



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

Submission from the Health-portfolio

(Department of Health, Disability and Ageing, Organ and Tissue Authority, National Blood Authority, National Health and Medical Research Council, and Office of Gene Technology Regulator)

4 July 2025

Introduction

This submission is reflective of the views of the Health-Portfolio Reference Group which includes the Department of Health, Disability and Ageing (Department), and portfolio agencies – Organ and Tissue Authority, National Blood Authority, National Health and Medical Research Council, and Office of the Gene Technology Regulator.

We welcome the opportunity to make a submission in response to the ALRC Review of Human Tissue Laws – Issues Paper.

We have considered the matters raised in the Issues Paper and agree with the proposed principles-based approach, scope and direction for the Review of Human Tissue Laws (Review). This includes the selection of high-priority issues likely to be considered, and the issues the Review is unlikely to focus on.

The harmonisation and modernisation of state and territory Human Tissue Acts (HTAs) will allow for a nationally consistent approach to human cell, tissue and organ donation, retrieval and transplantation that better support health outcomes for Australians.

State and territory HTAs should reinforce the existing national principles for organ and tissue donation and transplantation encapsulated in the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* including equity, effectiveness and transparency.

The need to achieve legislative consistency, whilst also ensuring adaptability to respond to emerging technologies, scientific research and clinical practice will be important.



Laws must have currency, value and adaptability into the future.

In undertaking legislative reform, it is important to ensure laws are not restrictive and remain adaptable. There are established clinical guidelines, frameworks and policy that guide clinical practices and scientific research. Understanding the delicate balance between law and policy and what is beneficial to legislate and what should remain as a matter of policy is important in this Review. Modernising laws will inherently drive modernisation of policy, frameworks and clinical guidelines. Keeping legislation broad will support its transformation into detailed policy and clinical practices to achieve desirable outcomes for all Australians across donation, transplantation and research.

This will also work towards preventing the unintentional restriction of research activities, where greater clarity on the definition of tissue for scientific (or research) purposes may be required. For example, whether cells, cell lines or, potentially, certain cell products fall under the definition of tissue for purposes of enabling or restricting research activity. Adaptability of law to support emerging technologies, products and practices is important in supporting modernisation and best practices for clinical and scientific purposes.

The guiding principles of equity and public trust are supported, but must be implementable in practice.

We strongly support the principle of equity guiding the reforms, to support equitable participation in, and reduce barriers in access to cell, tissue and organ programs. The Review may wish to consider how the legislation will embed this principle, noting the flow on implications to clinical practice, scientific research and other applications.

Consideration must be given to the context in which the equity principle is being operationalised to prevent implicit barriers to equity in legislation. For example, it is known that there is a disparity in access to transplantation between non-Indigenous and Aboriginal and Torres Strait Islander people due to structural barriers within health care systems. Legislation should not impede priority reforms to deliver equity of access to transplantation, noting that Aboriginal and Torres Strait Islander peoples and practices are not homogeneous. Different approaches will apply in different settings. The opportunities and benefits of embedding equity must be clearly outlined to provide clarity for sector stakeholders who will be responsible for enacting these principles.

Equity is also central to upholding public trust in the legislative frameworks that govern how cells, tissues and organs are obtained and used, and that these systems operate in a safe, fair and effective manner. We agree that participation in cell, tissue and organ donation and transplantation systems require a clear accountability structure and effective governance. Promoting information sharing and transparency in donation and



transplantation activity, whilst maintaining donor and recipient confidentiality will improve public trust. Furthermore, legislation should ensure that trade in human tissue is prohibited and provide clarity on how ethical exceptions could be consistently considered.

The principles of effectiveness, equity and transparency need to be agreed nationally, in order to achieve better outcomes for all Australians.

The Review should account for other reviews already underway.

Review of the National Blood Arrangements

Although the Review will explore arrangements for the donation, retrieval and transplant of human cells, tissues and organs, it may wish to take note of the current Review of the National Blood Arrangements which is currently under way. This Review will examine the key governance frameworks and administrative processes that support the national blood arrangements. Further information can be found at www.health.gov.au/topics/blood-and-blood-products/review-of-the-national-blood-arrangements

Review of gene technology legislation

Amendments to the Gene Technology Act 2000 are currently being finalised, following public consultation on a draft amendment bill from September to November 2024. Changes to definitions of *gene technology* and *genetically modified organism* in the Act may interface with any proposed changes to the human tissue laws related to these terms, such as definitions of cells, tissues or genetic material. OGTR's interest remains as a watching brief to ensure that legislative changes do not lead to unintended consequences regarding regulation of humans.

The Health-Portfolio Reference Group is poised to provide support on specific questions from the Commissioner.

Should the Review require additional information on the operation of current legislative frameworks within the responsibility of the Health-portfolio, please find enclosed a list of contacts (Attachment A). Please also note that individual portfolio agencies and/or Department policy areas may make individual submissions.

We look forward to the publication of the Review of Human Tissues Laws - Discussion Paper and how the issues considered are taken forward.

For any queries or further information related to this submission, please contact: organandtissue@health.gov.au.