

17th December 2025

Australian Law Reform Review of the Human Tissue Act

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

Australian Tissue Donation Network (ATDN) is a not-for-profit tissue bank located in Sydney NSW established in 2016. ATDN partners with many private hospitals to facilitate its Placental donation program and its Femoral Head Program.

ATDN facilitate the screening, recovery and storage and testing of tissue and remain the custodian of all tissue donated.

ATDN as part of the Tissue Sector in Australia, is a member of The Biotherapeutics Association of Australasia (BAA) and their Facilities Advisory Body. ATDN was a member of the Eye and Tissue Advisory Committee until all living Tissue Banks were terminated from the committee in 2024.

ATDN strongly supports the review into the Human Tissue Acts across Australia to ensure the safety, ethics and availability of Tissue Donation in Australia.

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

Donation is regulated at the state and territory level via individual Human Tissue Acts. – The outcome of this is that each state has slightly different laws and they have been interpreted quite differently e.g. WA has interpreted these Laws to mean that a medical practitioner or an Allograft specialist must be present at recovery, this can be cost prohibitive and can reduce the number of donors able to be recovered due to availability.

Each hospital or institution appoints "designated officers" (usually senior medical practitioners) responsible for ensuring legal compliance when authorising tissue removal from deceased individuals. - Although there is training and some national coordination through Donate Life each jurisdiction has slightly different laws which can impede standardisation. The main duty of this role is to ensure that consent has been obtained either from the donor (prior to death) or the senior next of kin and authorise the removal of tissue for transplantation or other uses such as research. If the death of a potential donor requires coronial approval the designated office must obtain coronial approval prior to removal for any tissue. Standardisation of the Human Tissue Act would allow for better oversight and standardise training for this role.



Donation is very time dependant; for most tissues this means that recovery must be completed or commenced with 24 hrs after death. Many countries do not use the designated officer model as once a potential donor has been referred to the Organ or Tissue team in that consent from Senior Next of Kin and coronial permissions are obtained by trained staff. The finding of a designated officer or executive staff member can be time consuming and can lead to the loss of potential donors. As donation is a rare occurrence these members of staff would not have the recency of practice nor often the experience to be the experts in their field that specialised donation staff are.

Having a standardised consent form will ensure uniformity across all States and Territories. Having a standardised consent form will also ensure that consent covers the use of tissue for therapeutic, research or education purposes with consistent language.

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

According to ANZOD Eye and Tissue Data published in January 2025 for the 2024 year there were:

1694 Eye donors Australia wide

182 MS Donors Australia Wide

75 of the MS donors were identified and came through the Organ and Tissue pathway.

State Tissue Banks are notified of deaths in public Hospitals, private hospitals do not as a standard notify of deaths in the hospital., many private hospitals have both Emergency Departments and ICU department, according to <https://www.bhi.nsw.gov.au> many public patients had their elective surgeries in private hospitals with over 70% of elective surgeries performed in private hospitals.

The difference in the numbers of eye donors compared to MS donors show that consent is not the issue, but that time of notification, delay, lack of infrastructure and resources for recovery leads to concern regarding recency of practice and skill retention.

The objectives we should be aiming for is to ensure that donation is available for those that wish to, ensuring that there is adequate infrastructure and resources. We should also be ensuring that Australia and it's laws are ready for new research and advanced therapies and has the integrity and ethical rigor required to safeguard all future donors, their families and the future recipients



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

Principles used to guide reform should include accessibility, we are far more restricted in the ability to donate if eligible by lack of infrastructure than we are in the accessibility of being able to receive an allograft.

Ensuring that we are guided by the recommendations from WHO, NHMRC and the OECD and allowing the TGA to guide the safety and efficacy and GMP of the tissue.

The Organ and Tissue Authority (OTA) currently only work with Tissue Banks who are involved with Donate Life, the focus is very significantly on Organ Donation which is not under the scope of this review. This does leave Tissue Donation very much as an afterthought and living donor tissue banks very much out of any sector communication.

ATDN therefore believes that the “establishment of a new statutory regulatory body which could incorporate the OTA as a branch within the new statutory regulatory body” would be the best solution.

To have a governing body that was adjacent to the OTA but focused on tissue at a federal level would hopefully increase awareness and allow tissue banks to work together and would allow collaboration with the OTA.

Do you agree that the issues set out in the section ‘Priority reform areas’ should be a focus for our Inquiry?

Unfortunately, there are many competing priorities, so these focus points are a great place to start.

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

Harmonisation across all states and territories so that all tissue banks in Australia has the same opportunities for donation.

The focus should be on ensuring the highest standards both ethically and clinically to provide the opportunity for donation for the community. Future therapies should be should also be considered and assurance that research, education and biotechnology advances are included in the review.

Are there inconsistencies between the HTAs that we have not identified in this Issues Paper that are causing problems and should be a reform focus for us?

Most of the commentary in the paper discusses organ, which are not regulated the same as tissue.



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ANZOD eye and Tissue report has the stats regarding eye and tissue donation which may be of more relevance.

Do you think it is important that we consider any of the issues in the section 'Issues we are unlikely to focus on in this Inquiry'? If so, why?

Whilst all of the matters are important, these matters are not in the scope of this reform and should be looked at independently once this reform is completed. These matters may be then addressed by the governing body if one is appointed.