Australian Government
Department of Health, Disability and Ageing

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

Submission from the Health portfolio

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

13 February 2026

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1. Introduction

The Health portfolio Reference Group (Reference Group) welcomes the opportunity to make a Submission in response to the ALRC Review of Human Tissue Laws Discussion Paper.

This Submission reflects the joint views of the Reference Group which includes the Department of Health, Disability and Ageing (Department), and portfolio agencies: the Organ and Tissue Authority (OTA), National Blood Authority (NBA), National Health and Medical Research Council (NHMRC), and Office of the Gene Technology Regulator (OGTR).

There are a range of frameworks, strategies and guidelines within the Health portfolio which intersect with human tissue laws. These can be found at **Attachment A**.

In providing this submission, the Reference Group acknowledges the contribution made by donors and their families to Australia's donation and transplantation system. We recognise that the donation and transplantation system exists because of the gift of donation. We have considered throughout how each area of reform respects and safeguards donors and families and safeguards the gift of donation. This includes how public trust can be sustained and support an effective donation and transplantation system for all Australians.

2. A Nationally Harmonised Regulatory Framework[1]

The Reference Group supports harmonisation of existing state and territory human tissue laws to reduce fragmentation and legal uncertainty across jurisdictions. This is to ensure equitable approaches across cell, tissue and organ donation and transplantation.

Legislation should recognise that equitable approaches may need to be operationalised differently across states and territories. Legislation should also consider local health system structures, cultural contexts and service delivery models.

Legislation should also remain adaptable to respond to emerging technologies, scientific research and clinical practice. Any nationally harmonised human tissue framework should be carefully designed to recognise and appropriately interface with existing arrangements.

One area where alignment may be demonstrated is assisted reproductive technologies (ART), including the use of reproductive tissues for research purposes. The use of reproductive tissues for clinical purpose is regulated through individual state and

[1] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 1, Proposals 1–4; Ch. 2, Proposal 6

territory legislation. Accreditation is provided by the Fertility Society of Australia with regard to the NHMRC 'Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research[2]'. ART research is also regulated through Commonwealth legislation, including the *Research Involving Human Embryos Act 2002*[3] and the *Prohibition of Human Cloning for Reproduction Act 2002*[4].

To achieve national consistency and ensure an effective donation and transplantation system, it is necessary to explore legislative approaches in detail. This may include how legislation and governance together may impact policy, operational and system interfaces within and across jurisdictions.

3. National Regulator function[5]

The establishment of a National Regulator is a matter for Government, including decisions on purpose (object of the legislation), scope and governance. The ALRC should consider clearly defining the term "National Regulator" to avoid ambiguity. This will clarify whether the proposed remit is regulatory, coordinating, or both, and to establish roles and responsibilities.

Any nationally harmonised regulatory framework should be developed while considering the intersection with existing national arrangements. This includes functions of the OGTR, TGA, NBA, OTA and the NHMRC so that functions are complementary and not duplicative.

3.1. Office of the Gene Technology Regulator (OGTR)

The National Gene Technology Scheme[6], administered by the OGTR, is an illustrative example of structured governance operating in parallel with other schemes.

The OGTR[7] supports the Gene Technology Regulator in their administration of the *Gene Technology Act 2000*[8] and corresponding state and territory laws. The OGTR's specific responsibility is to protect human health and the environment from risks relating to genetically modified organisms (GMOs). Its functions include risk

[2] https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-use-assisted-reproductive-technology
[3] https://www.legislation.gov.au/C2004A01082/latest/text
[4] https://www.legislation.gov.au/C2004A01081/latest/text
[5] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 1, Proposal 3; Ch. 2, Proposals 5-6
[6] https://www.genetechnology.gov.au/
[7] https://www.ogtr.gov.au/
[8] https://www.legislation.gov.au/C2004A00762/latest/text

assessment, licensing, monitoring compliance, and contributing to national and international regulatory harmonisation.

The National Gene Technology Scheme is a nationally consistent regulatory system that operates through agreement by all Australian governments. The scheme illustrates how a well-designed regulatory system with clear roles, engagement, and processes can support innovation while safeguarding public health.

3.2. Therapeutic Goods Administration (TGA)

The TGA[9] administers the *Therapeutic Goods Act 1989* (TG Act)[10] and regulates therapeutic goods manufactured domestically and overseas that are supplied in Australia. This includes products such as human cell and tissue-derived products, plasma derived products, blood and blood components. Some human derived therapeutic products are excluded from the TG Act, including organs, reproductive tissue and some types of stem cells.

Australia's Therapeutic Goods Regulatory framework for biologicals[11] demonstrates a nationally consistent regulatory environment for the quality, safety and efficacy of therapeutic products. This is achieved through mechanisms such as the Australian Register of Therapeutic Goods[12].

3.3. National Blood Authority (NBA)

The NBA[13] is a statutory agency established under the *National Blood Authority Act 2003*[14] to manage and coordinate the national supply of blood and blood products on behalf of all Australian governments. Through the National Blood Agreement[15], the NBA ensures an adequate, safe, secure and affordable supply of blood, blood products and related services. The TG Act provides the legislative basis for Australia's national standards for blood and plasma products.

A national regulatory system is critical to assuring the safety and quality of Australia's blood supply. It also supports the efficient and equitable use of scarce national resources. Australia must also have the ability to respond to new knowledge and technological developments to maintain a contemporary system.

[9] https://www.tga.gov.au
[10] https://www.tga.gov.au/resources/legislation/therapeutic-goods-act-1989
[11] https://www.tga.gov.au/products/biologicals/overview/regulatory-framework-biologicals
[12] https://www.tga.gov.au/products/regulations-all-products/about-australian-register-therapeutic-goods-artg
[13] https://www.blood.gov.au/
[14] https://www.legislation.gov.au/C2004A01114/latest/text
[15] https://www.blood.gov.au/national-blood-agreement

The NBA and the national blood arrangements demonstrate how national oversight and a central coordinating body can operate effectively in practice, providing a coherent and reliable system that delivers a sustainable blood supply.

3.4. Organ and Tissue Authority (OTA)

The OTA[16] is established under the *Australian Organ and Tissue Donation and Transplantation Authority Act 2008*[17]. The OTA is responsible for leading the national DonateLife program[18] to increase organ and tissue donation and transplantation. The OTA's functions are operational and delivery focused, including setting national clinical and community programs through frameworks, guidelines and protocols. The OTA works in partnership with the DonateLife Network, state and territory governments, and collaborates with hospitals, the organ and tissue donation and transplantation sectors and community.

The OTA's nationally coordinated deceased organ donation program model has shown that a consistent national approach increases organ donation and transplantation. This has been achieved through a focus on embedding best clinical practices within hospitals, supported by sustained public awareness.

3.5. National Health and Medical Research Council (NHMRC)

The NHMRC[19] is the Australian Government's expert body for the development of nationally consistent ethical guidelines for health and medical research. Through evidence-informed ethical frameworks and guidance, the NHMRC promotes high standards of integrity, respect and public trust in the conduct of research and clinical practice, including the use of human tissue.

The NHMRC ethics guidance, including the National Statement on Ethical Conduct in Human Research[20] and the Ethical guidelines for cell, tissue and organ donation and transplantation in Australia[21] (NHMRC ethical guidelines), supports ethical research and practice, and informs decision-making in Australia's donation and transplantation system. These guidelines align with community expectations that altruistic donations of human cells, tissues and organs are treated respectfully, equitably, and used effectively.

[16] https://www.donatelife.gov.au/
[17] https://www.legislation.gov.au/C2008A00122/2021-11-01/text
[18] https://www.donatelife.gov.au/about-us/who-we-are/national-program
[19] https://www.nhmrc.gov.au
[20] https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023
[21] https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-cell-tissue-and-organ-donation-and-transplantation

The NHMRC ethical guidelines highlight that national ethical guidance can facilitate consistency and integrity across clinical practice, program delivery and regulation. Any nationally harmonised framework should recognise and appropriately interface with the NHMRC's ethical guidance.

4. Modernising legislation to support a world's best practice policy and program delivery[22]

Modernising legislation should enable clinical practice to remain current and evidence based. In doing so, it should be drafted to support but not prescribe policy and program delivery.

Legislation should seek to set high-level objectives, obligations, prohibitions and governance. Regulations, codes, standards and guidelines could provide technical detail that can be updated as evidence and practice evolve. This approach will maintain legal certainty around core principles such as equity, dignity, autonomy, public trust, consent, and prohibitions of trade. It would also enable flexibility to support contemporary practices across donation, retrieval and transplantation.

National policies establishing clinical practice standards and guidelines in donation and transplantation are developed by peak professional bodies. This approach should be maintained and enabled to operate within legislation so they can reflect contemporary clinical need.

In the context of stem cells, this includes nationally recognised haematopoietic stem cell transplantation guidelines and standards. These are developed by professional clinical bodies such as the Australian and New Zealand Transplant and Cellular Therapies society[23] and alongside internationally aligned accreditation systems (e.g. Foundation for the Accreditation of Cellular Therapy[24]). These frameworks provide consistent, evidence-based guidance on donor selection, matching, collection of bone marrow, peripheral blood and cord blood stem cells, as well as post-transplant care. This ensures contemporary and nationally consistent clinical practice across transplant centres.

In the context of organ donation and transplantation, the OTA maintains relationships with peak professional bodies. These partnerships are central to an ensuring an effective and contemporary system. The OTA has responsibility for and leads the national deceased organ donation program, through coordination and oversight. Peak

[22] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 1, Proposals 2 and 4; Ch. 5, Proposals 10–13; Ch. 7, Proposal 24

[23] https://anztct.org.au/

[24] https://www.factglobal.org/

professional bodies support this by providing the OTA with expert advice and developing nationally consistent clinical statements and guidelines.

Legislation should recognise and support complementary relationships, with policy, program delivery, and system governance aligned with clinical guidance. This includes allowing flexibility to evolve in line with best available evidence and support clinical autonomy.

5. Definition of "Tissue" and objects of legislation[25]

The approach to how definitions are included in legislation should allow for flexibility for refinements to be made. This will ensure legislation is not prohibitive, is adaptable and future focused. Consideration could be given to harmonise the definition of human tissue with existing legislation and guidelines (e.g. NHMRC, OTA, TGA).

As definitions intersect across related legislative systems, harmonising terminology across legislation is important. This would avoid downstream inconsistencies, regulatory gaps, or misalignment in how tissue related activities are governed. An example is the *Biosecurity Act 2015*[26] , which rely on the definition of 'therapeutic use' as defined in the TG Act being applied to import conditions for human tissue.

Any reforms to legislation should consider public awareness programs that reflect community expectations. Consideration must be given to the varying awareness levels about cell, tissue and organ donation in the community.

The Reference Group supports the inclusion of clear objectives regarding the overarching purpose and principles. These being equity, dignity, autonomy, public trust, consent, and prohibition of trade.

6. Consent for cell, tissue and organ donation[27]

The Reference Group supports requirements for informed consent that are adequate and consistent across jurisdictions. A unified approach to consent should ensure clear pathways for determination of authorised decision makers that include culturally safe practices. Consent obtained must be clear in scope and purpose and documented before retrieval. The scope of the TG Act includes donor consent as set out in the Australian Code of Good Manufacturing Practice for human blood and blood

[25] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 2, Proposal 5; Ch. 4, Proposals 7–9

[26] https://www.legislation.gov.au/C2015A00061/latest/text

[27] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 6, Proposal 14; Ch. 7, Proposals 23, 28–31

components, human tissues and human cellular therapy products[28] and TGA inspections. This applies where state and federal requirements have stipulated this.

Safeguards should be designed to uphold donor dignity, autonomy and wellbeing, supported by appropriate documentation and traceability. They should also enable long-term follow-up of living donors to ensure and maintain transparency, safety, quality and public confidence.

6.1. Consent in the context of deceased donation for transplant

The Reference Group supports consent proposals that embed respect and dignity throughout the donation pathway. These should consider primacy of an individuals' preference of donation, family care, culturally responsive practices, appropriate recognition of diverse kinship structures, and clear, compassionate processes for discussions and decision making.

Initiatives such as the Australian Organ Donor Register[29] are important in increasing donor registrations and enabling individuals to share their preferences for donation. Further public education to raise awareness about donation and how consent operates in practice may also be needed. This is essential to maintain confidence in the system and encourage ongoing participation in donation programs.

6.2. Consent in the context of living donation for transplant

Legislative settings for living donation should value and safeguard the donation gift. They should ensure voluntary, non-remunerated donation and transparent governance, while protecting donors and recipients, and supporting equitable access to transplantation.

Legislation should embed robust safeguards that ensure consent is truly informed, voluntary and free from coercion or exploitation. This includes ensuring that prospective donors have appropriate access to medical, psychosocial and practical support both before and after donation. Implications, risks and long-term impacts of their decision should be understood.

Consideration should also be given to the potential for commercial conflicts of interest in seeking consent from living donors. Clear mechanisms and safeguards should ensure relationships between clinicians and service providers do not compromise the integrity of the donation pathway. This extends to organisations using donations to develop, manufacture, and distribute human tissue products.

[28] https://www.tga.gov.au/products/biologicals/manufacturing/australian-code-good-manufacturing-practice-human-blood-and-blood-components-human-tissues-and-human-cellular-therapy-products
[29] https://www.servicesaustralia.gov.au/australian-organ-donor-register

These protections are essential to support autonomous, well-informed decisions, while maintaining integrity and accountability, and are essential to upholding public trust.

6.3. Definition of senior next of kin[30]

The Reference Group recognises that definitions of "next of kin" or "senior next of kin" in some human tissue laws may be outdated. These may not reflect kinship and cultural authority structures recognised by many communities, including Aboriginal and Torres Strait Islander peoples. We support reforms that enable an authorised decision maker model to better reflect diverse family structures and cultural authority.

6.4. Disclosure of information, privacy and confidentiality[31]

The Reference Group supports maintaining anonymity of donors and recipients. This is essential to uphold ethical principles, protect privacy, and sustain confidence in the Australian donation and transplantation system.

The 'All Governments Statement' on the disclosure of information provisions in Commonwealth and state and territory Acts[32] states that donor and recipient identities must remain confidential and that mutually consenting contact between donors and recipients is not supported.

Privacy provisions for donors and recipients must apply universally and consistently across jurisdictions to avoid confusion and maintain public trust. Consideration should be given to harmonisation of provisions that clearly define circumstances where disclosure is permissible. This could include clinical communication, while protecting against unnecessary or inappropriate sharing of personal information.

7. Prohibitions and penalties for donated tissue for transplant

The Reference Group supports the enforcement of prohibitions and appropriate penalties.

This may be achieved through clear, harmonised non-commercialisation provisions, with explicit allowance for reimbursement of expenses. The NHMRC highlights ethical approaches relating to commodification or sale of human cells, tissues and organs in the NHMRC ethical guidelines[24]'. Legislation should align with international guidance

[30] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 7, Proposal 25; Ch. 12, Proposals 46–49
[31] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 12, Proposals 46-47
[32] https://www.donatelife.gov.au/sites/default/files/2023-06/Health%20Letterhead%20-%20All%20Governments%20Statement.pdf

promoting equity, justice, respect for human dignity and safety. It should also work to combat transplant tourism, organ trafficking, and transplant commercialism.

7.1. Prohibitions in reward and/or trade for donated tissue for transplant[33]

Prohibitions to trade in human tissue, including incentivisation of donation or allocation, are essential to maintain ethical integrity. Australian human tissue laws should uphold this by prohibiting reward or the exchange of tissue for valuable consideration.

In this context, work on pricing methodology including standards and application of definitions and processes for exemptions could assist. Any pricing or cost recovery arrangements for human tissue products should operate within a non-commercial framework. There should be a clear separation between financial arrangements and the donation, use and development of tissue products.

This is essential to prevent conflicts of interest and preserve public trust in the donation and transplantation system. This is consistent with the NHMRC ethical guidelines[24] which condemns any financial gain associated with transactions involving human body parts. The guidelines do permit for voluntary, non-remunerated donation, with only reasonable cost reimbursement.

7.2. Advertising related to donation and transplantation

The Reference Group supports reforms that provide consistent approaches to public communication regarding the prohibited trade of human tissue.

Reforms should consider permitted activities, such as public awareness campaigns about donation and transplantation, compared to prohibited activities such as communication regarding trade in organs.

Any changes must not inadvertently impede access to legally supplied tissue products or limit visibility of suitable and accessible therapeutic goods. Intersecting legislation should be considered such as the TG Act.

7.3. Reimbursable expenses, costs, loss or damage[34]

Reimbursement should continue to be permitted for necessary expenses directly associated with lawful donation, as is supported under the Supporting Living Organ Donors Program[35]. This program provides financial support to eligible living kidney or

[33] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 11, Proposal 44
[34] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 12, Proposals 46-47
[35] https://www.health.gov.au/our-work/supporting-living-organ-donors-program/resources

partial liver donors by reimbursing paid leave entitlements and out-of-pocket expenses.

Transparent and consistent criteria is needed to define what may be reimbursed or recovered by persons who retrieve, process, use and/or distribute human tissue. This should be limited to verifiable, reasonable, cost-based expenses (not profit). As the scope of the TG Act does not include donor or manufacturer remuneration, determining appropriate responsibilities would be required.

Establishing cost recovery mechanisms will maintain public trust, reinforce the altruistic nature of donation and non-commercialisation, while honouring the gift of donation. This will provide clear rules for services that retrieve, process, use and distribute human tissue. Approaches should include those developing medical products substantially derived from human tissue subjected to processing or treatments. This ensures that operational sustainability is achieved without undermining the gift of donation or enabling inappropriate commodification.

8. International donors and importation of human tissue[36]

The Reference Group recognises the increasing global movement of human tissue. This reinforces the need for settings that uphold Australia's ethical standards, protect donors and recipients, and maintain public confidence.

Approaches should therefore reflect the Australian Government's broader commitment to combat organ trafficking and organ transplant tourism[37,38].

8.1. Deceased donor tissue from international sources

Consideration should be given to the circumstances under which importation of deceased donor tissue may be appropriate. This should include whether distinctions for the importation of tissue that undergoes further manufacturing onshore are required. Whether the ethical standards applied overseas are

[36] ALRC Review of Human Tissue Laws, Discussion Paper, Ch. 11, Proposals 40–44; Ch. 12, Proposals 46–49

[37] Australian Government Response To The Senate Foreign Affairs, Defence and Trade Legislation Committee Report: Migration Amendment (Overseas Organ Transplant Disclosure and Other Measures) Bill 2023 (https://www.dfat.gov.au/publications/international-relations/australian-government-response-senate-foreign-affairs-defence-and-trade-legislation-committee-report-migration-amendment-overseas-organ-transplant-disclosure-and-other-measures-bill-2023#:~:text=Summary%20of%20publication,Bill%202023%20%5BPDF%20325%20KB%5D)

[38] Government Response. Compassion, Not Commerce: An Inquiry into Human Organ Trafficking and Organ Transplant Tourism. Tabled on 19 October 2021 (https://www.aph.gov.au/Parliamentary_Business/Committees/Joint/Foreign_Affairs_Defence_and_Trade/HumanOrganTrafficking/Government_Response)

equivalent to those applied domestically in Australia should also be considered. This extends to transparency, accountability and adherence to non-commercialisation principles.

It is essential that reasonable importation of tissue products is possible to meet the treatment requirements of Australian patients. Decisions will need to address the level at which such requirements may apply.

9. Closing Remarks

The Reference Group is poised to continue responding to specific questions from the Commissioner. The Reference Group offers technical expertise and policy insight on matters within the health portfolio.

We are committed to constructive engagement to ensure legislative outcomes are practical, future-focused, and aligned with national health priorities. Our ongoing collaboration will help deliver a coherent, ethical, and sustainable framework that supports donation and transplantation for all Australians. The Reference Group notes that portfolio agencies and/or department policy areas may make individual submissions to the Discussion Paper.

We look forward to the publication of the Review of Human Tissues Laws – Final Report. This includes how reforms in the donation and transplantation sector are to be taken forward.

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

Attachment A: cell, tissue and organ related strategies, frameworks and programs

Strategies

1. **National Strategy for Organ Donation, Retrieval and Transplantation (2024)**[1]

   The National Strategy for Organ Donation, Retrieval and Transplantation outlines the national strategic direction for improving Australia's organ donation and transplantation system.

   Developed and endorsed by all governments it provides future direction for the system across four priority areas:

   1. A national approach to optimise organ donation, retrieval and transplantation
   2. Equitable access for Australians who would benefit from organ transplantation with a focus on Aboriginal and Torres Strait Islander people and those living in rural, regional and remote areas
   3. Enhanced organ retrieval and transplantation capability and capacity to optimise transplant outcomes
   4. Enhanced systems and data collection and reporting to drive clinical best practice.

2. **Organ and Tissue Authority (OTA) Strategy 2022–2027**[2]

   The OTA Strategy 2022–2027 sets the national strategic direction for the deceased organ donation program to save and improve the lives of more Australian through organ and tissue donation and transplantation.

   It focuses on three overarching goals: building support for donation, optimising opportunities for donation, and enhancing systems to enable quality outcomes.

   The strategy emphasises commitment, collaboration, excellence, integrity and innovation as core organisational values. It responds to challenges within the operational environment and prioritises continuous improvement, through strong collaboration and partnerships, and building support to increase donation and transplantation nationally.

[1] https://www.health.gov.au/resources/publications/national-strategy-for-organ-donation-retrieval-and-transplantation?language=en
[2] https://www.donatelife.gov.au/about-us/strategy-and-performance

Frameworks

3. **National Eye and Tissue Sector Framework (2022)**[3]

   The National Eye and Tissue Sector Framework (Eye and Tissue Framework) provides the future directions for the Australian eye and tissue sector. The Framework sets the national objectives to achieve the vision that all Australians have safe, equitable and ethical access to life altering and/or lifesaving tissue transplantation, through a strong and effective Australian eye and tissue donation for transplantation sector.

   The Eye and Tissue Framework forms the response of all Australian Governments' to the Analysis of the Australian Tissue Sector[4] undertaken by PricewaterhouseCoopers and addresses the following areas:

   1. Scope
   2. Purpose
   3. Governance and oversight
   4. Self-sufficiency, importation and exportation of tissues and tissue-based products
   5. Tissue supply costs
   6. Stakeholder engagement
   7. Research
   8. Data and reporting.

   The Eye and Tissue Framework provides governments, the non-government sector, professional associations, health service providers, eye and tissue service providers and the community with a clear understanding of the principles for how the Australian eye and tissue sector needs to operate to support patient access to donated tissue and tissue-based products.

4. **National Haemopoietic Progenitor Cell (HPC) Framework (2022)**[5]

   The HPC Framework was endorsed by all Australian governments in October 2021. The Framework represents commitment from all governments to provide a policy basis for the effective, evidence-based future operations and management of the Australian HPC sector. It seeks to ensure continued and improved access to life-extending and lifesaving HPC transplants for Australian patients.

[3] https://www.health.gov.au/resources/publications/eye-and-tissue-sector-framework?language=en
[4] https://www.donatelife.gov.au/sites/default/files/2022-05/pwc_-_analysis_of_the_australian_tissue_sector_-_final_d16-1267056_2.pdf
[5] https://www.health.gov.au/resources/publications/national-haemopoietic-progenitor-cell-hpc-framework?language=en

5. **Regulation of the National Gene Technology Scheme**[6]

   Australia's national regulatory scheme for gene technology (Scheme) is established under the *Gene Technology Act 2000*[7] and *Gene Technology Regulations 2001*[8], supported by corresponding state and territory legislation. These instruments provide a nationally consistent framework for regulating dealings with genetically modified organisms (GMOs) to protect human health and the environment.

   Key elements of the Scheme include:

   - Scientific risk assessment and risk management planning.
   - Statutory public, intergovernmental and agency consultation processes.
   - Advisory structures, including technical and ethical committees.
   - Integration with other regulatory systems governing food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods.

   The regulatory Scheme is designed to remain adaptive, evidence based and proportionate to risk, ensuring robust safeguards while enabling responsible innovation.

6. **Regulatory Framework for Biologicals**[9]

   The Regulatory Framework for Biologicals (Biologicals Framework) commenced on 31 May 2011 and provides the legislative basis for the regulation of human tissue and cell-derived products and live animal cell, tissues or organs that are supplied, in or exported from, Australia.

   The Biologicals Framework applies different levels of regulation to products based on the risks associated with their use. It is designed to be flexible enough to accommodate emerging technologies.

   Information on the specific legislation, legislative instruments and standards are available on the Therapeutic Good Administrations website.

Ethical Guidelines

7. **Ethical guidelines for cell, tissue and organ donation and transplantation in Australia**[10]

   These guidelines provide a framework to support ethical practice and inform decision-making by all those involved in Australia's donation and transplantation system.

[6] https://www.genetechnology.gov.au/about-the-national-scheme/how-it-works/regulation#national-gene-technology-scheme
[7] https://www.legislation.gov.au/C2004A00762/latest/text
[8] https://www.tga.gov.au/resources/legislation/gene-technology-regulations-2001
[9] https://www.tga.gov.au/products/biologicals/overview/regulatory-framework-biologicals
[10] https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-cell-tissue-and-organ-donation-and-transplantation

8. **Ethical guidelines on the use of assisted reproductive technology in clinical practice and research**[11]

   Also known as the Assisted Reproductive Technology (ART) guidelines, these are used by professional organisations to set standards for the practice of ART. The 2023 update includes the addition of Part D to support the ethical introduction of mitochondrial donation into ART in Australia, along with minor administrative updates to the 2017 guidelines.

9. **National Statement on Ethical Conduct in Human Research**[12]

   This Statement promotes ethically good human research and is designed to clarify the responsibilities of institutions and researchers for the ethical design, conduct and dissemination of outputs and outcomes of human research.

Programs

10. **Supporting Living Organ Donors Program**[13]

    The Supporting Living Organ Donors Program (SLOD Program) aims to ensure that taking time off work and travel and accommodation expenses are not a barrier for individuals considering donation. The SLOD Program is not an incentive to donate. It is designed to help support those individuals who wish to donate but cannot afford to due to loss of income and the financial stress it would cause for them and their family.

    The Program supports living organ donors by reimbursing some of their income lost for donation and/or out-of-pocket travel and accommodation expenses.

11. **Bone Marrow Transplant Program**[14]

    The Bone Marrow Transplant Program (BMTP) assists approved applicants to access internationally sourced bone marrow, stem cells or umbilical cord blood (known collectively as haemopoietic progenitor cells (HPC)) for transplants, via the BMTP, if a suitably matched Australian resident donor is not available.

    BMTP funding covers the cost of collecting and transporting HPC from an overseas resident donor, or the travel expenses of a related donor to come to Australia for donation.

[11] https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-use-assisted-reproductive-technology
[12] https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023
[13] https://www.health.gov.au/our-work/supporting-living-organ-donors-program/about?language=en
[14] https://www.health.gov.au/resources/publications/bone-marrow-transplant-program-bmtp-guidelines?language=en

The program contributes to national transplant capability by providing a structured, regulated system that improves access, supports equity and complements Australia's broader organ and tissue donation and transplantation framework.

Reviews

12. Review of National Blood arrangements[15]

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.

13. Review of gene technology legislation[16]

Amendments to the *Gene Technology Act 2000*[17] 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.

The Office of the Gene Technology Regulator's interest remains as a watching brief to ensure that legislative changes do not lead to unintended consequences regarding regulation of human materials.

[15] https://www.health.gov.au/topics/blood-and-blood-products/review-of-the-national-blood-arrangements
[16] https://www.genetechnology.gov.au/reviews-and-consultations/past/consultation-draft-gene-technology-amendment-bill-2024
[17] https://www.legislation.gov.au/C2004A00762/latest/text