

# Review of Human Tissue Laws

## Proposals and Questions in the Discussion Paper

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Thank you for the second opportunity to bring my own and ShareLife's views to the attention of the Australian Law Reform Commission (**ALRC**) as part of the current review. I am absolutely convinced that the Discussion Paper has set a most promising future for organ donation in Australia.

In my initial submission I advised that, "In June 1999, I received a kidney and pancreas from a deceased donor." Sadly, after an amazing 26.5 years, my kidney function has started to decline. Due to the low organ donation rate in Australia, the chances of someone of my age and suffering from organ failure being approved as a patient on the organ transplantation waiting list is extremely low. I am now, like many others, dealing with the physical and emotional implications of this.

All my comments below should be read taking into account my detailed submission to the Issues Paper. Given my current medical condition, I do not have the energy to prepare as detailed a submission as I did six months ago, so I will only briefly address the most important issues:

### *National legislative framework*

#### *Proposal 1*

*The retrieval, storage, and use of human tissue in Australia for medical, educational or scientific purposes should be regulated either:*

- a. with substantial consistency across states and territories through a coordinated and harmonised set of state, territory, and Commonwealth legislation; or*
- b. uniformly by Commonwealth legislation.*

*A single National Regulator should be established (Proposal 3) and responsible for setting codes of practice, guidelines and standards, and for enforcing compliance.*

I support option b. and subject to my support for option b. in Proposal 3 below.

### *National Regulator*

#### *Proposal 3*

*The Australian Government should establish a National Regulator by:*

- a. expanding the powers and functions of the Organ and Tissue Authority by amending the Australian Organ and Tissue Donation and Transplantation Authority Act 2008 (Cth); or*
- b. establishing a new statutory regulatory body, which would incorporate the Organ and Tissue Authority as a branch within the new statutory regulatory body; or*
- c. establishing a new statutory regulatory body, which would supplement and support the existing powers and functions of the Organ and Tissue Authority in a way that is consistent with the goal for national governance set out in the National Strategy for Organ Donation, Retrieval and Transplantation.*

*The National Regulator could have the following powers and functions:*

- *set national policies in relation to human tissue;*
- *create binding codes of practice and standards;*
- *provide guidelines for medical practitioners, researchers, and organisations that retrieve, store or use human tissue;*

- provide educational material for the general public about tissue donation;
- accredit and license entities that retrieve, import, store, process, distribute, and/or export human tissue in the tissue banking and research sectors;
- monitor, collect data, investigate, and enforce compliance with human tissue laws and codes using both civil and criminal penalties.

To avoid duplication of responsibility for areas that are already regulated, in establishing the National Regulator, regard should be had to the scope of other regulatory entities in Australia, such as the:

- Therapeutic Goods Administration;
- National Blood Authority; and
- the Organ and Tissue Authority.

The Human Tissue Regulator should be adequately funded to carry out its powers and functions.

I support option b. subject to giving the National Regulator statutory authority to independently scrutinise all levels of government. From the community perspective, the National Regulator must be seen to speak freely and uninhibitedly.

The most important function of the National Regulator is to create an environment of trust in organ donation for transplantation in the wider Australian community. There is so much evidence that trust in the organ donation system, especially by the CALD communities, is absolutely essential for an organ donation system to be successful. The obsession by the current OTA with privacy above all else has led to a severe lack of trust.

I repeat what I wrote in my earlier submission:

3.6 “We submit that the OTA has similar problems to the National Mental Health Commission, and that in order to be effective, the OTA must:

- function as an independent body, separate from the Commonwealth Department of Health, and state and territory health departments; and
- be empowered with statutory authority to hold the Department of Health and state and territory health departments to account in connection with the expenditure of Commonwealth funds, and whether measurable outcomes in relation to organ donation are being achieved in line with the Government and community's expectations.”

*The objects of human tissue laws*

*Proposal 5*

*New human tissue legislation should include an opening section explaining that the objects of the legislation are to:*

- modernise and ensure adaptability and consistency in the laws and regulatory frameworks governing the donation of human tissue, and use of human tissue for medical, educational and scientific purposes;*
- increase access to human tissue, and to the benefits of human tissue donation, transplantation and use;*
- ensure that the donation, and use of human tissue for medical, educational or scientific purposes, is consistent with Australia's international human rights obligations;*
- promote equity and reduce inequities in access to human tissue and the benefits of human tissue use;*
- ensure respect for individual dignity and autonomy, and for the human body;*
- prevent the exploitation of individuals in relation to how their tissue is removed, and*

*used for medical, educational and scientific purposes; and  
g. promote public trust in the laws and regulatory frameworks that govern human tissue donation and use for medical, educational or scientific purposes.*

*Question 1*

*Do you agree with the objects listed in Proposal 5 for human tissue legislation?*

Yes, I agree.

Again, I can only repeat what I quoted in my earlier submission:

“We were jubilant when on 2 July 2008, 'The Rudd Government today proposed a major new national reform package to establish Australia as a world leader in organ donation for transplantation.’”

This should be the primary objective of all legislation relating to organ donation for transplantation. Everything else is secondary. Saving lives is the most important obligation of a civil society.

*Pre-mortem interventions*

*Proposal 26*

*New human tissue legislation should define pre-mortem interventions to mean any activity, procedure or investigation that is performed on a living person solely for the purpose of tissue donation after death, including to assess, maintain, or improve the viability of organs for transplantation.*

Yes, I agree.

*Improving access to data*

*Question 42*

*We have heard there is a need for data from donation agencies, tissue banks and other tissue product manufacturers, distributors, and sponsors to better understand the demand for tissue and inform future policy development.*

*If you agree there is a need for data, what type of data is needed?*

Yes, I agree.

This is such a broad topic. In addition to the data listed in my earlier submission, detailed data should be publicly available relating to the reasons de-identified potential donors did not proceed to organ donation. I have seen it privately presented as “Cascade Data”. Details regarding the CALD responses to organ donation Registration and Consent. This is not to blame but rather to provide a basis upon which the community can be involved in finding solutions to the low donation rates in many CALD communities.

*Question 43*

*In relation to Question 42, how should the data be reported?*

*For example, should there be:*

- a. voluntary reporting?*
- b. mandatory reporting?*

Given my experience of the secrecy since the establishment of OTA in January 2009, the National Regulator must have statutory authority to mandate reporting.

*Question 44*

*In relation to Question 43, if you support mandatory reporting, should the National Regulator (or alternative) have the power to conduct mandatory inspections of records?*

YES, I agree. It should extend beyond this to managing the accurate and systematic entry of the raw data. At the moment those making the decisions regarding the potential donors are self-reporting the data entry.

*Prohibiting non-consensual public disclosures of a tissue donor's or tissue recipient's personal information*

*Proposal 46*

*New human tissue legislation should prohibit the public disclosure of a human tissue donor's or human tissue recipient's 'personal information', unless consent to disclosure has been provided in accordance with Proposal 48.*

*'Personal information' is information that identifies an individual, or that makes an individual reasonably identifiable*

Yes, I agree.

*Who can consent to the disclosure of a tissue donor's or tissue recipient's personal information*

*Proposal 48*

*New human tissue legislation should provide that consent to the disclosure of a human tissue donor's or human tissue recipient's personal information may be given by:*

- a. the human tissue donor or the human tissue recipient themselves; or*
- b. the human tissue donor's or the human tissue recipient's authorised decision-maker if the human tissue donor or the human tissue recipient is deceased; or*
- c. the human tissue donor's or the human tissue recipient's authorised decision-maker if the human tissue donor or the human tissue recipient is a child or an adult who does not have decision-making capacity.*

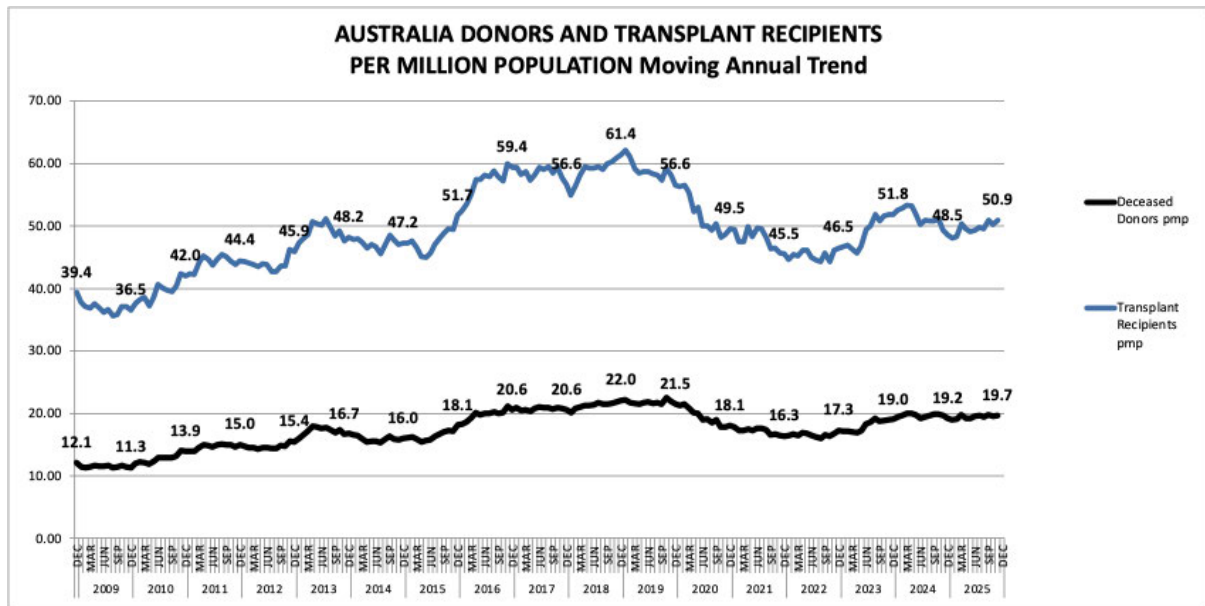
Yes, I agree.

I made it very clear in my earlier submission that, "In my view, a clear and consistent approach that permits consenting transplant recipients and donor families to be put in contact with each other ought to be formally brought within the remit of the OTA. Such a process ought to include a process through which consent may be sought and obtained at a future point in time."

Proposal 48 goes to the heart of the privacy obsession by OTA. Detailed data is seldom released to the public with the organisation always claiming that it will breach the privacy of donors and/or recipients. The DonatLife website is seen by the community as a mouthpiece of the government, for the politicians and the bureaucracy rather than all the various groups affected by organ donation for transplantation. For example, the December organ donation data is only released after the Minister has presented the media release for the year's results. There is no critical analysis presented to the community, simply praising the organisation and blaming the community for not registering to be organ donors.

This graph, updated to November 2025, continues to show that in the last 8 years the organ donation rate per million population (PMP) has been virtually stagnant while the number of

organ transplant recipients PMP has declined substantially. More and more people suffering from organ failure will die unless the changes contemplated by this Discussion Paper are implemented.



Again, I thank you for giving me the opportunity to present my views. I am extremely optimistic that this Discussion Paper has to potential to set in place an organ donation system that will achieve the government’s aim in 2008, “to establish Australia as a world leader in organ donation for transplantation”.