

22 January 2026

## **Submission by the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) Review of Human Tissue Laws**

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) welcomes the opportunity to contribute to the review of Australia's human tissue laws.

RANZCO is the professional body representing ophthalmologists and ophthalmology trainees in Australia and New Zealand. RANZCO members are directly involved in corneal donation, eye banking, tissue transplantation, and ocular research, and work closely with eye banks, hospitals, donor coordination services, and research institutions across all jurisdictions.

RANZCO supports reform that promotes national consistency, ethical integrity, public confidence, and system sustainability, while enabling innovation and responsiveness to future clinical and technological developments.

### **Reforms Supported by RANZCO**

#### **Authorisation to Recover Tissue**

RANZCO supports reform to expand the categories of appropriately trained and credentialed personnel authorised to recover human tissue.

#### **Tasmania case example**

In Tasmania, ocular tissue recovery is currently undertaken almost exclusively by ophthalmologists. This arrangement:

- places a disproportionate burden on a small specialist workforce,
- is not sustainable in the long term, and
- limits the capacity to increase donation rates.

Expanding authorised recovery roles would improve workforce resilience, support equitable access to tissue, and better align recovery processes with contemporary health service models, without compromising safety or ethical standards.

#### **Research Tissue Recovery and Biobanking**

RANZCO supports stronger legislative recognition of research tissue recovery and the role of biobanks.

In ophthalmology, access to donated tissue underpins research into corneal disease, glaucoma, retinal disease, inherited eye conditions, and emerging regenerative therapies. Eye banks already facilitate research access to ocular tissue; however, governance arrangements for this function are inconsistent across jurisdictions.

Clearer legislative support for research recovery pathways and biobanking will enhance consistency, reduce administrative barriers, and support high-quality, ethically governed research.

### **Cost Recovery and Accountability of Tissue Banks**

RANZCO supports a review of tissue bank cost-recovery models and greater transparency in pricing arrangements, including appropriate oversight of for-profit providers.

Current cost structures are often complex and difficult for hospitals and health services to interpret. Improved clarity and accountability will:

- support the sustainability of not-for-profit eye banks,
- promote equitable access to tissue,
- maintain donor altruism, and
- strengthen public confidence.

RANZCO considers that clearer cost-recovery principles would benefit all stakeholders, including those responsible for operating tissue banks.

### **Data Sharing and System Transparency**

RANZCO supports improved data sharing across the tissue sector, subject to appropriate governance and privacy safeguards.

Enhanced data availability would:

- provide national visibility of supply and demand,
- identify gaps in access and service provision,
- support workforce and service planning, and
- inform evidence-based policy development.

Improved transparency is essential to achieving a coordinated and equitable national system. Additionally, outcomes auditing is a critical step in the process of tissue transplantation to ensure safe and effective use of donated human tissue.

RANZCO recommends that outcomes data after *any* form of transplantation are important for research, benchmarking, patient safety and quality improvement, and should continue to be funded centrally.

### **National Governance Beyond the TGA**

RANZCO supports, in principle, the establishment of a national governance mechanism to address aspects of tissue regulation not covered by the Therapeutic Goods Administration. While the TGA appropriately focuses on recipient safety, there is currently no national oversight of:

- ethical governance,
- consent practices,
- business and pricing models, or
- interstate and international movement of tissue.

A national governance body could improve consistency and accountability, provided its role is clearly defined and duplication with existing regulatory frameworks is avoided.

### **Consent and Contemporary Kinship Structures**

RANZCO supports modernisation of consent processes and the concept of “next of kin” to reflect contemporary Australian society.

Reform in this area should:

- accommodate diverse family and kinship structures,
- support culturally appropriate decision-making, and
- better recognise donor intent.

Clear, contemporary consent frameworks are central to ethical practice and maintaining public trust.

### **Inter-Agency Collaboration**

RANZCO supports reforms that improve interoperability and collaboration between agencies involved in donation and transplantation, including hospitals, donor coordinators, eye banks, and transplant services.

Improved information sharing will reduce inefficiencies, minimise missed donation opportunities, and strengthen end-to-end governance of donated tissue.

### **Scope and Terminology of the Legislation**

RANZCO agrees that in-vitro fertilisation should remain outside the scope of the legislation due to the specific regulatory and ethical considerations applicable to that sector.

RANZCO supports a unified legislative framework for other human-derived biological materials and recommends consideration of broader terminology, such as “**Substances of Human Origin**”, to encompass tissue, blood, human milk, microbiome material, and other regulated biologicals. This approach better reflects contemporary regulatory practice and avoids unnecessary fragmentation.

### **Areas Requiring Further Development**

#### **Trade and Commercial Dealings**

RANZCO considers that provisions relating to trade and commercial dealings in human tissue require further development.

Additional clarity is needed regarding:

- permissible cost recovery,
- transparency obligations of for-profit providers,
- cross-jurisdictional movement of tissue, and
- safeguards to protect donor altruism.

This area is central to public confidence and system integrity.

### **Future Technologies and Therapies**

RANZCO recommends that the legislation explicitly anticipate future developments in cellular therapies, tissue engineering, bioengineered corneas, and regenerative medicine. Given the pace of technological change and the infrequency of legislative review, future-proofing is essential to ensure the framework remains fit for purpose.

### **Accountability of Transplanting Facilities**

RANZCO notes a gap in the current framework relating to accountability once tissue is supplied to transplanting facilities.

### **Hospital and day surgery case example**

After tissue is released from an eye bank and received by a hospital or day surgery facility, statutory accountability relies largely on contractual arrangements. There is limited legislative recognition of custodianship during this period.

RANZCO recommends that legislation explicitly recognise shared custodianship responsibilities while tissue is under the control of transplanting facilities, to:

- protect donor intent,
- support both banks and hospitals,
- enhance traceability, and
- reduce system risk.

## **4. Conclusion**

RANZCO supports reform of human tissue legislation to improve consistency, transparency, ethical governance, and sustainability across Australia.

The College considers that the proposed reforms, together with further development in the areas identified above, will strengthen donation systems, support research and innovation, and maintain public confidence over the long term.

RANZCO welcomes continued engagement as the review progresses.

Yours sincerely,



**Mark Carmichael**  
**RANZCO CEO**