Australian Government
National Health and Medical Research Council

NHMRC

The Hon Justice Mordy Bromberg
President
Australian Law Reform Commission

Re: Review of Human Tissue Laws

Dear Justice Bromberg

Thank you for the opportunity to make a submission to the Australian Law Reform Commission (ALRC) review of human tissue laws. On behalf of the National Health and Medical Research Council (NHMRC), I am pleased to provide the enclosed submission which provides comment on a number of issues raised in the *Review of Human Tissue Laws: Discussion Paper (2025).*

Through the work of its Australian Health Ethics Committee (AHEC), NHMRC has a legislated responsibility to advise the community on ethical issues regarding human health and for developing Australia's guidelines on the ethical use of human tissues, including those relating to assisted reproductive technologies (e.g. embryos and gametes). AHEC is the only national body with a statutory responsibility to provide advice on ethical issues related to health, and for developing human research ethics guidelines. AHEC's advice is used by policy makers, clinicians, researchers, human research ethics committees (HRECs) and members of research institutions to guide ethical decision-making on human research and matters of human health.

The current ethical position on human tissues is that appropriate access to human tissue is critical for both clinical and basic science research in Australia. Because current human tissue laws were designed without full consideration of their impact on research, it is vital that any new or amended tissue laws take the research context into account and that these laws are consistent across Australian jurisdictions to enable research that is national in scope or crosses jurisdictional boundaries.

NHMRC consents to its submission to this review being published in full.

Yours sincerely

[redacted]

Ms Prue Torrance
Acting Chief Executive Officer

14 January 2026

Australian Government
National Health and Medical Research Council

NHMRC

National Health and Medical Research Council submission to the Australian Law Reform Commission on the *Review of Human Tissue Laws: Discussion Paper (2025)*

The National Health and Medical Research Council (NHMRC) is Australia's leading government agency for supporting health and medical research for the improvement of individual and population health. It does this by funding high-quality research, supporting the translation of research into evidence-based practice and policy, providing guidance on responsible research practices and ethical issues, and the administering legislation governing research the use of human embryos.

NHMRC engages closely with a range of stakeholders across the health system and community to ensure that health and medical research meets the needs of the Australian community. These include governments, researchers, biotech industries and other business leaders, medical, nursing and allied health practitioners, Aboriginal and Torres Strait Islander health and research leaders, teaching and research institutions, health services, community health organisations, consumers and carers.

Through the work of its Australian Health Ethics Committee (AHEC), NHMRC has a legislated responsibility to advise the community on ethical issues regarding human health and for developing Australia's guidelines on the ethical participation of humans in research, including the use of human tissues and assisted reproductive technologies (ART).

The current ethical position on human tissues is that appropriate access to human tissue (referred to as 'human biospecimens' in the *National Statement on Ethical Conduct in Human Research*) is critical for both clinical and basic science research in Australia. Because most current human tissue laws were designed without full consideration of their impact on research (the exception being the use of human embryos in research), it is vital that any new or amended tissue laws take the research context into account and that these laws are consistent across Australian jurisdictions so as to enable research that is national in scope or crosses jurisdictional boundaries.

NHMRC recommends that the ALRC's review of human tissue laws remains clearly delineated from the established regulatory framework governing human embryo research. Research involving human embryos is already comprehensively regulated through the *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act), supported by the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (updated 2023) (ART Guidelines) and oversight of the Embryo Research Licensing Committee (ERLC). These instruments create a nationally harmonised and purpose-built system that reflects the ethical, scientific and legislative complexities unique to research involving embryos and gametes. Including embryos in the human tissue law reforms would conflate distinct regulatory frameworks and risk unnecessary duplication or inconsistency.

BACKGROUND

Australian Health Ethics Committee

NHMRC has legislated responsibility under the *National Health and Medical Research Council Act 1992* (NHMRC Act) to inquire into, issue guidelines on, and advise the community on ethical issues relating to health. This important function is carried out through the specialised work of AHEC, the membership of which is legislated and includes expertise in philosophy, the ethics of medical research, public health and social science research, clinical medical practice and nursing, disability, law, religion and health consumer issues.

AHEC is the only national body in Australia with a statutory responsibility to provide advice on ethical issues related to health, and for developing human research ethics guidelines. AHEC consults extensively with individuals, community

organisations, health professionals and governments, and undertakes formal public consultation when developing ethical guidelines. AHEC's advice is adopted across Australia and integrated into accepted processes.

Collection of human tissue for and use of human tissue in human research

Note: in this document 'collection' includes obtaining human tissue from existing repositories of biospecimens within Australia and commercial and other relevant sources external to Australia.

The major guideline on the ethical conduct of human research is the *National Statement on Ethical Conduct in Human Research* (National Statement). The National Statement provides extensive guidance on the collection, use, management, importation and exportation of human biospecimens in Chapter 3.2: Human biospecimens in laboratory-based research.

NHMRC has also recently published the *Ethical guidelines on cell, tissue and organ donation and transplantation in Australia*, in collaboration with the Organ and Tissue Authority (OTA). These guidelines are intended for use by health professionals and others involved in the donation, transplantation, manufacture, allocation, distribution, and custodianship of human cells, tissues and organs; potential donors and recipients of transplanted cells, tissues and organs, and their families, carers, and communities; public and private institutions, such as hospitals, donation services, eye banks, umbilical cord blood banks, tissue banks, tissue manufacturers, and donor or transplant recipient registries; and governments and regulatory bodies.

NHMRC notes that, while it publishes these ethical guidelines on cell, tissue and organ donation and transplantation, we do not consider the practices associated with donation and transplantation activity to be within our remit and we defer to the expertise of the OTA and others with respect to the matters raised in the Discussion Paper relative to these areas, with the exception of the comments related to the use of embryos and gametes below.

AHEC's advice on the ethical use of human reproductive tissues is published in the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (updated 2023)* (ART Guidelines). Compliance with the ART Guidelines is a requirement for every ART clinic (also referred to as IVF clinics) in Australia.

Reproductive tissue use: ethical and legislative context

Assisted reproductive technologies (ART), including the use of reproductive tissues, can be a controversial topic, with opinions influenced by a wide range of political, cultural, religious, ethical, scientific, professional and legal factors.

Some may regard the use of reproductive tissues in assisted reproduction as standard medical practice that should be available with minimal constraints, in the interest of scientific progress and out of respect for an individual's or a couple's reproductive choices. Others may regard it as ethically problematic, raising a number of issues and dilemmas that challenge humanity's core values, putting the needs and wants of the intended parent(s) above those of the potential child. Some may consider ART to be a direct contradiction of their religious faith. For some, ART may raise questions about the extent to which medicine should 'interfere with nature' or the manner in which medical technology may empower or disempower individuals and the control they have over their own lives, bodies and reproductive futures.

Despite these varied views, ART has an established place in modern health care systems. For individuals or couples facing infertility, assisted reproduction may offer the best, or in some cases, the only option to conceive a much-wanted child. Consequently, those who require ART do not want to face unnecessary obstacles. Rather they desire care that optimises outcomes and minimises risks to both themselves and the child who may be born.

The ART Guidelines support the ethical use of reproductive tissues in ART by providing an overarching framework for the conduct of ART in both clinical practice and research. Guiding Principles for the ethical practice of ART in Australia are described in Chapter 2 of the guidelines.

In Australia, all persons and bodies offering ART services must be accredited by the recognised accreditation body, the Fertility Society of Australia and New Zealand's Reproductive Technology Accreditation Committee (RTAC), or another body prescribed by the *Research Involving Human Embryos Act 2002*. RTAC accreditation requires ART clinics to comply with government laws and guidelines concerning the practice of ART, including the ART Guidelines.

Of relevance to this review, the ART Guidelines provide ethical guidance on the collection and storage of a person's gonadal tissue, gametes and/or embryos:

- in the clinical practice of ART, including donation to another person/s for clinical use

- for research (which may require a licence issued under the RIHE Act)
- for fertility preservation
- from persons who are deceased or dying including the posthumous use of the gametes or embryos.

The *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) establish the human embryo research regulatory framework. Human embryo research is regulated by NHMRC's Embryo Research Licensing Committee (ERLC). These acts establish a regulatory framework to prohibit certain practices, such as human cloning, and regulate the uses of excess assisted reproductive technology (ART) embryos, the creation or uses of other human embryos created through processes other than fertilisation and the practice of permitted mitochondrial donation techniques in Australia. There are strong penalties for non-compliance with the legislation.

PROPOSED REFORMS

Proposed reforms relating to a nationally harmonised legislative framework

Proposals 1,2

The provisions of the RIHE and PHCR Acts already creates a uniform, national, and comprehensive regulatory framework, meaning that embryo and gamete research should remain explicitly outside the scope of HTA reform. NHMRC recommends that the ALRC consider including an explicit statutory exclusion clause, such as: 'for clarity, this legislation does not apply to human embryos, gametes, human embryo models, or activities regulated under the RIHE and PHCR Acts.'

Proposed reforms relating to the definition of tissue

Proposals 7,8,9 and Questions 5,6,7

The Discussion Paper proposes including a definition of human 'tissue' that is broad and provides a flexible mechanism to adjust the definition. Consideration could be given to harmonising the definition of human tissue with existing legislation and/or guidelines promulgated by Commonwealth government agencies (e.g. NHMRC, OTA, TGA), for example from the National Statement, Introduction to Chapter 3.2 defining human biospecimens:

> any biological material obtained from a person including tissue, blood, urine and sputum [and] … any derivative of these, such as cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person.

Of the two definitions offered as options in the Discussion Paper based on legislation from the UK and New Zealand, the second example is preferable, although extending the definition to '… any constituent material [or] substance [that] … derives from human cells' may be overly broad for regulation of human tissue. An example of an unintended consequence of using this language would be the need to obtain consent for use of human biological material that is commonly considered not to be 'human tissue' in the international research sector, making international collaborative research problematic and potentially creating unforeseen complications in obtaining these resources commercially.

NHMRC supports the inclusion of cell lines under the definition of human 'tissue.' Failure to include cell lines would reinforce historical uncertainty in the research sector as to the application of human tissue laws and associated ethics guidelines to cell lines, which are a common and valuable subject of human research and are obtained for research from a variety of sources.

In our view, the alternative options provided for labels to replace the word 'tissue' are inferior to the use of 'tissue' itself, although we note a preference for 'biospecimens.'

The Discussion Paper flags that current jurisdictional legislation excludes living donation of gametes and embryos. NHMRC notes that while clinical ART practice is generally a state and territory responsibility, fragmentation in legislation affects consistency in donor gamete use, ART service delivery, and the interface of clinical ART practice with embryo research.

Proposed legislative safeguards for donation of human tissues

The Discussion Paper (paragraph 6.12) recognises that additional safeguards, such as NHMRC ethical guidelines, can be provided to support proposed legislation for valid consent to donate human tissues. NHMRC agrees that its ethical guidelines can be used to support legislation in this manner. In addition to the ART Guidelines, NHMRC notes the 2025

release of the *Ethical guidelines for cell, tissue and organ donation and transplantation in Australia*, which provide a framework to support ethical practice and inform decision-making by all those involved in Australia's donation and transplantation system.

Proposed reforms relating to deceased donation

Posthumous gametes

The ART Guidelines provides advice on the collection and use of gametes from persons who are deceased or dying and/or the posthumous use of stored gametes or embryos (ART Guidelines section 8.2). The ART Guidelines states that this practice warrants serious ethical consideration and recognises that it may also be subject to specific state and territory legislation. The ethical guidance in the ART Guidelines includes the requirements for consent and processes for using these gametes. NHMRC supports the continuing existence of legislation for the retrieval of posthumous gametes as proposed in paragraph 4.33 of the Discussion Paper, enriched and supported by the ethical guidance in the ART Guidelines.

Proposed reforms to tissue donations for research

NHMRC advises that broad consent processes should not be applied to **embryos or gametes**, due to existing regulation of these materials:

- RIHE Act requires *specific, informed consent* for embryo donation to research (s 24)
- ART Guidelines Part C: consent must cover purpose, processes, implications, and cannot be broad
- embryo use for research must be explicitly approved by a Human Research Ethics Committee (HREC) and ERLC.

The import and export of embryonic stem cell lines derived from human embryo clones is regulated by the Customs (Prohibited Import) Regulations 1956 (section 5L) and Customs (Prohibited Export) Regulations 1958 (section 8A). NHMRC has responsibility for the permit scheme that enables the import and export of embryonic stem cell lines derived from human embryo clones. Also, the RIHE Act establishes some restrictions on the movement and storage of embryos used under a research licence including for mitochondrial donation. The ALRC must ensure that HTA reforms do not override these schemes.

Proposed reforms relating to consent and authorisation for tissue removal for research – living persons

Proposals 32, 33, 34, 35 and Question 28

Particularly noting the recommendation in Proposal 34 about the overriding authority of legislation, care will need to be taken to ensure that any new legislation takes account of the complexities associated with the provision of consent (including 'broad' consent for future research) and the identifiability of samples and information associated with those samples. Examples of these complexities are:

- consent for participation in research (including research involving the use of human tissue) can be provided by authorised third parties in some circumstances
- the requirement for consent to participate in research (including research involving the use of human tissue) can be waived by an ethics review body
- identifiability, re-identifiability and deidentification of samples and information are statuses and processes that are undergoing significant conceptual change and definitions and governance models related to this aspect of research are currently in flux
- withdrawal of consent for future research use of unused samples/tissues may not be possible, operationally, in some research contexts.

With respect to Question 28, NHMRC refers ALRC to the framework for participation in research by adults with fluctuating or episodic decision-making capacity or those determined to be lacking such capacity in the National Statement (2025) at Chapter 4.5, specifically at paragraphs 4.5.10–4.5.24. NHMRC notes that whether this framework can be applied to the removal of human tissue for research is an untested proposition.

Proposed reforms relating to consent and authorisation to remove tissue for research after death

Proposals 36, 37, 38, 39

NHMRC supports recognition of the principle underpinning the proposal that new human tissue legislation should permit a form of 'advance directive' enabling posthumous removal of tissue from a person if they (or that person's authorised decision-maker) have provided consent to that removal for the purpose of research.

NHMRC notes that Proposal 37 may raise issues similar to those described in comments related to Proposal 34, above.

Consent and authorisation for use of tissue samples (general)

Questions 29, 30
Any imposition of a legal consent requirement should take account of ethical guidance related to scope of consent described in Chapter 2.2 of the National Statement, specifically paragraphs 2.2.8 and 2.2.14 – 2.2.18, that recognise three levels of consent for research: specific, extended and unspecified (also known as 'broad') consent. NHMRC also notes some lack of clarity in the question, i.e. the possible requirement for obtaining consent from people who have provided tissue samples for research or other purposes that they did not (previously) consent to (Q29) and possible exceptions to this requirement (Q30).

Reforms relating to stored tissue collections
Questions 31, 32, 33, 34
NHMRC recommends against creating a legal framework to regulate storage, access, transfer and disposal of human tissue used in research biobanks for two reasons: (1) the area is adequately self-regulated at present and (2) there is too much variation amongst types and uses of biobanks to merit a single set of legal rules which are, intrinsically, insufficiently flexible to address these variations.

While it may be beneficial to have some form of guidance and/or oversight for research biobanks and other tissue repositories or collections, national regulation is problematic for the reasons articulated in the immediately preceding paragraph.

If new human tissue legislation is enacted, individuals who have chosen to donate their tissue to a tissue repository or collection should not be afforded a right to access this tissue; doing so would make the operations of such repositories unstable and reduce their value to researchers.

Proposed reforms relating to the prohibition of trade in human tissue (i.e. prohibiting the exchange of human tissue for reward within Australia)
Proposals 40, 42 and Questions 35, 36
NHMRC supports the ongoing intent to prohibit the monetisation of human tissue and trade in donated tissues and organs. However, we note the negative consequences of this policy on research that requires the use of cell lines. NHMRC recommends that an exclusion be applied to enable the use of cell lines created in Australia, including commercial transactions within Australia involving cell lines (presuming its inclusion in the definition of human tissue) for the purpose of research, where appropriate safeguards, as specified under relevant privacy and ethical guidelines, are in place.

This exception would reduce the need to obtain this material from overseas sources, which is currently outside the scope of human tissue law prohibitions on the sale of human tissue in Australia. Failure to enable access to cell lines stored and/or created within Australia incentivises international commercial transactions in which the provenance and conditions of consent of the source material may not be as easily discernible. This creates complications for conformance with ethical requirements for use of cell lines in research (see National Statement 3.2.7 – 3.2.10 and 3.2.13 – 3.2.14), noting the established and potential benefit of this research to scientific progress and the development of clinical treatment.

However, should the ALRC recommend continued or extended prohibitions on trade in human tissue, NHMRC does not support giving extra-territorial effect to any such prohibitions – at least insofar as they would apply to transactions involving cell lines.

NHMRC strongly recommends continued alignment with principles that prohibit commercial trade in human gametes and embryos, consistent with ART Guidelines and the ethical prohibition on commodification of reproductive material. It is an offence under section 21 of the *Prohibition of Human Cloning for Reproduction Act 2002* for a person to give or receive 'valuable consideration' for the supply of a human egg, human sperm or human embryo. Any HTA reform must maintain or reinforce, not complicate, these prohibitions.

Proposal 43 and Questions 37 and 40
NHMRC questions whether the proposed mechanisms to allow for exemptions on prohibition of exchanges for reward are viable without further information on the criteria that would be used by a National Regulator (or under an alternative model) and the scope of their application.

Further information
Further information about NHMRC ethical guidelines is available from the NHMRC website:

- *National Statement on Ethical Conduct in Human Research*
- *Ethical guidelines for cell, tissue and organ donation and transplantation in Australia*
- *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*