Government of **Western Australia**
Department of **Health**

Review of Human Tissue Laws 2025

WA Department of Health Submission – Issues Paper 51

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Overview

The Department of Health, Western Australia (the Department) is pleased to provide a submission to the Australian Law Reform Commission (the Commission) for its input into the review of Human Tissue Laws issues paper 51 (the Review).

In Western Australia (WA), the Department is the agency responsible for the *Human Tissue and Transplant Act 1982*, the *Anatomy Act 1930* and the *Human Reproductive Technology Act 1991*.

- The *Human Tissue and Transplant Act 1982* has recently undergone review and amendment.
- A review of the *Human Reproductive Technology Act 1991* is currently underway, with legislative amendments expected to proceed in 2025.
- The *Anatomy Act 1930* is yet to undergo substantial review or amendment.

Policy Officers and Medical Advisors with extensive experience in both the recent legislative amendments and the ongoing regulatory work of the various Acts have been involved in developing this submission.

Human tissue laws should uphold the paramount importance of the safety, welfare, dignity, and right to privacy of donors and recipients; ensure equity of access to donation and transplantation; and support the safe and sustainable national supply of donated organs and tissue.

The Department requests the Commission consider canvassing State and Territory authorities for their views on developing a single 'National Law' model for human tissue laws in Australia, that can be applied or adopted by jurisdictions. There are examples of national law models in health including the *Therapeutic Goods Act 1989* (Commonwealth), and the *Health Practitioner Regulation National Law Act 2009* (Queensland) which are laws applied as a law of the State, in WA. This model is a more efficient mechanism than jurisdictions maintaining separate legislation, and by its nature enables a collaborative approach to policy development.

Priority reform areas

The Department supports the inclusion of the issues set out in the section 'Priority reform areas' in the Commission's Review.
Additional information to support the Review is provided for selected issues. Where no additional information has been provided, this should not be interpreted as consideration by the Department that the issue is of lesser importance.

What should be included in the definition of tissue?

In WA, human milk is considered to fall within the definition of tissue as a substance extracted from a part of the human body. If the definition of tissue moves towards those used internationally (e.g. 'Substances of human origin' or 'Medical product of human origin') then consideration would be needed regarding how fecal microbiota, cell lines, recombinant products, human milk fortifiers, acellular matrix, bioink and biogels should be regulated.

What legal protections are needed for adult living donors?

Proposed strategies to increase Australian self-sufficiency for blood derived products may include a hybrid model of renumerated and non-renumerated blood and plasma donation. Blood donation in Australia is currently non-renumerated however there is some degree of coercion in the form of targeted messaging to blood donors. Blood donors are incentivised to donate regularly using a gifts program (currently low value items). Incentive programs or donor remuneration schemes may lead living donors to prioritise donation over their own wellbeing. Potential risks for plasma donors may also include those arising from the transfusion of RhD incompatible cells to produce anti RhD immunoglobulin.
Strong regulatory frameworks are needed to minimise potential risks to living donors of regenerative tissue including blood, plasma, milk.

What protections are needed for children?

Proposed stem cell donor recruitment strategies would potentially target 16- and 17-year-olds for inclusion in the Australian Bone Marrow Donor Registry (the Registry). This would only apply to inclusion on the Registry; donation of stem cells would still require the donor to be 18 years-old or older.
For cord blood donations, there needs to be clear determination if the donor is the mother or the newborn.

How should ‘death’ be defined?

The Standing Committee on Public Administration’s Report: ‘The donation conversation: Organ and tissue donation in Western Australia’ (Report 41), identifies the current definition of death as a legislative barrier in WA to the use of Normothermic Regional Perfusion and this is regarded as a high priority for review and potential reform.

Who should be able to authorise tissue donation when a person dies?

How a deceased person’s expressed wish regarding organ or tissue donation may be recognised or upheld may include registration on the Australian Organ Donor Registry, however in Western Australia, an Advanced Health Directive (AHD) cannot be used to register intent to be an organ or tissue donor. Recommendation 5 of Report 41 is that the *Guardianship and Administration Act 1990* (WA) be amended to provide the ability for an individual to record a decision on organ and tissue donation in an AHD. Further consideration of potential additional avenues for registering an expressed wish regarding organ or tissue donation may be required.

In clinical settings in WA, the expressed wish of family members regarding organ or tissue donation may override a deceased person’s previously expressed wish. Recommendation 6 of Report 41 is for a provision in the *Human Tissue and Transplant Act 1982* (WA) for a person to appoint a substitute decision maker to represent them after death for the purpose of consent to organ or tissue donation.

Who should be authorised to remove tissue?

In WA, there had been occasions when the retrieval of musculoskeletal tissue could not go ahead within the timeframe required by the Therapeutic Goods Authority when the retrieval team’s medical practitioner was unavailable due to competing clinical demands. Section 24 of the *Human Tissue and Transplant Act 1982* was amended to allow appropriately trained and qualified individuals to retrieve ocular, skin and musculoskeletal tissue from eligible donors without the physical presence of a medical practitioner.

How should we ensure potential donors are identified in hospital?

For patients who are receiving end of life care through a palliative care program, it is preferable that discussions about donation occur prior to the final admission to hospital, to minimise distress for the patient and their family.

Mandatory referrals to DonateLife might be seen as reducing patient autonomy and not in keeping with patient-centred care. There may also be issues around cultural safety to be considered.

Section 106 of the *Voluntary Assisted Dying Act 2019* (WA) contains certain prohibitions regarding the access, use and disclosure of information which may have implications when considering the introduction of mandatory referrals of potential donors receiving end of life care in hospital.

Recommendation 21 of Report 41 is to introduce amendments to the *Voluntary Assisted Dying Act 2019* and the *Human Tissue and Transplant Act 1982* to incorporate provisions to support the right of patients accessing Voluntary Assisted Dying to become organ and tissue donors.

How should steps and interventions that occur before death be regulated?

The following concerns have been raised about how premortem interventions and investigations might fit within a good end of life care model:

- When someone becomes palliated, and especially in the terminal phase; it is in the best interests of the patient to minimise the number of investigative procedures to attain suitable levels of comfort for the patient.
- If pre-mortem interventions have adverse effects on the patient such as unnecessarily prolonging suffering and anticipated death, then this might be regarded as an injustice to the patient.

How should donor and recipient information be handled?

The prohibition on the disclosure of information regarding the identity of donors and recipients is an important issue for review in consultation with all stakeholders including community donor family advocacy groups.

How should consent for body donation be regulated, and how should schools of anatomy be regulated?

A nationally consistent approach to body donation for anatomical examination and the regulation of 'Schools of Anatomy' would provide more clarity for donors, families and institutions and promote the upholding of ethical standards.
WA recommends that the scope of the Review includes the following:

- Purposes for donation and how these are defined – 'anatomical examination' or 'scientific purpose' might not adequately reflect the range of activities conducted in Australia, which may include the education of health students and professionals, surgical skills training, and research.
- Consent for body donation – who may provide consent for donation.
- Minimum requirements for informed consent:
  - Specified purpose or purposes.
  - Duration of retention of body, body parts, plasticised specimens.
  - Disposal wishes.
- Access to medical information to assess suitability for donation.
- Regulation of 'Schools of Anatomy' or of designated facilities where donated bodies may be lawfully stored or handled:
  - Licensing and accreditation of appropriate facilities.
  - Codes of Practice or Standard Operating Procedures for facilities and staff.
  - Inspections.
  - Reporting requirements.
- How long bodies, parts and images may be retained, noting new techniques including plastination and digitisation.
- 'Digitisation' of bodies and parts (videography, 3D photography, digital reconstructions) and subsequent use for online teaching.
- Privacy, confidentiality, and de-identification of bodies.
- Transfer of bodies between licenced facilities.
- How recovery of costs associated with storage, preparation or processing, transfer and disposal are defined and regulated.
- How the importation of fresh frozen bodies and plastinated specimens for anatomical examination is regulated.

In WA, the *Policy Requirement for Anatomy Licence Holders* supports the requirements of the *Anatomy Act 1930* in relation to Schools of Anatomy and is available on request.

How should tissue removed in post-mortem examinations be used?

The storage and use of tissue removed during post-mortem examinations in WA is subject to the gazetted *Non-Coronial Post-Mortem Examinations Code of Practice 2022*, issued under the *Human Tissue and Transplant Act 1982*.

How should trade in human tissue and tissue products be regulated?

Compensation for donors needs to be reviewed – should this be expanded to account for incentive programs such as the Lifeblood gifts program, or remuneration for plasma donation?
How a cost-recovery amount is determined should be part of the Review, ensuring consistency across jurisdictions.

Should the law regulate public requests for tissue donation?

Public requests or solicitation for tissue donation may include requests from families to promote blood or stem cell donor recruitment drives for a particular individual, where there may be difficulty finding a compatible donor for the recipient.

How should donated tissue be allocated?

The inclusion of how donor tissue is allocated in legislation is likely to be overly restrictive and may create unintended barriers to transplantation.

What are some other uses for tissue and bodies and how should they be regulated?

In WA the prohibition on trade applies to the display of plastinated bodies in public exhibitions. Questions regarding provenance of such bodies have been raised, including if donation was altruistic and if informed consent was provided. The Human Tissue Advisory Body may provide advice to the Minister regarding contracts or arrangements for such displays.
Small tissue samples are used for scientific purposes including diagnostic testing, teaching, or quality assurance. Specifying these purposes is important in order to allow for recovery of costs arising from tissue processing.

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

- Ensuring true informed consent is obtained from donors for tissue potentially used for research or for the development of new commercial products, is essential.
- Emerging CAR-T and CAR-NK therapies are derived from allogenic sources (e.g. blood, cord blood, bone marrow). Whilst these therapies use in vitro expansion, they are not far removed from the original source material. There is a potential risk that cord blood donations currently held by cord blood banks could be sold on and utilised for significant commercial application without the donor's knowledge or consent.
- The management of privately held human skeletal remains used historically in medical education needs to be addressed. These remains were often acquired through unregulated international markets, and there is currently no clear legal framework for their retention or disposal. A nationally consistent and feasible approach to the ethical and respectful disposal of these legacy remains should be considered.

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?

The safety of donor human milk is not adequately dealt with by other regulatory frameworks:

- Processed donor human milk (PDHM) is not regarded as a therapeutic good by the Therapeutic Goods Administration, due to the tradition of use as a food for humans.
- The Department determined that neither the *Food Act 2008* (WA) and the Australia New Zealand Food Standards Code, nor the Operational Guidelines for Milk Banks in Australia and New Zealand would provide a sufficient enforceable regulatory framework to ensure a safe and sustainable supply of PDHM to vulnerable neonates in WA neonatal intensive care units.
- The *Supply of Processed Donor Human Milk in Western Australia Code of Practice 2024* sets out minimum standards for the safe and ethical processing and supply of donor human milk in WA.

The regulation of human gametes and embryos is currently under review in WA:

- The *Human Tissue and Transplant Act 1982* (HTT Act), Part 3 currently regulates the donation of human tissue after the death of a person, including collection of gametes (human sperm) after the death of a person. In this case, under the HTT Act, the subsequent use of the tissue for reproduction has been considered a 'medical purpose'.
- The subsequent use of posthumously collected gametes is, however, currently prohibited under Direction 8.7 of the *Human Reproductive Technology Directions 2021* of the *Human Reproductive Technology Act 1991*.

The Department is currently reviewing the collection, usage and management of reproductive materials as part of the development of a new assisted reproductive technology and surrogacy legislation in WA.

The Department would like to thank the Commission for their time and attention to these issues, and we look forward to working closely with you in the future.

If you have any further questions regarding this submission, please contact the Office of the Chief Medical Officer at the Department at [redacted]

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