June 26th, 2025

To whom it may concern,

RE: Australian Law Reform Commission Review of Human Tissue Laws

Melbourne IVF (MIVF) has offered Fertility Preservation services to preserve patient future fertility, particularly following a cancer diagnosis, for more than 2 decades. MIVF continues to preserve ovarian tissue for adults over the age of 18 years but has also previously offered Fertility Preservation services for individuals under the age of 18 (both ovarian and testicular). Any preserved tissue is available for the patient to use by grafting into their body, with the aim of producing gametes for reproduction using gonadotropin treatment in the context of an IVF cycle. However, only those aged over 18 at the time of preservation can also opt to donate any ovarian tissue excess to their needs to research (testicular tissue is not often collected after puberty).

Removal, storage and use of reproductive (gonadal) tissue is governed by the *Human Tissue Act 1982*, supplemented by guidelines set out in the *NHMRC Ethical Guidelines for the Use of Assisted Reproductive Technology in Clinical Practice and Research 2017* (updated 2023) and state-specific ART Acts. In Victoria, the *ART Act 2008* is also referenced. A summary of current use is provided in **Table 1**.

Notably, neither the *Human Tissues Act 1982* nor the *NHMRC Ethical Guidelines for the Use of Assisted Reproductive Technology in Clinical Practice and Research 2017* (updated 2023) provides clarity around non-clinical use of gonadal tissue. Therefore, current legislation is very unclear on how gonadal tissue can be used.

In this submission, we therefore seek to specifically address the priority reform areas 'Issues related to the donation of tissue by living persons' and 'Issues related to the donation of tissue after death' pertaining to gonadal tissue (e.g. ovarian and testicular tissue) that has been collected for reasons of Fertility Preservation. We call for clarity and harmonisation relating to tissue use, particularly donation for scientific purposes.

Table 1: Current usage in Victoria for cryopreserved ovarian and testicular tissue based on age at collection based on conservative interpretation of the *Human Tissue Act 1982*, *NHMRC Ethical Guidelines for the Use of Assisted Reproductive Technology in Clinical Practice and Research 2017*, and the Victorian *Assisted Reproductive Technology Act 2008*.

Ovarian tissue (age at collection)	Own use (grafting)	Donate to research	Gamete donor
Paediatric (<18y)	Y	N	N
Adult (>18y)	Y	Y	N
Testicular tissue			
Paediatric (<18y)	Anticipated*	N	N

*methods for grafting testicular tissue are not yet well developed

Donation of Gonadal Tissue for Research

Individuals who seek Fertility Preservation over the age of 18 can donate their excess tissue to research. This is a valuable source of tissue that helps improve methods for preservation and grafting, as well as development, evaluation and validation of emerging technologies.

As per the *Human Tissue Act 1982*, removal of ovarian/testicular tissue for patients under 18 requires parental consent, a decision made on behalf of their child. However, upon the child's death the tissue must not remain in storage and must be discarded. That is, the parent is no longer authorised to make decisions about the fate of the tissue. Consequently, there is no ability to donate the tissue to research. This stance contrasts with 'additional use' of tissues removed for valid clinical reasons (reference 35 cited in the Human Tissue Laws Issue Paper).

While cryopreservation and grafting methods are well established for ovarian tissue in adults, methods remain in the early stages of development for paediatric ovarian tissue due to a lack of tissue for research. Indeed, current methods are almost exclusively based on those developed for adult tissue, which may not adequately support the immature state of the tissue. Methods for testicular tissue are even less well defined, with no clinical options yet developed that result in functional sperm, similarly limited by tissue availability for research. Consequently, the scientific community lacks an understanding of the best methods to cryopreserve, culture and graft paediatric tissue, especially since it is frequently collected from pre-pubertal patients.

Section 26(3)(b) of the *Victorian ART Act 2008* prohibits gametes obtained from a child for fertility preservation purposes from being used for research purposes (where tissue represents a 'gamete' according to the *NHMRC Ethical Guidelines for ART*).

As such, current legislation prevents <u>any</u> research into the safety, effectiveness, and best practices for preserving and grafting paediatric (particularly pre-pubertal) tissue. Similarly, the tissue cannot be used to assess (disease) treatments. Yet this population is by far the most prevalent in undertaking Fertility Preservation in Australia (Melbourne IVF data). Clarity in tissue use options is also lacking for adults from whom tissue was collected when they were under 18. This contrasts with regulations in other countries such as Belgium which have been pioneers in Fertility Preservation, through donation of paediatric gonadal tissues for research. As a leader in innovation in Fertility Preservation [3, 4], Australia could be at the forefront of technologies that improve outcomes for these patients.

Importantly, current restrictions on the use of paediatric gonadal tissue for research appear to be at odds with ethical principles set out in the National Statement on Ethical Conduct in Human Research (NHMRC, updated 2023). Section 2.1 affirms that research is ethically acceptable when the potential benefits justify the risks. In the case of paediatric gonadal tissue, the benefits of research (such as generating critical insights into how prepubertal tissue responds to preservation, priming, and grafting) are substantial, particularly given the increasing number of children undergoing Fertility Preservation. Research approaches, such as tissue priming followed by staining for viability markers or grafting into animal models, mirror those historically used to develop effective protocols for adults. These studies do not involve fertilisation, embryo creation, or reproductive use of the tissue and are essential for validating safe and effective procedures. These activities would be subject to full HREC review, ensuring compliance with ART regulations and alignment with Sections 3.2 (Human biospecimen research) and 4 (Children and Young People) of the National Statement. Moreover, Section 2.2 supports the inclusion of 'unspecified future research' clauses in consent forms at the time of tissue collection, which is a widely accepted practice in

biobanking and could help navigate current regulatory hurdles related to storage limitations and the need for project-specific approval. Where such consent has not been obtained and the child is deceased, Section 2.3 allows for a waiver of consent where it is impracticable to recontact decision-makers—an approach already accepted in adult research ethics. With appropriate oversight, these mechanisms could permit ethically and legally sound research using paediatric gonadal tissue in Victoria, aligning national policy with evolving clinical practice and community expectations.

Removing barriers to the use of paediatric gonadal tissue for research would enable significant improvements in patient care in the future.

Posthumous gonadal tissue collection

The *Human Tissue Act 1982* does not currently confer jurisdiction for the posthumous collection of gonadal tissue for reproductive use, with laws differing by State. For example, the *South Australian ART Act 1988* only allows the posthumous use of sperm, eggs and embryos already collected prior to death. Other States permit the collection of testicular tissue (via aspiration, biopsy or testis removal) for the purposes of having a child related to a deceased individual, provided written consent was given by the deceased individual and is for use by the deceased partner/spouse, aligning with the *NHMRC Ethical guidelines for the use of ART*. However, no document specifically addresses posthumous tissue collection. Further, there are no clear regulations around posthumous ovarian tissue collection from women.

There is therefore a need for clear Human Tissue reforms to incorporate equity across men and women, and consistency in legislation nationally, in being able to have gonadal tissue collected posthumously according to an individual's wishes, particularly given the potential of current (cryopreservation) and emerging technologies ('Artificial ovaries' and 'In vitro growth') to preserve eggs and sperm.

Principles to guide reform

There is significant psychological stress associated with the process of ovarian/testicular preservation, often at a time when decisions around related treatment must be made quickly. The psychosocial aspects of tissue preservation and use, particularly for children and their parents, as well patients with tissue surplus to their needs, should be used to guide reform.

Parents have the authority to act in the best interests of their child and make decisions regarding the preservation of their child's gonadal tissue. However, they are removed from this decision-making process upon their child's death. This is despite *NHMRC Ethical guidelines for the use of ART 2017*, clause 3.5 noting that "when the individual does not have the capacity to provide valid consent (e.g. children or the deceased) a representative must be involved in decision making". Many parents have expressed a desire for 'something good' to come from their child's death and are frequently disappointed that the preserved tissue cannot be used for research. That is, they are supportive of research use of paediatric gonadal tissue. A lack of involvement in the decision making around their child's tissue following death is neither just nor respectful of free choice. Likewise, clear legislation for tissue use for adults whose tissue was frozen when they were under 18 years of age is also lacking.

The potential for emerging technologies to make it possible to eliminate malignant cell grafting risks, could provide meaningful use of tissue not only for patients who have tissue excess to their needs in storage, but also to patients seeking donor gametes. Development of a framework that accommodates choice, like other forms of gamete donation, as well as accounting for future technological advances, would ease the distress in deciding/needing to remove tissue from storage.

Reform should empower Fertility Preservation patients and their parents to be actively involved in the decisions relating to the use of their or their child's tissue, frequently in a posthumous manner.

Concluding remarks

Current legislature pertaining to gonadal tissue use, particularly in a research scenario, lacks clarity. Existing barriers, including the inability to donate paediatric tissue for research, remove patient (or parent) choice and the potential to improve patient outcomes through research. Strong reform of Human Tissue laws with respect to gonadal tissues requires consideration of the urgent issue of provision of choice for patients and their families in the use of previously collected tissue. Reforms must therefore balance patient wishes and expectations and empower them to feel involved and fulfilled in the decisions being made around their (or their child's) tissue.

We welcome

Regards,

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