Australian Law Reform Commission (ALRC) Review of Human Tissue Laws Discussion Paper

NT Health Submission

NORTHERN TERRITORY GOVERNMENT

Contents

1. Introduction

Human tissue laws regulate the donation, removal, storage, use, and disposal of human organs and tissues for transplantation, medical research, and education. Organ and tissue donation, and transplantation, is regulated by Commonwealth, state and territory legislation.

Following the Australian Law Reform Commission (ALRC) 1977 report, *Human Tissue Transplants*, human tissue legislation was enacted by all Australian jurisdictions. The ALRC's recommendations were aimed at harmonising laws across Australia regulating the donation of blood, tissues and organs for transplantation, and their use for scientific, therapeutic and medical purposes. Almost fifty years later, human tissue laws have not kept pace with significant social, technological, and scientific changes and amendments to legislation have created increasing inconsistencies between jurisdictions.

It is acknowledged that in Australia, and around the world, there is not enough human tissue available to meet people's needs for life saving and life enhancing transplants, nor for research that could result in important public health benefits and enhance lives. Legislative reform may assist in facilitating change and removing inconsistencies and unnecessary barriers in donation, transplantation, medical research and education.

NT Health supports the need for contemporary and harmonised laws which reflect the significant social changes and technological and scientific advancements that have occurred since the enactment of human tissue laws, including the Northern Territory's *Transplantation and Anatomy Act 1979*.

Any reforms, including legislative reform, to increase access to human tissue must respect human rights, dignity, culture and autonomy; support equitable participation in, and access to, donation and transplantation systems; and promote and uphold public trust.

In addition to responses provided by NT Health staff as part of the ALRC stakeholder consultation process, NT Health provide this submission responding to some of the proposals and questions contained in the ALRC Review of Human Tissue Laws Discussion Paper.

2. NT Health Feedback on ALRC Discussion Paper

2.1. Response to Discussion Paper Proposals

2.1.1. Proposal 1 – National legislative framework

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.**

NT Health supports the regulatory model used by the *Health Practitioner Regulation National Law Act 2009 (Qld)* where a host jurisdiction drafts and enacts a template Act and the other jurisdictions adopt the law as reflected in the host jurisdictions Act. This model is very effective in terms of harmonisation (as it avoids inconsistencies developing between the jurisdictions) and is efficient as it avoids the delays associated with individual states and territories having to draft separate legislation and then find a legislative timeslot to introduce the draft legislation into Parliament.

2.1.2. Proposal 3 – National regulator

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.**

NT Health recommends adopting option c (establishing a new statutory regulatory body, which would supplement and support the existing powers and functions of the Organ and Tissue Authority). Given the current governance and operational functions of the Organ and Tissue Authority, and the proposed expanded governance role as set out in the National Strategy for Organ Donation, Retrieval and Transplantation, a separate statutory body would be more appropriate.

2.1.3. Proposal 4 – Implementing a national legislative framework

To implement Proposals 1–3, the Commonwealth, states, and territories should come to an intergovernmental agreement to implement national uniform legislation. The structures of national uniform legislation that could be implemented include:

a) **referred legislation;**

b) **applied legislation;**

c) **mirror legislation; or**

d) **hybrid legislation — referred/applied legislation or mirror/applied legislation.**

NT Health recommends adopting option b (applied legislation) model, implemented so that the NT automatically adopts the legislation of the host jurisdiction meaning that future amendments are adopted automatically. This is efficient and allows for national consistency.

2.1.4. Proposal 5 – The objects of human tissue laws

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

a) **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;**

b) **increase access to human tissue, and to the benefits of human tissue donation, transplantation and use;**

c) **ensure that the donation, and use of human tissue for medical, educational or scientific purposes, is consistent with Australia's international human rights obligations;**

d) **promote equity and reduce inequities in access to human tissue and the benefits of human tissue use;**

e) **ensure respect for individual dignity and autonomy, and for the human body;**

f) **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.**

NT Health supports the objects listed in Proposal 5.

2.1.5. Proposal 11 – New statutory location for the determination of death provisions

Commonwealth, state and territory legislation should contain a consistent legal standard for determining death, as set out in Proposal 10. By an intergovernmental agreement, measures should be put in place to maintain consistency of this definition over time.

NT Health supports a single national definition to ensure uniformity. The location of a definition outside of the *Transplantation and Anatomy Act 1979 (NT)* would create a useful separation between the meaning of death as applied for any law of the Territory and the issue of tissue donation. A Uniform Death Act could be enacted by an intergovernmental agreement. To achieve national consistency, an applied model could be adopted as per our response to Proposal 1.

2.1.6. Proposal 11 – New statutory location for the determination of death provisions

New human tissue legislation should replace current HTA definitions of 'senior available next of kin' with a definition of 'authorised decision-maker' that sets out a hierarchy of decision-makers modelled on section 13 of the *Health Care Decision Making Act 2023* (NT).

NT Health supports replacing the current definitions of 'senior available next of kin' in human tissue acts with a definition of 'authorised decision-maker' that sets out a hierarchy of decision-makers modelled on section 13 of the *Health Care Decision Making Act 2023* (NT). This ensures consideration is given to any legislative appointments (advanced personal plans and guardianship) and acknowledges familial or other connections, including appropriate relatives under Aboriginal or other customary law or tradition.

2.1.7. Proposal 26 – Pre-mortem interventions

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.

NT Health supports a broad definition of pre-mortem interventions. This would capture a wide range of activities without being too prescriptive and would allow for the future inclusion of interventions based on technological advancements and evidence-based practice.

2.1.8. Proposal 48 – Who can consent to the disclosure of a tissue donor's or tissue recipient's personal information?

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.**

NT Health supports the proposal to allow donor families to publicly identify that their deceased family member was a donor. This could stimulate broader conversations within the community, de-mystify organ donation for First Nations Australians and the wider public.

2.2. Response to other matters raised in the Discussion Paper

2.2.1. Question 16 – Consent and authorisation for removal of tissue after death

Under current legislation, the Designated Officer is required to authorise tissue removal when a person dies in a hospital. Do you agree the role of the Designated Officer is no longer necessary?

- **If you agree that Designated Officers are no longer necessary, please explain why.**
- **If you think the Designated Officer role remains necessary, please explain why.**

NT Health supports retaining the Designated Officer authorisation role if there is to be organ/tissue removal activity taking place within a hospital. This enables the Designated Officer to be informed of the activity occurring within the hospital, information exchange, and independent oversight to ensure necessary matters have been considered and the tissue removal is being undertaken with the appropriate consent and in accordance with the relevant legislation, policies and guidelines.

2.2.2. Question 24 – Coronial consent to donation

Should new human tissue legislation provide factors for coroners to consider when deciding whether to consent to donation of tissue from human bodies under their jurisdiction? If so, what factors should a coroner take into account?

NT Health supports specifically setting out in the legislation the factors a coroner should consider when deciding whether to consent to donation. The three dot points set out on page 88 at 7.94 are not onerous and could help avoid unnecessary refusals. This would increase the number of transplants and would assist in respecting any expressed wish for organ donation by the deceased/deceased's family.

2.2.3. Question 27 – Use of tissue removed during a post-mortem examination

Should new human tissue legislation contain an exception to the need for consent so that 'small samples' can be used for scientific, medical, or educational purposes? If so, what samples should fall within the exception?

NT Health advises consent from the deceased person's family should be obtained before taking samples for scientific, medical or educational purposes during a post-mortem examination and the proposed exception should not be adopted. The family should consent and be fully informed as to the proposed use of the samples, the duration of storage etc. to ensure full disclosure and maintain public trust.

2.2.4. Question 35 – Giving extra-territorial effect to the prohibition

Should the prohibition on exchanging human tissue for reward have extra-territorial effect? If so, what would be the best mechanism to achieve this? For example, an amendment in new human tissue legislation, or an amendment to the Criminal Code Act 1995 (Cth)?

NT Health believes there is merit in having an extra-territorial provision to avoid Australians seeking to buy organs from an overseas donor, who may be living in poverty, and thereby engaging in organ trafficking.

2.2.5. Question 40 – Reforms relating to tissue importation ethics and oversight

Should new human tissue legislation include a mechanism to help make sure that imported tissue has been ethically sourced?

If so, should the mechanism be:

a) **A prohibition of the importation into Australia of human tissue that was originally obtained without the consent of the donor, or in exchange for reward or profit? or**

b) **A reporting mechanism similar to that contained in the Modern Slavery Act 2018 (Cth)?**

NT Health believes that if the new legislation proposes to contain a mechanism to ensure that the imported tissue has been ethically sourced, then the reporting mechanism should be similar to that contained in the *Modern Slavery Act 2018* (Cth). The reporting obligations would minimise the risk of modern slavery.

3. Conclusion

NT Health supports the national review of human tissue laws and designed to create a modern and nationally consistent framework for human tissue regulation and looks forward to the release of the ALRC Final Report.

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