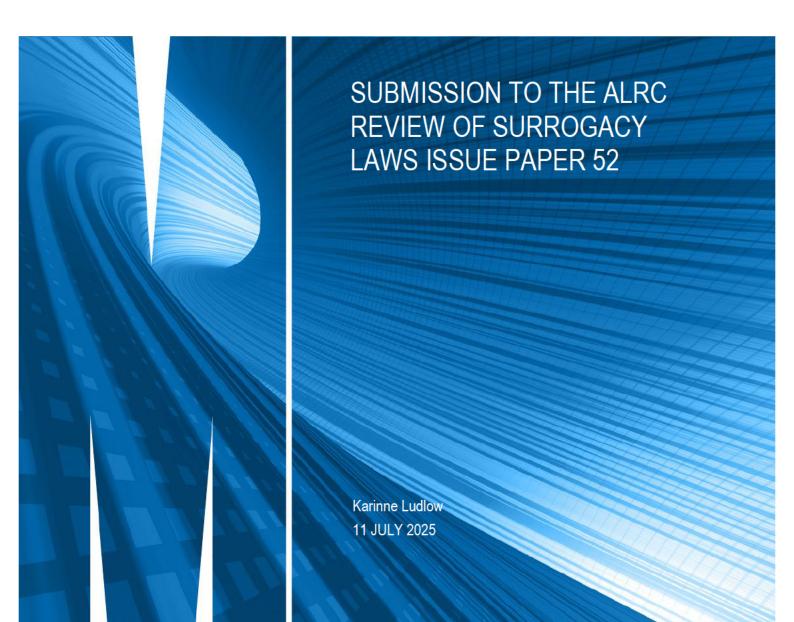


HEALTH LAW GROUP, MONASH LAW SCHOOL



INTRODUCTION

The Health Law Group (HLG) is a research group within Monash Law School focusing on the legal and ethical aspects of health and healthcare. It encompasses a broad range of research areas including the ethical and legal aspects of accident, workplace and health insurance, healthcare practice, environmental health, gender and health, emerging technologies, data and cybersecurity, public health, global health, intellectual property and trade, and research governance. The HLG also offers academic opportunities for students interested in health law, including specific units and postgraduate supervision. Information about the HLG, its people and activities are available here: https://www.monash.edu/law/research/centres-and-groups/law-health-wellbeing

This submission has been written by Associate Professor Karinne Ludlow from the Health Law Group, Faculty of Law, Monash University. Ludlow is a member of the Australia-wide consortium led by Monash University and funded by the Federal Medical Research Future Fund to conduct the mitochondrial donation (MD) pilot program called the mitoHOPE (Healthy Outcomes Pilot and Evaluation) Program. The research that informs this submission was conducted before the mitoHOPE trial and was funded by the Australian Government Department of Health's Medical Research Future Fund: project 76744.

The Commonwealth Attorney-General has requested that the Australian Law Reform Commission (ALRC) conduct a review of surrogacy laws in Australia. In June 2025, the ALRC called for input into its Issues Paper on its review of surrogacy laws. In this submission I discuss insights and lessons for surrogacy laws that can be drawn from regulatory changes to enable another reproductive technique offering people the opportunity to have a genetically related child: mitochondrial donation (MD).

Background to Mitochondrial Donation

Both surrogacy and MD require a third person to be involved in the creation of a child for intended/ intending parents although in the case of surrogacy, this is through gestation rather than contribution of DNA itself. In MD, the third person contributes mitochondrial DNA to the future child by donating an egg. The nuclear DNA of the donated egg is discarded but the remaining material is reconstructed (before or after fertilisation), including by insertion of nuclear DNA from the intended parent, before the embryo is transferred for gestation. While MD differs from surrogacy in very important ways and is still at the research and clinical trial stage in Australia, legalisation of MD provides a useful model and lessons for surrogacy laws.

MD was legalised as a new reproductive procedure pursuant to changes made by the *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* (Cth) to Australia's embryo research regulatory regime. Because MD is still a research technique (rather than in clinical use), the state and territory laws around ART do not prevent MD. The most significant parts of the embryo research regime are two federal Acts (*Prohibition of Human Cloning for Reproduction Act 2002* (Cth) and *Research Involving Human Embryos Act 2002* (Cth)), accompanying regulations (*Research Involving Human Embryos Regulations 2017* (Cth)), state and territory legislation that adopts the federal legislation, and the NHMRC *Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research 2017 (updated 2023*) ('NHMRC ART Guidelines').

Surrogacy in Australia (and Questions 14 and 22)

The Issues Paper notes (at [21]) that federal, and state and territory regulations apply to surrogacy and that these regulatory requirements differ from jurisdiction to jurisdiction. It is useful to expressly note that beyond the state regulatory frameworks, the ART and IVF sector is self-regulating through the Fertility Society of Australia and New Zealand (FSANZ) and Reproductive Technology Accreditation Committee (RTAC).

Further, relevant federal regulation includes that which controls the availability (or not) of Medicare funding for surrogacy and the ART treatments that accompany it. The Senate Community Affairs References Committee recommended in its 2023 report following the *Universal Access to Reproductive Healthcare* inquiry, that the Australian Government implement the recommendations of the Medicare Benefits Schedule Review regarding removal of the exclusion of in vitro fertilisation (IVF) services for altruistic surrogacy purposes.¹

This has not been done but this submission supports Medicare funding for surrogacy as essential to making access to domestic surrogacy achievable and equitable. As Kneebone et al's submission to that inquiry explained,

- 'Surrogacy is currently excluded from the relevant MBS item numbers because surrogacy
 arrangements were illegal in some states at the time when these items were created.² Altruistic
 surrogacy is now legal in all Australian states and territories and so the Schedule should be updated
 to reflect this.
- 2. Providing MBS funding for patients engaged in surrogacy would help to reduce the high costs of fertility treatments, which is well established to be a significant barrier to access.³
- 3. The financial burden is exacerbated for many heterosexual couples who, before turning to surrogacy, have also attempted to conceive with assisted reproductive technologies, spending on average \$33,219 on out-of-pocket expenses.⁴ This cost is now likely to be significantly higher.
- 4. Reducing the barriers to altruistic surrogacy in Australia may reduce the number of people seeking overseas compensated arrangements. In such instances, there is an increased risk of exploitation and human rights violation for all parties.⁵
- 5. People engaged with surrogacy arrangements are already entitled to other government assistance. For example, surrogates and intended parents are eligible for the Australian Government's paid parental leave scheme. A consistent national policy on this issue is needed to truly support those engaged with surrogacy.
- MBS funding for surrogacy would not create a significant government expense, as just 0.36% of all assisted reproductive technologies cycles in Australia and New Zealand in 2020 involved surrogacy arrangements.⁶

 $https://npesu.unsw.edu.au/sites/default/files/npesu/data_collection/Assisted\%20 Reproductive\%20 Technology\%20 in\%20 Australia\%20 and \%20 New\%20 Zealand\%202020.pdf$

¹ 'Ending the postcode lottery: Addressing barriers to sexual, maternity and reproductive healthcare in Australia' May 2023, recommendation 33.

² Medicare Benefits Schedule Review Taskforce (2020) 'Taskforce Report on Gynaecology MBS Items', accessed 31 November 2022. https://www.health.gov.au/sites/default/files/documents/2020/12/taskforce-final-report-gynaecology-mbs-items.pdf

³ Gorton M (2019) 'Final Report of the Independent Review of Assisted Reproductive Treatment', accessed 22 November 2022. https://content.health.vic.gov.au/sites/default/files/migrated/files/collections/research-and-reports/a/art-review-final-report.pdf

⁴ Everingham S, Stafford-Bell MA and Hammarberg K (2014) 'Australians' use of surrogacy', *Medical Journal of Australia*, 201(5):270-273. doi: 0.5694/mja13.11311

⁵ Standing Committee on Social Policy and Legal Affairs (2016) 'Surrogacy Matters. Inquiry into the regulatory and legislative aspects of international and domestic surrogacy arrangements', accessed 29 November 2022. https://www.aph.gov.au/Parliamentary_Business/Committees/House/Social_Policy_and_Legal_Affairs/Inquiry_into_su rrogacy/Report

⁶ Newman JE, Paul RC, Chambers GM (2022) 'Assisted reproductive technology in Australia and New Zealand 2020', Sydney: National Perinatal Epidemiology and Statistics Unit, the University of New South Wales, Sydney, accessed 22 November 2022.

7. It is unlikely that MBS funding for surrogacy would create widespread public disapproval as most of the Australian public is supportive of the practice.⁷

ART is necessary to achieve most surrogacies. However, ART regulation and the blurred boundaries between it and surrogacy, add another level of complexity and inconsistency to surrogacy regulation around Australia. Harmonisation of ART regulation and a possible national model for regulation and governance was recommended in a 2024 industry led review, called the *FSANZ Review of Governance and Standards in ART and IVF Sector*, and is currently being considered by the National Council of Australian Health Ministers. The interface of the surrogacy and ART regulatory regimes will need careful consideration in making recommendation for reform of surrogacy regulation.

Potential reform options (and Question 22)

The creation of a consistent national approach on surrogacy, as suggested in the Issues Paper [72], is strongly supported by this submission. However, achievement of ongoing consistency is difficult. First, as discussed in the section above, the interaction of surrogacy regulation with state ART laws, which have many differences when compared with each other, creates uncertainty around what is to be harmonised.

Secondly, past approaches to harmonising laws in the reproductive space show that even where ongoing national harmonisation is intended, it has not been successful. Such challenges may arise for harmonisation of surrogacy laws if state adoption of model federal laws is relied on as the method of harmonisation.

As discussed in the Background section above, MD regulation occurs pursuant to the laws around human embryo research. A national approach to embryo research regulation was created from 2002 through the passing of (mostly) uniform legislation in all Australian jurisdictions to adopt federal legislation. Nevertheless, laws around human embryo research are not consistent throughout Australia and for MD, this means MD continues to be prohibited in Western Australia despite it being intended that the technique would be available in all states.

As explored in an earlier article by this author, this has arisen because WA's legislation (the *Human Reproductive Technology Act 1991* ('HRT Act')) was not updated following Lockhart Review amendments made to the federal legislation in 2006 (the same amendments were made to all other Australian jurisdictions except WA). This caused the WA legislation to lose its status as a 'corresponding state law' (on 12 June 2007). As a result, 'the NHMRC Licensing Committee has not been able to grant a licence for embryo research under the HRT Act and research on human embryos that would require an NHMRC licence has not been permitted in WA'. ⁸ This prevents all research (whether laboratory or clinical trial) on human embryos in WA involving new and emerging technologies, including MD. The Western Australian government has stated that it intends to changes its' laws on embryo research, ART and surrogacy but this has not yet occurred.⁹

Harmonisation around MD regulation has also been attempted through use of the NHMRC ART Guidelines. In particular a new part has been included in the Guidelines, which in turn make Parts

⁷ Constantinidis D and Cook R (2012) 'Australian perspectives on surrogacy: the influence of cognitions, psychological and demographic characteristics', *Human Reproduction*, 27(4):1080-7. doi: 10.1093/humrep/der470; Tremellen K and Everingham S (2016) 'For love or money? Australian attitudes to financially compensated (commercial) surrogacy', *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 56(6):558-563. doi: 10.1111/ajo.12559

⁸ Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy (MEP) Final Report 2023 p 18.

⁹ Ludlow, Karinne, 'Implications of Law's Response to Mitochondrial Donation' (2024) 13 Laws https://www.mdpi.com/journal/laws p 3.

A and B of the Guidelines important. While this approach offers many benefits (such as speed and expert input), the cross referencing to pre-existing guidelines has created unnecessary uncertainty.

Children's rights

The Issues Paper (at [31]) raises the right of the child to be cared for by their parents, and the right to privacy, family and home. In addition to the important issue identified in the Issues Paper around these particular rights, is confusion around the ability of caregivers (usually intended parents) to consent to treatment of a newborn in the period after birth and until a formal transfer of parentage occurs. Children are usually in the care of the intended parents before that transfer, despite the intended parents not having clear legal authority to be decisionmakers for the child during this period. Reform could address this problem.

The Issues Paper also identified the right of the child to preserve their identity and nationality. The paper explains that, in the context of international surrogacy, it may be challenging for a child to access genetic or gestational information. It is noted that even under Australian domestic laws, children born through surrogacy are unlikely to be entitled to genetic information about their surrogate or gamete donor (if donor gametes have been used). Children are entitled to the name of their surrogate and donors, but not genetic information, although such information may be available to a clinic through the screening and medical process.

Surrogates' rights and reimbursement / compensation (and Questions 16 and 17)

This submission strongly supports reform on the important issue of reimbursement and compensation of surrogates to enable compensation of the surrogate. Although numerous government inquiries have addressed surrogacy, and recommended the continued prohibition of commercial surrogacy, evidence or research on that issue has not been considered by those inquiries. The 2009 Standing Committee of Attorneys-General, for example, concluded that there was 'widespread agreement' that commercial surrogacy should remain prohibited, without evidence demonstrating that commercial surrogacy causes harm. ¹⁰ The most recent Victorian review into ART did not consider whether commercial surrogacy should be permitted, although it made numerous recommendations around altruistic surrogacy. ¹¹

Evidence around the Australian public's attitudes to compensation of third parties involved in reproduction in the case of MD, in particular mitochondrial donors where a person donates an egg for use in research or reproduction involving MD shows support for compensation of the donor. A survey undertaken as part of research project aimed to increase public trust in genomic technologies, including MD, found that 62% of 1042 members of the Australian general public believed egg donors for MD should be financially rewarded by the intended parents. Twenty per cent of the public disagreed with this and 11% were unsure.¹²

Public consultation along the way to reform permitting MD, also showed that the Australian public (at least in regard to MD), supports the promotion of choice and reproductive freedom.¹³ An

¹⁰ SCAG, the Austn Health Ministers' Conference and the Community and Disability Services Ministers' Conference Joint Working Group, *A Proposal for a National Model to Harmonise Regulation of Surrogacy* Jan 2009 http://www.scag.gov.au/lawlink/SCAG/11 scag.nsf/pages/scag pastconsultations

¹¹ Gorton (n 3 above).

¹² Final Report. Preventing Mitochondrial Disease Using Genomics – Ethical, Social and Legal Aspects (MRFF 76744), p 9. (Copy available on request).

¹³ Australian Government Department of Health 2021. Consultation Summary Report. Public Consultation on the Approach to Introduce Mitochondrial Donation in Australia. Available online: https://www.health.gov.au/sites/default/files/documents/2021/03/public-consultation-on-the-approach-to-introduce-mitochondrial-donation-in-australia-summary-report.pdf p 2.



important justification for legalisation of MD is that it offers intended parents the opportunity to have a healthy, genetically related child. Use Surrogacy offers similar opportunities.

Further information

Monash University Wellington Road Clayton, Victoria 3800 Australia

E: karinne.ludlow @monash.edu monash.edu.au

¹⁴ Australian Senate Community Affairs References Committee 2018. Science of Mitochondrial Donation and Related Matters. Australian Parliament, 27 June. Available online: https://apo.org.au/node/180206 recommendation 1