopaedic or spinal surgery
 - tendons assist in restoring mobility for orthopaedic patients.
- 1.8. The DTBV also facilitates retrieval of corneas by the Lions Eye Donation Service, used to restore eyesight.
- 1.9. The DTBV donation program operates in collaboration with partners through the DonateLife Network. Partners include DonateLife Victoria, DonateLife Tasmania and the Lions Eye Donation Service in Melbourne. The Living Donor Program also collects tissue from patients undergoing routine hip replacements at several hospitals across Victoria and collaborates with The Royal Children's Hospital to collect cardiac valves from heart transplant recipients.

2. Comments on the principles for human tissue laws

- 2.1. The VIFM supports the principles for human tissue laws set out in the Issues Paper and, in particular, the principles that reform should support increased access to human tissue in Australia and equitable participation in and access to



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donation and transplantation systems. These comments are also relevant to the priority area of donation of tissue after death.

- 2.2. Increasing tissue donation relies on timely information about deaths. There are currently a range of operational barriers that mean that the DTBV does not always receive timely information about all deaths in hospital.
- 2.3. These barriers include:
 - difficulties in accessing information from hospitals required to assess suitability for tissue donation
 - reliance on the DonateLife network, which only operates in Critical Care Units and Intensive Care Units of hospitals.
- 2.4. A further barrier is the Victorian legislative requirement that a death be verified by a medical practitioner prior to donation retrieval procedures. This requirement impacts donation opportunities for deaths that occur in the community when doctors are often not present. Similarly for cases that come into the VIFM overnight, if a doctor is not available, the opportunity to donate can be lost.

3. **Comments on the proposed priority reform areas**

- 3.1. The VIFM intends to make further submissions in relation to the following issues.

Definition of tissue

- 3.2. The Human Tissue Act has not kept up with technological change in the manufacture of tissue products over the past 40 years. A revised definition will require consideration of the range of allografts now produced from tissue manufacture.
- 3.3. Further, the VIFM notes that the definition of tissue used in human tissue laws is fundamental and impacts on the range of the VIFM's forensic medical and scientific services, in addition to its tissue banking services.

Scientific, medical and therapeutic use of tissue removed under the Coroners Act 2008

- 3.4. The VIFM relies on the authority under the *Human Tissue Act 1982* (Vic) to use tissue removed from the body of a deceased person during a post-mortem examination for therapeutic, medical or scientific purposes. In particular, the VIFM relies on this authority for the validation of its scientific equipment and for research that has been approved by the VIFM Human Research Ethics Committee.
- 3.5. Further, there are potential secondary uses of tissue removed during a coronial process, which are not clearly covered by the authority, for example, tissue sought by families for paternity testing.

Advertising and trade in human tissue

- 3.6. Current Victorian legislation allows for tissue banks to recover reasonable costs associated with tissue banking. While profit should never be made on the altruistic gift of tissue donation, current cost-recovery models do not allow or encompass a tissue bank's need for capital equipment, facility management or research and development services, all of which are vital for a tissue bank's continued operations.



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3.7. The current restrictions on “advertising” in Victorian legislation may impact negatively on opportunities to promote tissue banking or to advise hospitals and surgeons of the availability of tissue.

Allocating donated tissue

3.8. There are opportunities to provide greater support for the coordination of the tissue banking sector in Australia. While the Australian Organ and Tissue Authority provides a strong coordination role for organ retrieval and allocation, it is not funded to provide on-the-ground support for tissue donations in each State.

3.9. The development of a uniform set of donor selection criteria, and tissue banking procedures and quality standards would reduce cost and lost opportunities for donation.

Uses for tissue and regulation

3.10. The VIFM notes an issue with access to critical tissue, such as skin, particularly in times of natural disasters. Where local supply is low, Australia may need to resort to seeking imported tissue. However, there is no guarantee that supply of imported tissue will always be reliable.

3.11. Further, access to overseas tissue is subject to a different regulatory regime, including ethical and risk standards. These may not be appropriate to the Australian context.

3.12. Reliance on imported tissue may also undermine the skills in the Australian tissue donation, processing and banking sector.

School of Anatomy

3.13. The VIFM is a gazetted School of Anatomy and has an interest in any proposed amendments to Part 7 of the *Human Tissue Act 1982* (Vic).