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Dear Program Manager.

Thank you for the opportunity to contribute to the Review of the Western Australian Human Reproductive Technology Act 1991 and the Surrogacy Act 2008.

We are the Chief Investigators of an ongoing Australian Research Council-funded study into 'The legal and ethical aspects of the inheritable genetic modification of humans: The Australian context' (ARC DP170100919). This project examines the ethical and legal aspects of the technologies of Mitochondrial Replacement Therapy and CRISPR-Cas9.

We hope our research to date assists the Review in considering the operation and effectiveness of the *Human Reproductive Technology Act 1991 (HRT Act)* and other matters.

Sincerely,



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## OVERVIEW

Mitochondrial donation is a relatively new scientific advance in the sphere of assisted reproductive technologies. It allows for the replacement of mitochondrial DNA affected by mutations in an egg or zygote by transferring the nuclear DNA into a healthy donated egg that is not affected. The aim of this is to stop the transmission of mitochondrial disease, which is inherited from the maternal line.

In 2015, the British Parliament legalised the clinical use of mitochondrial replacement therapy (MRT). Significantly, these techniques allow for interventions that may be inherited by all subsequent generations of offspring of the person that the modified embryo may grow to be. Further, the embryo created using MRT contains the genetic material of three people.

These international developments raise significant questions about the moral and legal permissibility of MRT, which Western Australia and other Australian jurisdictions must address now in order to moderate undesirable effects and capitalise on positive ones. Clinical use of this technique is currently prohibited under Western Australian legislation, as are some forms of basic research. However, the breadth of that prohibition and the legal consequences of amendment to legalise some or all uses of these techniques is unclear. Further, the normative justification for continuing prohibition or amending the law must be examined in light of the new realities of human genetic modification.

Given the uniquely interdisciplinary nature of our research team, we are able to provide insight across many of the Review's terms of reference. In the following submission, we particularly address points 1, 2, 9 and 11 with respect to the *HRT Act*, as well as point 1 with respect to the *Surrogacy Act*.

Our study also comprises qualitative interviews with scientists, policy makers, disability representatives, and people living with mitochondrial disease. Interviewees are asked to speak to how viable heritable genetic modification techniques are, what ethical issues might be associated with them, what the arguments in favour and against are, and how effective the Australian ethics and policy landscape is in this context. Data collection and analysis is currently underway. However, we present select preliminary findings for the Review's consideration in this submission.

## 1. B: ETHICAL CONSIDERATIONS, INCLUDING SAFETY AND EFFICACY CONCERNS

1.1 Genetic interventions in assisted reproduction have traditionally been seen as characterised by a moral ‘bright line’ that separates **somatic (non-heritable) from germline (heritable) modifications**. Many see heritable modification as objectionable on grounds of safety and ethics. Mitochondrial replacement therapy sits in an ambiguous position to this distinction, due to the uncertain status of mitochondrial DNA.

There are **notable differences in how the UK, US, and Australia respond to fundamental questions** related to mitochondrial donation. For example, both Australia and the UK treat mitochondrial donation as a kind of germline modification, unlike in the US. Somewhat in contradiction, UK regulation does not treat mitochondrial donation as a form of inheritable *genetic* modification, which they limit to heritable changes to nuclear DNA. We think there is little justification for this limitation to nuclear DNA.

The US have sidestepped the issue of heritability by recommending that only male embryos are selected following mitochondrial donation, to ensure that no modified mitochondrial DNA is later passed on. This effectively nullifies the most widely acknowledged issue with germline modification, that it has roll-on effects for future generations. However, this option requires the sex selection of embryos for non-medical reasons, which is currently not permissible in Western Australia.

We consider mitochondrial donation under the umbrella of ‘heritable genetic modifications’, which we define as genetic changes that can be passed on to subsequent generations.

- However, our interviews suggest mitochondrial donation is not seen as posing the same ‘slippery slope’ risks as, for example, gene editing (eg. using CRISPR-Cas9), which risks being misused to enhance personal characteristics. Our respondents considered mitochondrial donation as more difficult to misuse than gene editing.

1.2 Much of the public debate of mitochondrial donation focuses on the issue of safety; however, these concerns are unlikely to rule out the use of the technology in the longer term.<sup>1</sup> **It is never possible to know in advance whether new reproductive technologies will risk the health of the children born as a result, or their descendants.** The first use of any new reproductive technology will be essentially experimental and risk unanticipated consequences for those children born of it, no matter how carefully it has been tested *in vitro* or in animal models. Presuming that it is implausible to argue that it would *never* be ethical to trial a new reproductive technology, **the real question about risk, then, is: when it is ethical to impose unknown risks on future children?**

- Interviewees for our project agree that ensuring the **safety of mitochondrial donation** is paramount, and also point out that some degree of uncertainty at the time that this technology enters clinical use will be unavoidable. One interviewee suggested that a licensing model similar to that used in the UK would help to ensure a sound and well regulated environment for mitochondrial replacement therapy in practice.

In determining the appropriate balance of risks and benefits, mitochondrial donation has to be assessed in the **context of existing (medical) options for potential users**, ie couples affected by mitochondrial disease who are wish to reproduce and seek to ensure that their child is not affected by mitochondrial disease. Existing reproductive options, such as Preimplantation Genetic Diagnosis (PGD), may be objectionable to some prospective parents on religious grounds, since it entails the destruction of embryos. Moreover, PGD is not reliable for the detection of mitochondrial disease, since PGD tests one cell of a very early embryo, and mitochondrial diseases may not appear in all cells. Nevertheless, there are safe reproductive options available, such as the use of donor gametes (eggs), or in some circumstances, adoption. The promotion of mitochondrial donation as the only option for prospective parents affected by these conditions is premised on the unquestioned value of genetic parenthood (see further on this below).

We believe it is important to maintain transparency about the **therapeutic efficacy** of mitochondrial donation, as well as in discussions of **access** to the technology. Mitochondrial diseases can be caused by mutations in nuclear DNA that control mitochondria, as well as mitochondrial DNA. While the latter of these is inherited maternally, the former follows Mendelian patterns of inheritance. Further, in some cases, mitochondrial disease results from new (de novo) mutations in genes and occurs in people without any family history of the disease. It is important in

discussions of mitochondrial donation that its capacity to ‘cure’ mitochondrial disease is not overstated. In fact, this technology only addresses mitochondrial disease that arises from mitochondrial DNA. There are also efficacy and safety issues to consider here, such as the current incomplete understanding of the interaction of donor DNA with nuclear DNA .

For mitochondrial donation to be performed as safely and ethically as possible, the whole of a patient’s medical team (including specialists, general practitioners, genetic counsellors, etc) will need regularly updated **training and education about the technology**. As mitochondrial donation would enter the clinical sphere as a novel medical technology, it should not be assumed that this expertise would be currently available. Potential introduction of the technology also requires developing expertise in the clinical setting in advance.

**1. 3 Other ethical considerations beyond safety and efficacy also arise with mitochondrial donation. One concern is the relatively unquestioned moral value of its therapeutic purpose.** The perceived benefits and moral permissibility of mitochondrial donation and other genetic modification technologies typically rest on their utility in correcting genetic disorders in human embryos. Indeed, it has been argued that it would be morally negligent not to use genetic technologies for this reason where possible.<sup>2</sup>

However, the identification of a condition as a disability or disease, and thus as eligible for treatment, is informed by cultural and medical conceptions of normality. While these may have a profound impact on the experience of living with a condition, they do not necessarily determine that experience.<sup>3</sup> The perspectives of persons living with disabilities may challenge the “therapeutic imperative” that drives much discussion of inheritable genetic modification.<sup>4</sup> In fact, inheritable genetic modification raises questions not only about the first-person valuation of life with disability, but wider societal valuations as well.

Disability scholars have argued that using genetic selection technologies constitutes a form of **discrimination against people with disabilities** insofar as it ‘sends a message’ to persons with disability that their lives are not worth living.<sup>5</sup> This expressive characteristic may also be born out by inheritable genetic modifications, including mitochondrial donation. Further, inheritable genetic modification also raises the possibility of a world in which some genetic conditions no longer exist. For most commentators, this seems an unmitigated good. But from another perspective, it raises questions about the social value of disability and the loss entailed in its elimination, and the correlative reduction in genetic diversity. Garland Thomson has recently made a case for the importance of conserving disability, while Sparrow has criticized this idea.<sup>6</sup>

The “therapeutic imperative” is underpinned by a **conception of disability and disease** that sees it as necessarily a harm that ought to be prevented or avoided.<sup>7</sup> It is often taken for granted in contemporary debates that procreators should be at liberty to make decisions about reproduction – including when, how, with whom – based on their own values. But typically this autonomy is limited to actions that do not cause significant harm to others, prompting questions about what constitutes harm, and what is significant enough as to place limits on liberty. These questions are especially complicated in regards to reproduction, where harm may be considered either ‘person affecting’ or ‘non-person-affecting’. This distinction emerges from the so-called ‘non-identity problem’, which indicates that, so long as a congenital condition is not so bad as to make life not worth living, then no harm is done to the person born with that condition (since otherwise they would not be born at all). In relation to mitochondrial donation, this raises a question about the extent to which couples affected by mitochondrial disease who are seeking to reproduce would be obliged to or feel pressured to use the technology of mitochondrial donation if it were available.

While there is currently no data about **attitudes toward mitochondrial donation** from persons with mitochondrial disease themselves in Australia [such data will be compiled as part of this project], there is some data from the UK. This suggests that attitudes toward mitochondrial donation of women affected by mitochondrial disease is varied. For instance, while some women were not opposed to making mitochondrial donation available, they expressed reluctance about using the technology themselves. This was because of concerns about safety and not wanting to undertake what is essentially an experimental procedure, or a more general sense that mitochondrial donation overly technologized pregnancy. For these reasons, women sometimes expressed a preference for safer alternative options such as donated gametes and/or adoption.<sup>8</sup>

**1. 4. The prospect of the clinical use of mitochondrial donation has generated significant concern about the genetic parenthood of children created using the technique.** There has been much media and bioethics discussion of ‘3-parent babies’, and the implications this might have for the resulting children and for ideas of parenthood. Some commentators worry that, if used widely, such techniques would precipitate a rupture in familial and personal narratives, possibly in ways that do damage to personal identity, especially to the children born of the technology.<sup>9</sup>

However, this line of thinking remains underdeveloped, and the normative implications of such a rupture in narratives of identity are unclear.

Further, it remains unclear whether mitochondrial donors should be considered parents, at least in a minimal genetic sense. UK legislation treats mitochondrial donors as equivalent to organ, rather than gamete (egg or sperm), donors. This means that they have no rights to a parental relationship with the recipient of their mitochondrial DNA (or parental obligations to them). However, the reasoning behind this decision is inconsistent (see Ludlow, 2018 for a full discussion): it hinges on the supposedly inconsequential status of mitochondrial DNA, at the same time as mitochondrial donation is seen as necessary because of the significant consequences of mitochondrial DNA.<sup>10</sup> Other analysts, including the US National Academies and the Nuffield Council of Bioethics, acknowledge that mitochondrial DNA might also contribute to personal characteristics in ways that are not yet well understood.

Concerns about the capacity of assisted reproductive technologies to **“confuse and disrupt” our understanding of kinship, parenting and familial identity** have been central to bioethical discussion of genetics for some time. This capacity is further increased with mitochondrial donation, since it not only raises questions about the value of genetic relatedness, but also fundamentally disrupts our understanding of what it entails (ie. two genetic progenitors rather than three). While it has long been recognised that being a genetic progenitor is not necessary to establish parenthood (as in adoption), it is something else again to suggest that being a genetic progenitor is not sufficient to establish genetic parenthood.

Establishing parenthood has significant implications, both ethical and legal. For instance, recent interventions consider the obligations parents acquire in bringing children into the world.<sup>11</sup> It may be that inheritable genetic modification technologies extend the obligations that parents have to their own children in various ways. For instance, if a genetic modification affects not only the resultant child, but also that child’s offspring, what, if any, obligations do the parents have to the ‘more than next’ generation? Legally, the status of parenthood may potentially allow children born of mitochondrial donation to find out information about their donor. This is discussed further in the following section of this submission.

Consideration of these moral topics has direct bearing on the justification of legal frameworks that regulate research and clinical application of technologies using human embryos and assisted reproductive technologies in Western Australia. However, the relevant legislation and NHMRC Guidelines were developed in a context where inheritable genetic modification technologies such as CRISPR-Cas9 and mitochondrial replacement therapies were not yet a scientific or clinical reality. In light of recent technological and legal developments, a question arises as to whether, and if so how, Australian and State legislation ought to be reformed in order to meet this new reality. Our ongoing research will address this question through consideration of the moral issues at stake in the inheritable genetic modification of humans, and the consequences of these for potential legal reform.

## **E: LEGAL FRAMEWORKS AND CHANGES THAT WOULD BE REQUIRED IF MITOCHONDRIAL DONATION WAS TO BE INTRODUCED IN WESTERN AUSTRALIA**

If legalised, regulation of **mitochondrial donation will span federal (and corresponding state) regulation of embryo use and state regulation of clinical assisted reproductive technologies** in a novel fashion. **Multiple governance bodies will be implicated in any attempt to legalise clinical use of mitochondrial donation.**

Western Australia’s current regulatory frameworks for dealing with embryo use and assisted reproductive technologies was developed in a context where mitochondrial donation was not yet clinically feasible. Consequently, a question arises about whether this framework is adequate to meet this new reality.

**2.1 Legality of Technique’s Use** - We draw the Review’s attention to a publication by Ludlow (2018), which analyses possible governance responses to mitochondrial donation, noting in particular the following:

- The most straightforward legal route would be to treat mitochondrial DNA as separate from the human genome. This approach parallels the UK process and resonates with existing legislation of embryos and cloning, as well as current legal definitions of genetic material and the genome, which are highly opaque. There are alternative approaches but these raise their own, not necessarily insurmountable, challenges:

- Repeal the prohibition on heritable genetic changes or include an exception allowing the technique, which may contravene UNESCO's Universal Declaration on the Human Genome and Human Rights, to which Australia is a signatory; or
  - Revise regulation around embryo sex selection to enable the technique's use only in male embryos, which could attract opposition given the recent public rejection of sex selection in family planning contexts.
- Key definitional issues which must be resolved before legislation can be developed around mitochondrial donation include:
    - whether this technology constitutes genetic modification / gene technology according to current definitions;
    - whether it can be considered either germline or somatic modification, and whether this distinction remains useful; and
    - how mitochondrial and nuclear DNA should be defined and regulated.
  - A regulatory framework for clinical use will need development, addressing governance issues such as access to the technique for reasons other than to address mitochondrial disease.

**2.2 Parentage and Kinship** - We draw the Review's attention to a publication by Ludlow (2015), which summarises current legislation in Western Australia and across Australian federal and other state jurisdictions regulating genetic and legal parentage through the lens of mitochondrial donation, noting in particular the following:

- **Parentage and kinship in Australia is regulated at the state level.** By current definitions in the *HRT Act*, *Surrogacy Act 2008* and *Artificial Conception Act 1985*, a mitochondrial DNA donor would likely be considered to be the resulting child's biological and genetic, though not legal, parent. In such an arrangement, the child would have access to information on the donor's identity.
- Mitochondrial donation may be used in the conception of a child, who is then to be gestated by a surrogate. The *Surrogacy Act* requires that donors whose gamete (egg) is to be used for conception sign a written agreement before pre-approval of the surrogacy arrangement. Consideration is needed of the appropriateness of the consequential extension of this requirement to mitochondrial donors because of the mitochondrial donor's classification as a gamete donor.
- Western Australian law (namely, pursuant to the *HRT Act*) requires that the genetic origins of the resulting child not be deliberately confused. This does not prevent mitochondrial donation but constrains the implantation of more than one embryo into one woman where mitochondrial donation has been used.

**There are lessons to be taken from the development of legislation around mitochondrial donation in other countries.** For example, the UK, US, and Australia differ in many critical respects: the UK treats mitochondrial donation as germline modification, yet UK regulation does not consider it to be *genetic* modification. UK legislation also positions mitochondrial DNA donors as more analogous with organ rather than gamete (egg or sperm) donors, redacting any rights to a parental relationship with the resulting child. However, the reasoning behind these decisions is inconsistent (see Ludlow 2018 for a full discussion), and does not align with the views of some international bodies, for example the US National Academies and the Nuffield Council of Bioethics.

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- <sup>1</sup> Lanphier, E. et al. 2015. Don't Edit the Human Germ Line. *Nature*. 519(26 March): 410-411. Harris, J. 2015. Germline Manipulation and Our Future Worlds. *Am J Bioeth.* 15(12): 30-4.
- <sup>2</sup> Harris, J. 2007. *Enhancing Evolution: The Ethical Case for Making Better People*. Princeton: Princeton UP.
- <sup>3</sup> Warren, N. and L. Manderson. eds. 2013. *Reframing Disability and Quality of Life: A Global Perspective*. Springer: Dordrecht.
- <sup>4</sup> Scully, J.L. 2006. IGM and Disability: Normality and Identity. In *The Ethics of Inheritable Genetic Modification: A Dividing Line?*. J.E.J. Rasko, G.M. O'Sullivan, and R.A. Ankeny (eds). Cambridge: Cambridge UP: 175-192.
- <sup>5</sup> Parens, E. and A. Asch. 2000. *Prenatal Testing and Disability Rights*. Washington D.C: Georgetown UP.
- <sup>6</sup> Garland Thomson, R. 2012. The Case for Conserving Disability. *J Bioeth Inq.* 9(3): 339-55. Sparrow, R. 2015. Imposing Genetic Diversity. *Am J Bioeth.* 15(6): 2-10.
- <sup>7</sup> Mills, C., 2011. *Futures of Reproduction: Bioethics and Biopolitics*. Dordrecht: Springer.
- <sup>8</sup> Herbrand, C. 2017. Mitochondrial replacement techniques: who are the potential users and will they benefit? *Bioethics*. 31(1): 46-54.
- <sup>9</sup> Baylis, F. and J.S. Robert, 2006. Radical Rupture: Exploring Biological Sequelae of Volitional Inheritable Genetic Modification. In *The Ethics of Inheritable Genetic Modification: A Dividing Line?*, J.E. Rasko. et.al, eds. Cambridge: Cambridge UP: 131-148.
- <sup>10</sup> For a fuller discussion, see Ludlow, K. 2018. The policy and regulatory context of US, UK and Australian responses to mitochondrial donation governance. *Jurimetrics*. 58: 247-265.
- <sup>11</sup> DeGrazia, D. 2012. *Creation Ethics: Reproduction, Genetics and Quality of Life*. New York: Oxford UP. Prusack, B.G. 2013. *Parental Obligations and Bioethics: The Duties of a Creator*. New York: Routledge.

## APPENDIX 1: ACADEMIC ARTICLES FOR FURTHER REFERENCE



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# Genes and gestation in Australian regulation of egg donation, surrogacy and mitochondrial donation

Karinne Ludlow\*

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*This article considers genetic and legal relatedness for the purposes of Australian regulation of egg donation, surrogacy and parentage by examination of that regulation through the lens of mitochondrial (mt) donation. The article addresses whether mt donors would be a child's genetic parents following clinical use in that child's conception should mt donation be legalised for such use in Australia. It then considers how genetic and gestational relatedness are relevant in the discourse around legal parentage following egg donation and surrogacy and argues that the current approach is in need of reform so that intending parents of all children are deemed to be the resulting child's legal parents at birth.*

## INTRODUCTION

Genes and gestation matter in individual reproductive choice, science and in the regulation of egg donation, surrogacy and parentage. However, while intending parents in donor conception cases are given the advantage of having the child's biological ties with others severed so that they are the resulting child's legal parents at birth, intending parents in gestational surrogacy arrangements are not. As this article explains below, both gestational surrogates and egg donors have significant clinical effects on the resulting child's genes but, pursuant to legislation in all Australian jurisdictions, a gestational surrogate will not be a genetic parent of the resulting child. Further, unlike genetic parents of donor-conceived children, gestational surrogates (and their partner, if any) are preferenced over intending parents in Australian parentage legislation.<sup>1</sup>

Regulatory scholars have previously identified that the law perennially faces problems when confronted with (bio)technology innovation.<sup>2</sup> On assisted reproductive technology (ART), Sheldon has pointed out the ability of new technology to "confuse and disrupt our understanding of parenthood".<sup>3</sup> Using a recent development in ART known as mitochondrial (mt) donation, this article offers a close analysis of the relevance of genetic and gestational relatedness to legal parentage of children born through donor conception or surrogacy in Australia. It also examines how the mt donation technique would fit within existing Australian regulation if it were to be legalised here. This tool shows inconsistencies in the law's response to the biological reality of genetic and gestational links.

The article begins by explaining the technique of mt donation and its place in the widening space of reproductive choice. The law's response to genetic and gestational links in its regulation of legal parentage is then examined to show first, that mt donors will be genetic parents and gestational surrogates will not. Further, and more importantly, parentage laws make that genetic link irrelevant in cases of donor conception but resurrect its importance in surrogacy arrangements. This inconsistency together with other confusion regarding the relevance of genetic relationships to parentage transfer decisions identified below, means the weight to be attached to genetic and gestational relatedness by courts addressing parentage transfer applications is unclear and that Australian regulation is

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<sup>1</sup> Surrogate is used for the woman who gestates and gives birth to the child and intending parent(s) refers to the person(s) who will parent the child. Different terms are used in the various Acts discussed in this article.

<sup>2</sup> See, for example, Roger Brownsword, "Regulating Human Genetics: New Dilemmas for a New Millennium" (2004) 12 Med L Rev 14.

<sup>3</sup> Sally Sheldon, "Fragmenting Fatherhood: The Regulation of Reproductive Technologies" (2005) 68 MLR 523, 524.



inadequate for ongoing developments in reproductive choice. Instead, this article suggests that legal parentage should be given to intending parent(s) upon a child's birth, regardless of the technique used to assist their conception and birth.

## MITOCHONDRIAL DONATION AND REPRODUCTIVE CHOICE

The United Kingdom (UK) Parliament has now allowed clinical application of mt donation.<sup>4</sup> The entry into force of the *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* (UK) on 29 October 2015 allows licensing of the technique's use on embryos intended for implantation.<sup>5</sup> The United States (US) is similarly considering approving this technique for clinical application.<sup>6</sup> In late 2014, the US Food and Drug Administration tasked a US Institute of Medicine ad hoc committee (Committee on Ethical and Social Policy Considerations of Novel Techniques for Prevention of Maternal Transmission of Mitochondrial DNA Diseases) to consider the modern technique.<sup>7</sup> The Committee has begun holding public and closed sessions on the social and ethical issues raised by the technique. A consensus report will be produced at the end of that process.<sup>8</sup> Some forms of mt donation are allowed for research purposes in Australia but there are legal obstacles to its clinical use here.<sup>9</sup> Although in need of examination, such obstacles are not within the scope of this article. This article proceeds on the basis that mt donation may be legalised for clinical use here.

Mt donation aims to replace an intending mother's "faulty" mtDNA with the healthy mtDNA of another woman to allow the intending mother to have a genetically related child of her own. In simplistic terms, when an egg and sperm (known as gametes) combine to develop into an embryo, that embryo is endowed with a combination of DNA from its two genetic parents. Most of that DNA (over 20,000 genes) is in the cell's nucleus but a small amount (37 genes – about 0.1% of the cell's total DNA) is present in small packages (or organelles) called mitochondria in the surrounding environment (or cytoplasm) of the cell.<sup>10</sup> Each cell contains about 400 mitochondria, responsible for converting food energy into chemical energy and leading to mitochondria being referred to as a cell's "batteries".

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<sup>4</sup> Research into mt donation has been licensed in the UK since 2005: Human Fertilisation & Embryology Authority (HFEA), "HFEA Grants Licence to Newcastle Centre at LIFE for Mitochondrial Research" (Press Release, 8 September 2005) <[www.hfea.gov.uk/671.html](http://www.hfea.gov.uk/671.html)>.

<sup>5</sup> The Regulations amend the *Human Fertilisation and Embryology Act 1990* (UK). There are objections to these changes on a number of bases, not considered here, including that such technique is eugenic, genetic modification, incompatible with human dignity and contrary to international law. See Department of Health (UK), *Mitochondrial Donation: Government Response to the Consultation on Draft Regulation to Permit the Use of New Treatment Techniques to Prevent the Transmission of a Serious Mitochondrial Disease from Mother to Child* (2014) <<https://www.gov.uk/government/consultations/serious-mitochondrial-disease-new-techniques-to-prevent-transmission>>; Parliamentary Assembly of the Council of Europe, *Creation of Embryos with Genetic Material from More than Two Progenitor Persons* (3 October 2013).

<sup>6</sup> An early form of partial mt donation was used in the US in the 1990s, which involved injecting cytoplasm from one woman's egg into the intending mother's egg. The US Food and Drug Administration eventually asserted that the cytoplasm was a drug for these purposes, needing approval for use. No approval has been granted. Jaques Cohen et al, "Birth of Infant after Transfer of Anucleate Donor Oocyte Cytoplasm into Recipients Eggs" (1997) 350(9072) *The Lancet* 186; Nuffield Council on Bioethics, *Novel Techniques for the Prevention of Mitochondrial Disorders: An Ethical Review* (2012) [2.8]-[2.14].

<sup>7</sup> Food and Drug Administration (US), Advisory Committees, *2014 Meeting Materials, Cellular, Tissue and Gene Therapies Advisory Committee* (25-26 February 2014) <[www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/ucm380047.htm](http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/ucm380047.htm)>.

<sup>8</sup> On differences between the US and UK regulation of the mt donation technique, see I Glenn Cohen, Julian Savulescu and Eli Y Adashi, "Transatlantic Lessons in Regulation of Mitochondrial Replacement Therapy" (2015) 348(6231) *Science* 178.

<sup>9</sup> See, for example, *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) ss 13, 20(3) and (4)(c) and mirroring State legislation. For research use, see *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 23 and *Research Involving Human Embryos Act 2002* (Cth) s 10A(b)(ii) and mirroring State legislation.

<sup>10</sup> Nuffield Council on Bioethics, n 6, [1.5]-[1.6].

Faults, or mutations, occur in all DNA. In mtDNA, mutations cause severe non-curable neurological, muscular and other diseases in at least one per 10,000 individuals. Diseases linked to mtDNA mutations include muscular dystrophy and other life-threatening conditions. At least one in 250 Australians carry mtDNA mutations.<sup>11</sup>

Only maternal mitochondria are passed on to offspring in human reproduction.<sup>12</sup> Whether a woman's mutant mtDNA presents as disease in her offspring depends largely on the proportion of mutant, relative to total, mtDNA in the particular egg used in the conception of a particular child. Mutant mtDNA numbers vary between individual eggs. For some women, though, the chance of passing on mtDNA mutation is great. Alternatives such as genetic screening of embryos prior to implantation are insufficient to determine the risk to the embryo in all cases, particularly as the number of mutant mtDNA can differ between cells that makeup the embryo. A sample embryonic cell will therefore not necessarily represent all embryonic cells. Mt donation is an alternative in addressing the problem.

There are variations in the actual procedure – maternal spindle, pronuclear and polar body transfer<sup>13</sup> – but essentially the nuclear DNA, containing the bulk of the DNA, from the intending mother's egg (or from a zygote made with her egg and a sperm) is moved to an egg (or zygote) of a woman with healthy mtDNA. The nucleus of the "normal" egg or zygote is removed first, leaving the healthy mitochondria.<sup>14</sup> Any child born as a result of this procedure will have nuclear DNA from one man and woman and mtDNA from another woman. The child's DNA is accordingly from three individuals, including two women. Furthermore, and just as controversially, if the child is female, the changes will be inherited by each of that child's children and the descendants of her daughters.

An alternative for women who carry these mutations and do not want to risk passing them onto their children is to use both the nuclear and mtDNA from the one donated egg. As discussed below, egg donation for use in ART by another woman is allowed in all Australian jurisdictions, and legislation addresses the parentage of the resulting children. However, as noted in the 2014 review of the science for the UK ART regulator, using a donated egg this way "means that any resultant child will not be genetically related to the [intending] mother".<sup>15</sup>

Surrogacy is another option for women seeking to have a genetically related child. All Australian jurisdictions allow surrogacy in some circumstances<sup>16</sup> and all, except the Northern Territory (NT), have legislation providing for the parentage of such children.<sup>17</sup> However, surrogacy where the intending mother carries mtDNA mutation only addresses that problem if an entire donated egg (containing the donor's nuclear and mtDNA) or embryo is used, removing a genetic link between intending mother and child. The donated egg could be provided by the surrogate (called a genetic or

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<sup>11</sup> David Thorburn in Australian Science Media Centre, "DNA Transfer Prevents Mitochondrial Disease in Humans – Experts Respond", *Rapid Roundup*, 15 April 2010 <[www.smc.org.au/rapid-roundup-dna-transfer-prevents-mitochondrial-disease-in-humans-nature-experts-respond](http://www.smc.org.au/rapid-roundup-dna-transfer-prevents-mitochondrial-disease-in-humans-nature-experts-respond)>.

<sup>12</sup> This paragraph is drawn from Daniel Paultet al, "Nuclear Genome Transfer in Human Oocytes Eliminates Mitochondrial DNA Variants" (2013) 493 *Nature* 632.

<sup>13</sup> See HFEA, *Third Scientific Review of the Safety and Efficacy of Methods to Avoid Mitochondrial Disease Through Assisted Conception: Update* (3 June 2014) <<http://www.hfea.gov.uk/8807.html>>. Regarding polar body transfer technique, see HFEA, *Review of the Safety and Efficacy of Polar Body Transfer to Avoid Mitochondrial Disease. Addendum to "Third Scientific Review of the Safety and Efficacy of Methods to Avoid Mitochondrial Disease Through Assisted Conception: 2014 Update"* (2014). See also HFEA, *Mitochondrial Donation: An Introductory Briefing Note* (2014).

<sup>14</sup> Institute of Medicine (US), *Ethical and Social Policy Considerations of Novel Techniques for Prevention of Maternal Transmission of Mitochondrial DNA Diseases* <<http://www.iom.edu/Activities/Research/MitoEthics.aspx>>.

<sup>15</sup> HFEA, n 4, [3.1.1].

<sup>16</sup> *Parentage Act 2004* (ACT); *Surrogacy Act 2010* (NSW); *Surrogacy Act 2010* (Qld); *Family Relationships Act 1975* (SA); *Surrogacy Act 2012* (Tas); *Assisted Reproductive Treatment Act 2008* (Vic); *Surrogacy Act 2008* (WA). See also Jenni Millbank, "The New Surrogacy Parentage Laws in Australia: Cautious Regulation or '25 Brick Walls'?" (2011) 35 *MULR* 165; Paul Boers, "Surrogacy – The Varied Approaches of the States and Territories" (2011) 22 *AFL* 28.

<sup>17</sup> *Parentage Act 2004* (ACT); *Surrogacy Act 2010* (NSW); *Surrogacy Act 2010* (Qld); *Family Relationships Act 1975* (SA); *Surrogacy Act 2012* (Tas); *Status of Children Act 1974* (Vic); *Surrogacy Act 2008* (WA).

traditional surrogacy) either through ART in a clinical setting or informally without ART.<sup>18</sup> More commonly, though, the surrogate's egg is not used and instead an embryo created using ART is implanted into the surrogate's uterus.<sup>19</sup> The egg could be sourced from the intending mother or a donor.<sup>20</sup> Such surrogacies are referred to as gestational surrogacies.

Both egg donors, whether for use in mt donation or for conventional ART, and gestational surrogates have input into the resulting child's genetic makeup. Although mt genes are important for the reasons explained above, it is arguable whether the genetic influence of the third person is greater in surrogate pregnancies than in mt donation assisted pregnancies because "the environment of the womb is now recognised to program the way various genes are expressed and potentially affect health outcomes in later life".<sup>21</sup>

The article next examines how genetic relationships with children are understood in Australian regulation of egg donation, surrogacy and parentage and the relevance and prioritisation of such relationships in State and Territory parentage laws. The results of that examination are then used to inform later discussion.

## HOW DO GENES AND GESTATION MATTER IN AUSTRALIAN REGULATION?

### Introduction

Regulation of donor conception, surrogacy and legal parentage occurs on a State-by-State basis. Relevant parts of that regulation are summarised in the Table at the end of this article. Four States – New South Wales (NSW), South Australia (SA), Victoria and Western Australia (WA) – regulate donor conception through ART legislation. The remaining jurisdictions rely on the National Health and Medical Research Council (NHMRC) *Ethical Guidelines on Assisted Reproductive Technology in Clinical Practice and Research* (2007) and the accreditation requirements of the Fertility Society of Australia.<sup>22</sup> In summary, conception using donor eggs is permitted in all jurisdictions and the parentage of donor-conceived children is regulated through specific parentage legislation. That legislation legally severs the genetic link between donor and child, and parentage is instead endowed on the intending parent(s) through statutory presumption.<sup>23</sup>

All jurisdictions also allow altruistic surrogacy in some circumstances, regulating it through their ART legislation, specific surrogacy legislation or the NHMRC Guidelines. The exception is the NT which has no surrogacy legislation. As explored by Millbank, "genetics as determinative of the 'real' or 'biological' parents of children" was a prominent theme in both parliamentary and media accounts regarding the most recent wave of surrogacy law reforms.<sup>24</sup> However, despite the emphasis of a genetic link to legitimise legalisation of surrogacy, the surrogate and not the genetic parents is the child's legal parent at birth in all jurisdictions.<sup>25</sup> Justification for this is most commonly that it is in the child's best interests, although in some cases it is also justified as allowing surrogates the opportunity

<sup>18</sup> Millbank, n 16, 170.

<sup>19</sup> Others have considered whether the separation of a genetic link by prohibiting the use of the surrogate's egg (or her partner's gamete) is appropriate: for example, Pip Trowse, "'Surrogacy': Is it Harder to Relinquish Genes?" (2011) 18 JLM 614.

<sup>20</sup> Millbank, n 16, 170.

<sup>21</sup> Thorburn, n 11.

<sup>22</sup> Reproductive Technology Accreditation Committee, *Code of Practice for Assisted Reproductive Technology Units* (Fertility Society of Australia, 2014) 13. These are relevant in all jurisdictions but subject to any contrary legislation. See generally, Belinda Bennett and Malcolm Smith, "Assisted Reproductive Technology" in Ben White, Fiona McDonald and Lindy Willmott (eds), *Health Law in Australia* (Thompson Reuters, 2nd ed, 2014).

<sup>23</sup> See Senate Legal and Constitutional Affairs References Committee, Parliament of Australia, *Donor Conception Practices in Australia* (February 2011).

<sup>24</sup> Jenni Millbank, "From Alice and Evelyn to Isabella – Exploring the Narratives and Norms of 'New' Surrogacy in Australia" (2012) 21 GLR 101, 105.

<sup>25</sup> The surrogate's partner may also be a parent, although there are differences between the States.

to change their mind regarding parenting the child.<sup>26</sup> While the surrogate's interests are very important, the strength of those interests is not within the scope of this article. Instead, the focus is on the inconsistencies such an approach creates when compared with parentage regulation in donor conception cases where consideration of the child's best interests has meant genetic links to adults other than intending parents are severed.

All jurisdictions (other than the NT) allow legal parentage to be transferred from the surrogate to the intending parents, but only after birth albeit with significant variation in the conditions required for transfer. The presence or absence of genetic relatedness between those involved creates a spectrum of legislative responses in regards to relevance for applications for parentage transfer. In some States, transfer of parentage requires at least one of the intending parents to be the genetic parent of the child. Another group of States prohibit parentage transfer if there is a genetic link between the surrogate and/or her partner and the child. Even in the remaining jurisdictions though, genetic connection is to be addressed by courts considering applications to transfer parentage.

For each jurisdiction, the concept of genetic relatedness used in their regulation of donor-conception and surrogacy and where mt donation fits within this is considered below. The relevance of genes and gestation to parentage presumptions and parentage transfer is also considered, providing the basis for consideration later of the areas in need of reform.

### **Australian Capital Territory**

The ACT does not have ART legislation, the NHMRC Guidelines instead being relevant. The Guidelines make clear that donated gametes can be used in the conception of children and that the resulting child has the right to identifying information on the donor.<sup>27</sup> The same approach is taken in regards to donated embryos.<sup>28</sup> The Guidelines explain that disclosure is required because donor-conceived persons are entitled to know their genetic parents.<sup>29</sup> While the Guidelines use the terms genetic parent / offspring / sibling / material, these terms are not defined. The Guidelines also use the term gamete provider, defined as “[t]he person who is the biological (that is, genetic) source of the gamete”.<sup>30</sup> This term is likely to include mt donors because, as in all jurisdictions, “gamete” is defined to mean a human sperm or egg.<sup>31</sup> Mt donors clearly provide an egg, even though it is eventually enucleated (nucleus removed).

On surrogacy, the Guidelines note that it is a controversial practice<sup>32</sup> and observe considerations needing further community discussion. Some of these considerations raise genetics-based issues. Supportive of surrogacy, for example, is the consideration that “the use of a surrogate mother who is also the genetic mother can prevent the transmission of serious genetic diseases by allowing a commissioning mother who is the carrier of that disease to avoid pregnancy”.<sup>33</sup> Amongst considerations against surrogacy, the NHMRC notes that “surrogacy is less about the autonomous choices of the women involved than about enabling men to have children with whom they have a genetic connection”.<sup>34</sup>

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<sup>26</sup> The Standing Committee of Attorneys-General, Joint Working Group, Parliament of Australia, *A Proposal for a National Model to Harmonise Regulation of Surrogacy* (2009) 8-12.

<sup>27</sup> NHMRC, *Ethical Guidelines on Assisted Reproductive Technology in Clinical Practice and Research* (2007) Guideline 6.

<sup>28</sup> NHMRC, n 27, Guideline 7.

<sup>29</sup> NHMRC, n 27, Guideline 6.1.

<sup>30</sup> NHMRC, n 27, Explanation of Key Terms, 96.

<sup>31</sup> NHMRC, n 27, Explanation of Key Terms, 96.

<sup>32</sup> NHMRC, n 27, Guideline 13.2.

<sup>33</sup> NHMRC, n 27, Appendix C3, 92.

<sup>34</sup> NHMRC, n 27, Appendix C3, 92.

The *Parentage Act 2004* (ACT) provides for parentage of donor-conceived and surrogate born children. A child cannot have more than two parents at any one time,<sup>35</sup> parent being defined in the *Legislation Act 2001* (ACT) as the child's mother or father or someone else presumed under the *Parentage Act* to be parent.<sup>36</sup> Parent for these purposes is therefore the legal parent and there is no such restriction on the number of genetic parents.

For donor-conceived children, the intending parents (which will include the gestational mother) and not those who provide gametes used in the child's conception will be the legal parents upon birth because of a conclusive statutory presumption that if a woman becomes pregnant other than as a result of sexual intercourse,<sup>37</sup> she is the mother of any child born as a result of that pregnancy.<sup>38</sup> The Act goes on to clearly sever the genetic link for parentage purposes by providing that:

If the ovum used in the procedure was produced by another woman, that other woman is conclusively presumed not to be the mother of any child born as a result of the pregnancy.<sup>39</sup>

In regards to children born through surrogacy arrangements, the ACT has mandatory requirements regarding genetic links before parentage transfer from surrogate to intending parents can occur. The legislation provides that an application for parentage transfer can be made if, *inter alia*, neither birth parent is a genetic parent *and* if at least one intending parent is a genetic parent.<sup>40</sup> Genetic parent of a child is defined to mean "a person whose gametes were used to create the embryo",<sup>41</sup> which would include mt donors but not gestational surrogates. Gamete is undefined.

Millbank observes that the ACT provisions were closely based on UK legislation<sup>42</sup> but the ACT added the need for the surrogate not to be genetically related to the child and prohibiting the use of the surrogate's partner as a gamete donor.<sup>43</sup> Millbank notes that no rationale for this variation was given in the parliamentary materials, the Explanatory Statement only noting the requirements for no genetic connection between surrogate and child but not explaining the reason for it.<sup>44</sup> She suggests that it may be because the practice of the only clinic that provided ART for surrogacy arrangements in the ACT at the time followed that practice.<sup>45</sup>

## New South Wales

Pursuant to the *Assisted Reproductive Technology Act 2007* (NSW), donated gametes can be used in ART and the resulting child has a right to identifying information about the donor.<sup>46</sup> Gamete provider is defined broadly as "in relation to a gamete, means the individual from whom the gamete has been obtained and in relation to an embryo means an individual from whom a gamete used to create the embryo was obtained".<sup>47</sup> The term is similarly defined for the purposes of surrogacy<sup>48</sup> and would include mt donors. The Act does not use the term genetic parents, instead using biological parents which is undefined. Biological parents is used in the definition of offspring of a person, whereby

<sup>35</sup> *Parentage Act 2004* (ACT) s 14.

<sup>36</sup> *Legislation Act 2001* (ACT) Dictionary "parent".

<sup>37</sup> *Parentage Act 2004* (ACT) s 11(9) "procedure".

<sup>38</sup> *Parentage Act 2004* (ACT) s 11(2).

<sup>39</sup> *Parentage Act 2004* (ACT) s 11(3).

<sup>40</sup> *Parentage Act 2004* (ACT) s 24.

<sup>41</sup> *Parentage Act 2004* (ACT) s 3, Dictionary.

<sup>42</sup> *Human Fertilisation and Embryology Act 1990* (UK) s 30.

<sup>43</sup> See Millbank, n 16, 179.

<sup>44</sup> Millbank, n 16, 179.

<sup>45</sup> Millbank, n 16, 179-180.

<sup>46</sup> *Assisted Reproductive Technology Act 2007* (NSW) s 37.

<sup>47</sup> *Assisted Reproductive Technology Act 2007* (NSW) s 4(1).

<sup>48</sup> *Assisted Reproductive Technology Act 2007* (NSW) s 41A.

offspring means an individual to whom the person is a biological parent.<sup>49</sup> Both gestational surrogates and mt donors would arguably be biological parents for these purposes.

In the context of surrogacy arrangements, the term biological sibling is also used. It is defined by reference to blood as a brother or sister of a person, “whether the relationship is of the whole blood or half blood”.<sup>50</sup> Children gestated by the same woman or conceived using eggs from the same mt or nuclear DNA donor would be within this definition.<sup>51</sup> Further, full identifying information on any surrogate and gamete provider for the pregnancy is to be recorded and available to the child.<sup>52</sup>

Pursuant to the *Status of Children Act 1996* (NSW) there is an irrebuttable statutory presumption of motherhood for any woman, including surrogates, that becomes pregnant other than as a result of sexual intercourse and that the egg donor is not the child’s mother.<sup>53</sup> The *Surrogacy Act 2010* (NSW) provides for the transfer of parentage for children born under surrogacy arrangements. It requires applications for parentage orders to be accompanied by an independent counsellor’s report on various matters, including their assessment on “any contact arrangements proposed in relation to the child and his or her birth parent or parents or biological parent or parents”.<sup>54</sup> The term genetic parent is not used and biological parent is not defined but arguably includes mt donors but not gestational surrogates, who would instead be the birth parent.

### Northern Territory

ART regulation in the NT is the same as in the ACT, namely the NHMRC Guidelines are relied on. NT parentage legislation, the *Status of Children Act 1978* (NT), addresses the status of children born through the use of donated gametes or embryos.<sup>55</sup> A woman who gives birth is the mother of the child, regardless of the source of the egg used in the child’s conception.<sup>56</sup> The donor of an egg used in a fertilisation procedure<sup>57</sup> is not the mother of any resulting child.<sup>58</sup> NT has no provisions specifically concerning surrogacy. However, pursuant to the general “maternity” provision referred to above, a surrogate would be presumed to be the mother of any child she gives birth to.<sup>59</sup> The terms genetic, biological and gamete provider are not used. Parentage transfer would follow SA’s legislation.

### Queensland

Queensland also does not have ART legislation, instead relying on the NHMRC Guidelines as described in regards to the ACT. Its legislation concerning the parentage of donor-conceived children, the *Status of Children Act 1978* (Qld), provides for the same irrebuttable statutory presumptions as NSW.<sup>60</sup>

Of all jurisdictions, genes have the least relevance in surrogacy arrangements in Queensland. This is reflected in a guiding principle in its *Surrogacy Act 2010* (Qld), which provides that the same status, protection and support is to be available to children born as a result of surrogacy arrangements

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<sup>49</sup> *Assisted Reproductive Technology Act 2007* (NSW) s 4(1).

<sup>50</sup> *Assisted Reproductive Technology Act 2007* (NSW) s 41A.

<sup>51</sup> See *Assisted Reproductive Technology Act 2007* (NSW) s 41F and *Assisted Reproductive Technology Regulation 2014* (NSW) r 20. See also Legislative Council Standing Committee on Law and Justice, Parliament of New South Wales, *Legislation on Altruistic Surrogacy in NSW* (2009) [3.73]-[3.75].

<sup>52</sup> *Assisted Reproductive Technology Act 2007* (NSW) s 41F.

<sup>53</sup> *Status of Children Act 1996* (NSW) s 14.

<sup>54</sup> *Surrogacy Act 2010* (NSW) s 17(3)(d).

<sup>55</sup> *Status of Children Act 1978* (NT) Pt IIIA.

<sup>56</sup> *Status of Children Act 1978* (NT) s 5C.

<sup>57</sup> *Status of Children Act 1978* (NT) s 5A(1).

<sup>58</sup> *Status of Children Act 1978* (NT) s 5E.

<sup>59</sup> *Status of Children Act 1978* (NT) s 5C.

<sup>60</sup> *Status of Children Act 1978* (Qld) ss 19, 19E, 23.

regardless of whether there is a genetic relationship between the child and any of the parties to the arrangement.<sup>61</sup> There is no definition of genetic relationship.

When addressing an application for a parentage order, the *Surrogacy Act* requires the Court to be satisfied that a report by an independent counsellor supports the parentage transfer.<sup>62</sup> There is no express requirement that the report provide information regarding genetic relationships. However, as in the other jurisdictions, the report is required to address certain matters. These include each party's understanding of the social and psychological implications of parentage transfer and that openness and honesty about the child's birth parentage are needed for the wellbeing of the child.<sup>63</sup>

## South Australia

The *Assisted Reproductive Treatment Act 1988* (SA) adopts the requirements of the NHMRC Guidelines and professional registration rules into law.<sup>64</sup> The terms genetic or biological parent are not used in that legislation. However, there is reference to donors of human reproductive material, that material being defined as a human embryo, human semen and a human ovum.<sup>65</sup> This would include mt donors.

In regards to children conceived following fertilisation procedures, whether donor-conceived or born through a surrogacy arrangement, as in the other States any woman that gives birth is the mother<sup>66</sup> and the egg donor is not the child's mother.<sup>67</sup>

Under the *Family Relationships Act 1975* (SA), recognition of a surrogacy agreement so that parentage transfer can occur requires that the agreement, inter alia, provide that the parties intend that at least one of the intending parents will provide "human reproductive material" with respect to creating an embryo for the purposes of the pregnancy,<sup>68</sup> unless the intending parents satisfy a medical-based exemption.<sup>69</sup> Such an exemption requires both intending parents to be infertile or unable to provide human reproductive material to create an embryo for medical reasons.<sup>70</sup> Like the State's ART legislation, the parentage legislation uses the term "human reproductive material" rather than genetic or biological material, and defines this as "human semen or a human ovum".<sup>71</sup> This would include mt donors but not gestational surrogates.

## Tasmania

Tasmania does not have legislation regulating donor conception, instead adopting the same approach as the ACT. Its *Status of Children Act 1974* (Tas) provides that any woman becoming pregnant other than as a result of sexual intercourse is to be treated as the child's mother and the egg donor is not to be treated as the child's mother.<sup>72</sup>

The *Surrogacy Act 2012* (Tas) provides for the transfer of parentage from the birth mother to the intending parent(s) in certain circumstances. The Act includes the same guiding principle regarding genetic relatedness as the Queensland legislation.<sup>73</sup> However, unlike in Queensland, the Act permits a

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<sup>61</sup> *Surrogacy Act 2010* (Qld) s 6(2)(b)(ii).

<sup>62</sup> *Surrogacy Act 2010* (Qld) s 22(2)(i). This can be dispensed with in exceptional circumstances pursuant to s 23(2).

<sup>63</sup> *Surrogacy Act 2010* (Qld) s 32(d).

<sup>64</sup> *Assisted Reproductive Treatment Regulations 2010* (SA) r 8.

<sup>65</sup> *Assisted Reproductive Treatment Act 1988* (SA) s 3.

<sup>66</sup> *Family Relationships Act 1975* (SA) s 10C(1).

<sup>67</sup> *Family Relationships Act 1975* (SA) s 10C(2).

<sup>68</sup> *Family Relationships Act 1975* (SA) s 10HA(2)(viii)(B).

<sup>69</sup> *Family Relationships Act 1975* (SA) s 10HA(2)(viii)(B), (5).

<sup>70</sup> *Family Relationships Act 1975* (SA) s 10HA(5).

<sup>71</sup> *Family Relationships Act 1975* (SA) s 10HA(1).

<sup>72</sup> *Status of Children Act 1974* (Tas) s 10C.

<sup>73</sup> *Surrogacy Act 2012* (Tas) s 3(2)(b)(ii).



Court addressing applications for parentage orders to request an independent counsellor's report on matters, including "any arrangements proposed for the child to have contact with his or her birth parent or birth parents or a person, other than an intending parent, who has provided some of the child's genetic material".<sup>74</sup> There is no definition of genetic relationship or genetic material but it is submitted these terms include mt donors.

## Victoria

The *Assisted Reproductive Treatment Act 2008* (Vic) (ART Act) allows donor conception and provides for donor-conceived children to obtain identifying information on their donors.<sup>75</sup> It reinforces this right by providing in its guiding principles that "children born as result of the use of donated gametes have a right to information about their genetic parents".<sup>76</sup> Although the term genetic parents is used, the term is undefined. Donor gamete is defined to include donor eggs and so would include mt donors.<sup>77</sup> The *Status of Children Act 1974* (Vic) creates the same irrebuttable statutory presumptions regarding motherhood, as is the case with the NSW legislation.<sup>78</sup>

The provisions in the ART Act regarding surrogacy involving an ART provider result in a requirement for an absence of a genetic link between the surrogate and child if the intending parents want to become the legal parents of the resulting child. Unless and until a transfer of parentage occurs, the same presumptions under the *Status of Children Act* as described above apply.<sup>79</sup> Under the *Status of Children Act*, where an ART provider is involved in the child's conception, transfer of parentage from surrogate to the intending parents can only occur where the Victorian Patient Review Panel (PRP), the body responsible for decision-making regarding many ART procedures under the ART Act,<sup>80</sup> has pre-approved the ART procedure.<sup>81</sup> Pursuant to the ART Act, PRP approval of surrogacy arrangements requires, amongst other things, that the surrogate mother's egg not be used in conception,<sup>82</sup> although that can be waived in exceptional circumstances and if it is reasonable to do so.<sup>83</sup> Other considerations can also be considered by the Court. However, where an ART provider is not involved in the surrogacy, prior approval by the PRP is unnecessary and the restriction on genetic surrogacy will not apply. The *Status of Children Act* allows for parentage to be transferred from the surrogate to the intending parents by parentage order despite the genetic connection in those cases. There is no use of the term genetic or biological parent in the Victorian parentage legislation.

The restriction on the use of surrogates' eggs in ART-assisted surrogacy was a last minute addition to the parentage legislation.<sup>84</sup> It is justified in the *Parliamentary Debates* on the basis that it meant the surrogate "will not have her genetic or biological material in that child".<sup>85</sup> This was considered necessary to accommodate community expectations and concerns,<sup>86</sup> although there was no evidence the restriction was to the child's benefit. As this provision predates clinical use of mt donation, there is no discussion of the possibility of more than one egg donor being involved in a

<sup>74</sup> *Surrogacy Act 2012* (Tas) s 18(2)(d).

<sup>75</sup> *Assisted Reproductive Treatment Act 2008* (Vic) Pt 6.

<sup>76</sup> *Assisted Reproductive Treatment Act 2008* (Vic) s 5(c).

<sup>77</sup> *Assisted Reproductive Treatment Act 2008* (Vic) s 3.

<sup>78</sup> *Status of Children Act 1974* (Vic) ss 10E(2)(a), (b) and (3), 13(1)(a) and (2), 14(1)(a), (d) and (2), 16(1)(a), (c) and (2).

<sup>79</sup> *Status of Children Act 1974* (Vic) s 19.

<sup>80</sup> *Assisted Reproductive Treatment Act 2008* (Vic) Pt 9.

<sup>81</sup> *Status of Children Act 1974* (Vic) s 22(1)(b).

<sup>82</sup> *Assisted Reproductive Treatment Act 2008* (Vic) s 40(1)(ab).

<sup>83</sup> *Assisted Reproductive Treatment Act 2008* (Vic) s 41.

<sup>84</sup> Trowse, n 19. See Victoria, *Parliamentary Debates*, Legislative Council, 4 December 2008, 5442 (Brian Tee).

<sup>85</sup> Victoria, n 84, 5442 (Brian Tee).

<sup>86</sup> Victoria, n 84, 5444 (Gavin Jennings).

child's conception. It is also noteworthy that justification for prohibiting a genetic link between surrogate and child entirely ignores the biological impact of the surrogate on the resulting child's genes.

### Western Australia

The *Human Reproductive Technology Act 1991* (WA) addresses both ART and embryonic research. While this Act refers to genetic parents, it does not define the term. Instead, it defines biological parent by reference to genetic parent providing that a biological parent is a person who:

- (a) is the source of a human egg or human sperm used in an artificial fertilisation procedure; and
- (b) is the genetic parent of a human embryo developed, or of a child born, as a consequence of that procedure.<sup>87</sup>

This would include mt donors but not gestational surrogates.

The *Artificial Conception Act 1985* (WA) concerns "the status of persons conceived by artificial means". There is no definition of genetic material, but the legislation provides that the donor of genetic material has no status as parent.<sup>88</sup> Under the general rule regarding presumption of maternity, the birth mother is the child's mother.<sup>89</sup>

In regards to surrogacy, WA requires any surrogacy arrangement to have been approved by an oversight body (Western Australian Reproductive Technology Council), prior to the surrogacy taking place, if a court is to subsequently make a parentage order.<sup>90</sup> Amongst other things, the *Surrogacy Act 2008* (WA) provides that approval by the Council requires satisfaction of certain mandatory conditions. These include that the surrogacy arrangement is signed by all parties, including "any other person (a donor) whose egg or sperm is to be used for the conception of the child".<sup>91</sup> This would include mt donors. However, the court can dispense with certain requirements when making parentage orders (namely around the need for the surrogate to consent to the transfer, be counselled and receive legal advice regarding this, and the need for the child to be living with the intending parents at the time of the application)<sup>92</sup> if the child is genetically related to one or both intending parent and is not genetically related to the birth mother.<sup>93</sup> Genetic parent is defined for these purposes as "a person from whose egg or sperm the child is conceived" and would include mt donors but not gestational surrogates.<sup>94</sup> The purpose of these exceptions is to address cases where a surrogate refuses to surrender the child and privileges the genetic parent's interests over other considerations in the event of such a dispute.

### Summary

The examination above shows that intending parent(s) in donor conception cases are the legal parents of the child and that genetic relationships between the child and gamete donors are irrelevant to legal parentage. This reflects society's expectations that such children be the legal children of those desiring to raise them and that it is in their best interests that this occur. In such cases, the birth mother who gestates the child will also be the intending mother so prioritisation between gestating and intending mother is unnecessary. In surrogacy arrangements, though, the law preferences the gestating mother by making her the child's legal parent at birth. However, in this case the gestating mother is not the intending mother and it is submitted that this preferencing is inconsistent with society's expectations regarding legal parentage as demonstrated in its regulation of the parentage of donor-conceived children.

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<sup>87</sup> *Human Reproductive Technology Act 1991* (WA) s 3.

<sup>88</sup> *Artificial Conception Act 1985* (WA) s 7.

<sup>89</sup> *Artificial Conception Act 1985* (WA) s 5(1).

<sup>90</sup> *Surrogacy Act 2008* (WA) s 16(1).

<sup>91</sup> *Surrogacy Act 2008* (WA) s 17(b)(iii).

<sup>92</sup> *Surrogacy Act 2008* (WA) ss 21(3) and 21(2)(e) respectively.

<sup>93</sup> *Surrogacy Act 2008* (WA) s 21(4).

<sup>94</sup> *Surrogacy Act 2008* (WA) s 21(5).

The above examination also shows that it can be expected that mt donors will be treated as genetic parents and therefore will not have legal parentage of resulting children. In contrast, the law endows gestational surrogates, who also have a biological relationship with the child, with legal parentage of the child. Confusingly, parentage legislation then instructs courts considering parentage transfer from the surrogate to the intending parents that genetic relationships are relevant without clearly explaining how so. These problems are discussed next by first considering the law's preferencing of genes over gestation in determining genetic parentage and then the law's preferencing of gestation over genes in regards to legal parentage.

## DISCUSSION

### Genetic parents: Preferencing genes over gestation

The concepts of genetic and biological relatedness are used interchangeably in State regulation of egg donation. For those jurisdictions relying on the NHMRC Guidelines to regulate egg donation (ACT, NT, Queensland and Tasmania), various genetic relationships, namely parent, offspring and sibling, are referred to and recognised but undefined. The term gamete provider is also used, defined as "the person who is the biological (that is, genetic) source of the gamete".<sup>95</sup> This would include mt donors but not gestational surrogates.

Amongst the four States with legislation regulating egg donation, two – NSW and SA – regulate without reference to genetic parent, although the NSW legislation uses the term biological parent, which is not defined. Like the NHMRC Guidelines, the legislation of both States instead refers to gamete provider (in NSW) or donor of human reproductive material (in SA) and this would include mt donors but not gestational surrogates. Victorian and WA legislation use the term genetic parents but do not define it. The WA legislation also uses biological parent, defined by reference to the genetic parent, providing that the biological parent is, inter alia, the genetic parent of the resulting child. The Victorian Act uses the defined terms donor and donor gamete but refers to the genetic parents of a child in its Guiding Principles. Neither the NHMRC Guidelines nor State legislation imposes a restriction on having more than two genetic parents.

Given that mt donation requires the donation of an egg, there is no scientific reason or regulatory language requiring that a distinction be drawn between nuclear DNA egg donors and mtDNA egg donors. There is no limit in science or law to one egg in relation to the conception of the same individual. Two egg donors can therefore each be treated as the genetic parents of the same child. However, genetic or biological relatedness for the purposes of egg donation regulation is dependent on the contribution of a gamete, such as an egg, towards a child's conception. Therefore, while science may treat gestational surrogates as a biological and possibly genetic parent because of the significant clinical effects of gestation on the child's genes, the law will not. Mt donors, on the other hand, while possibly having less impact than gestational surrogates on the child's genes, will be genetic parents for both scientific and Australian legal purposes.

In contrast, although the UK Government has acknowledged that three individuals contribute to the child's DNA where mt donation is used, mt donors are excluded as genetic parents by regulations providing that mt donors are not to be treated as a person who provided gametes for the creation of the embryo.<sup>96</sup> According to the Explanatory Note, the purpose of this is to clarify that there is no legal relationship between the donor and the resulting child and that the donor cannot apply for a parental order on the basis of that donation alone.<sup>97</sup> The Explanatory Memorandum explains that this reflects the government's position that mt donors do not have the same legal status as full gamete donors<sup>98</sup>

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<sup>95</sup> NHMRC, n 27, Explanation of Key Terms, gamete and gamete provider.

<sup>96</sup> *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* (UK) reg 18, amending *Human Fertilisation and Embryology Act 1990* (UK) s 54.

<sup>97</sup> Explanatory Note, *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* (UK).

<sup>98</sup> Explanatory Memorandum, *Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015* (UK) [7.12].

because mtDNA does not impact the child's physical characteristics.<sup>99</sup> In the UK then, the impact of mt donation on the resulting child is considered to be of insufficient impact to justify any claim to genetic or legal parentage.

Before leaving donor conception, it should be noted that the NHMRC Guidelines and Victorian and WA legislation all expressly prohibit the deliberate confusion of children's biological parentage. Mixing gametes, embryos or eggs undergoing fertilisation from different donors in the same ART procedure so that it is not possible (without genetic testing) to know who is/are the genetic parents is prohibited.<sup>100</sup> This would not necessarily prevent mt donation but would require that mtDNA from the same woman be used in the creation of all embryos implanted at the same time in an intending mother.

Turning to surrogacy, all States again use the concepts of genetic or biological relatedness in their regulation, in particular in relation to parentage. Legislation in the ACT, SA and WA all use the concept of genetic parent (although SA's term is provider of human genetic material) defined essentially as a person whose gametes are used to create the embryo. NSW uses the term biological parent and Queensland uses genetic relationship but neither defines the terms. The Tasmanian Act refers to a person who provides some of the child's genetic material, but does not define genetic material. While one State, ACT, expressly provides that a child cannot have more than two parents at any one time, this is in regards to legal rather than genetic, parentage. Again, mt donors would be included in the concept of genetic parent for the purposes of surrogacy regulation but gestational surrogates would not.

The majority of the most recent round of parliamentary and law reform commission inquiries into surrogacy also treated genetic and biological relatedness as the same concept, and failed to acknowledge that gestation has an important biological impact on the resulting child's genetics.<sup>101</sup> However, the NSW and Queensland inquiries noted they had received submissions pointing out the biological link created by gestation<sup>102</sup> and the NSW body commented that for that reason care should be taken in using the terms in regards to surrogacy. More broadly, the Queensland report expressly considered the importance of a genetic connection concluding that "[i]t is clear to the committee that genetic connection means different things to different people".<sup>103</sup> However, as with all of these inquiries, the Queensland report predates the possibility of clinical use of mt donation and therefore genetic relatedness simply refers to the provision of a gamete. That more than two eggs may be involved in the creation of one embryo is not addressed. This means that mt donors will be genetic parents of both donor-conceived children and children born through surrogacy arrangements. The parentage laws around the use of donor gametes, however, sever those links for legal purposes. In the surrogacy legislation, though, statutory processes are provided to genetic parents that can lead to parentage transfer or at least make that relatedness a relevant consideration.

Whether mt donors are treated in the same way as other egg donors and considered a genetic (or biological) parent of the child is significant. Being a genetic parent creates legal obligations including providing identifying information, that information be recorded and disclosed to certain people, in particular the resulting child. The UK regulation means that mt donors will not be treated as persons

<sup>99</sup> Department of Health (UK), n 5, 15-16.

<sup>100</sup> NHMRC, n 27, Guideline 6.1; *Human Reproductive Technology Act 1991* (WA) s 17. Directions made for the purposes of the Act, provide that there is to be no deliberate confusion of biological parentage: *Human Reproductive Technology Act Directions* (2004) Direction 8.6 <[http://www.slp.wa.gov.au/gazette/GAZETTE.NSF/gazlist/28FA432BECED857B48256F58002444B8/\\$file/gg201.pdf](http://www.slp.wa.gov.au/gazette/GAZETTE.NSF/gazlist/28FA432BECED857B48256F58002444B8/$file/gg201.pdf)>; *Assisted Reproductive Treatment Act 2008* (Vic)s 27(1).

<sup>101</sup> Legislative Council Standing Committee on Law and Justice, n 51; Investigation into Altruistic Surrogacy Committee, Parliament of Queensland, *Report* (2008); Social Development Committee, Parliament of South Australia, *Inquiry into Gestational Surrogacy* (2007); Legislative Council Select Committee on Surrogacy, Parliament of Tasmania, *Report on Surrogacy* (2008); Victorian Law Reform Commission, *Assisted Reproductive Technology and Adoption: Final Report* (2007); Department of Health (WA), *Review of the Surrogacy Act 2008* (2014). The NSW Attorney-General is also currently undertaking a statutory review of the NSW Act.

<sup>102</sup> Legislative Council Standing Committee on Law and Justice, n 51, [3.69]; Investigation into Altruistic Surrogacy Committee, n 101, 45-46.

<sup>103</sup> Investigation into Altruistic Surrogacy Committee, n 101, 54.

who provided gametes for the creation of the embryo and so are excluded as genetic parents and only non-identifying information about them will be available to the child. The UK Government's view is that mt donation is fundamentally different to gamete donation and that "[a]s a matter of biological fact, the contribution made by a mitochondrial donor is quite different to that of a full genetic donor".<sup>104</sup> In effect, the mt donor is treated like a donor of non-reproductive tissue, such as kidneys or blood. Whether this is satisfactory for the resulting child will require more study into the ramifications of such conception in resulting children.<sup>105</sup> However, it is observed here that unlike non-reproductive tissue, for females at least, the mt genes are passed onto their offspring and this alone makes mt donation different.

If mt donors are recognised as genetic parents of the resulting child, new developments in science will continue to push this boundary. The media reported in April 2015 that overseas trials have replaced a single gene in a human embryo with a "healthy" gene from a donor.<sup>106</sup> If, and when, such modification becomes reality in children's conception, should the contribution of a single gene be sufficient to make the donor a genetic parent of any resulting child? Should it matter whether the gene concerned is part of the nuclear rather than mtDNA? The Nuffield Council on Bioethics review into mt donation observed that "[i]t is our view that the clear material difference between mitochondrial and nuclear genes means, in practice, that the adoption of [mt donation] would not necessitate the adoption of nuclear transfer or nuclear modification technologies if they were to emerge in future". The Council also noted that nuclear modification was outside their remit and did not comment on its desirability.<sup>107</sup> The amount and type of DNA contributed is not relevant to genetic relatedness under current State regulatory frameworks, except that there is a requirement that donors provide a gamete.<sup>108</sup>

### Legal parents: Preferencing gestation over genes

The clear genetic link between mtDNA egg donor and the resulting child is rendered irrelevant to legal parentage in all jurisdictions by legislation providing that gamete donors have no claim to parentage. As noted above, this is also the case under the UK regulation of the mt technique. Before ART's development, it was medically impossible to separate maternal genetics from gestation. When egg or embryo donation became clinically possible, it was recognised that it was not clear in Australian law that gestation was sufficient to ensure that the gestating mother was the child's legal mother. All jurisdictions therefore amended their legislation to clarify that gestational mothers of donor-conceived children were the legal mothers without any formal legal process needing to be followed, even where there was no genetic relationship between gestational mother and child. This approach is generally thought to be appropriate because the gestational mother is the (or one of the) person(s) intending to parent the child and it reflects the view that it is usually in the child's best interests that the person who intends to parent them be recognised as legal parent, regardless of genetic parentage.<sup>109</sup>

The legislation around parentage in surrogacy, however, has the opposite result. The Victorian surrogacy inquiry concluded that intending parents should have the same powers and responsibilities as all other parents. Nevertheless, it recommended that "recognition of [intending parents'] parental

<sup>104</sup> Department of Health (UK), n 5, 36, also explaining why the concerns raised in the Nuffield Council on Bioethics, *Donor Conception: Ethical Aspects of Information Sharing Report* (2013), could be disregarded.

<sup>105</sup> The Victorian Law Reform Commission noted there had been little work around the "significance donor-conceived people attach to their donors and the absence of genetic connection with their parents": Victorian Law Reform Commission, n 101, 119.

<sup>106</sup> Reuters, "Chinese Experiment which 'Edits' DNA of Human Embryos", *ABC News*, 25 April 2015 <<http://www.abc.net.au/news/2015-04-24/human-embryos-editing-experiment-ignites-ethical-furore/6418818>>. See further Puping Liang et al, "CRISPR/Cas9 – Mediated Gene Editing in Human Triprenuclear Zygotes" (2015) 6 *Protein & Cell* 363; Ainsley J Newson and Anthony Wrigley, "Identifying Key Developments, Issues and Questions Relating to Techniques of Genome Editing with Engineered Nucleases" (Background Paper, Nuffield Council on Bioethics, 2015).

<sup>107</sup> Nuffield Council on Bioethics, n 6, [5.5].

<sup>108</sup> DNA modification of an early stage embryo is illegal under Australian law: *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) s 15(1).

<sup>109</sup> See Susan B Boyd, "Gendering Legal Parenthood: Bio-genetic Ties, Intentionality and Responsibility" (2007) 25 *Windsor YB Access Just* 63, regarding competing claims of intentionality and genetic ties in legal parenthood.

status should be subject to court supervision”.<sup>110</sup> This approach, taken in all States and the ACT, preferences the gestational surrogate’s interests over those of the child and intending parents. Legislation makes the surrogate the child’s legal mother unless and until there is a parentage transfer after birth regardless of the fact that there is no intention, at least at conception, that the surrogate parent the child and that a gestational surrogate is not the child’s genetic parent for the purposes of egg donation, surrogacy and parentage legislation.<sup>111</sup> There is also a compulsory delay in all jurisdictions except NSW, before which a parentage transfer can occur.<sup>112</sup> Further, in all jurisdictions whether the child is living with the intending parents is a relevant consideration, and in three States (Queensland, Tasmania and WA) this is a requirement before parentage transfer can occur.<sup>113</sup> The child therefore must be raised by people who cannot be its legal parents and cannot make particular decisions regarding the child’s welfare until a prescribed period has passed. As Sheldon has observed, this may leave some children particularly vulnerable and, it is submitted here, is not in their best interests.<sup>114</sup>

All jurisdictions (except NT) address genetic relatedness in regards to parentage transfer, in many cases instructing the court that it is a matter of relevance. The relationship created by mt donation would be included in these considerations. ACT, SA, Victoria and WA require the intending parents to be genetically related to the child to become the legal parent and/or no genetic relationship between surrogate and child for that to happen. WA goes the furthest, albeit in limited circumstances, allowing intending parents to override a surrogate’s claim to legal parentage and have parentage transferred away from her if there is a genetic relationship between intending parents and child and not between surrogate and child. The genetic link is therefore prioritised.

In Queensland and Tasmania, legislation provides that children born through surrogacy arrangements have the same status, protection and support regardless of whether there is a genetic relationship between the child and any other parties to the arrangement. Genetic relationship is not defined, although the legislation’s requirements mean that for this principle to be relevant where mt donation was used, the mt donor would have to be party to the surrogacy arrangement. When making a decision on parentage transfer, courts in NSW, Queensland and Tasmania may consider an independent counsellor’s report which could address genetic relationship issues and in NSW and Tasmania this is expressly required to be included. The Tasmanian legislation expressly includes arrangements for the child to have contact with “a person, other than an intending parent, who has provided some of the child’s genetic material” as a matter that a court may request the report to address. In NSW, a report must accompany transfer applications, which includes contact arrangements between the child and his or her biological parent(s).

While all States require parentage decisions to be made in the child’s best interests, none of them clearly explain the prioritisation of genetic and intending parentage. In light of legislative responses to donor conception, it is arguable that intending parents should be given priority and that other third parties, whether mt donor or gestational surrogate, should not.

## CONCLUSION

Although children’s best interests support legal parentage by those who parent them, parentage legislation preferences gestating mothers over intending parents in surrogacy arrangements. The interests of the child, and intending parents, are intended to be met by allowing parentage transfer

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<sup>110</sup> Victorian Law Reform Commission, n 101, 8.

<sup>111</sup> The Victorian Law Reform Commission also noted that making the surrogate the legal parent at birth meant that the surrogate may find herself responsible for a child not originally intended to be hers: Victorian Law Reform Commission, n 101, 173.

<sup>112</sup> *Parentage Act 2004* (ACT) s 25(3); *Surrogacy Act 2010* (NSW) s 16; *Surrogacy Act 2010* (Qld) s 21(1); *Family Relationships Act 1975* (SA) s 10HB(5); *Surrogacy Act 2012* (Tas) s 15; *Status of Children Act 1974* (Vic) s 20(2); *Surrogacy Act 2008* (WA) s 20.

<sup>113</sup> *Parentage Act 2004* (ACT) s 26(3)(a); *Surrogacy Act 2010* (NSW) s 33; *Surrogacy Act 2010* (Qld) s 22(2)(b); *Family Relationships Act 1975* (SA) s 10HB(9)(a); *Surrogacy Act 2012* (Tas) s 16(2)(j)(i); *Status of Children Act 1974* (Vic) s 22(1)(c); *Surrogacy Act 2008* (WA) s 21(2)(e).

<sup>114</sup> Sheldon, n 3, 83.

from surrogate to intending parent(s) after the child's birth. Further, in decision-making in such cases all State and Territory courts may (and in some jurisdictions, must) consider the presence or absence of genetic links between the surrogate and child or intending parent(s) and child.

This instruction to the courts sits uneasily with the approach taken in all jurisdictions to gamete donors, whereby genetic relatedness is dismissed to prevent claims to legal parentage by gamete donors. That tension creates confusion regarding the weight courts should give to the presence or absence of genetic and biological links and the contact the child has with such "relatives".

It would be better for both children and intending parents if gestational surrogates were treated in the same way as adults with genetic relationships with the child, and have their parentage claims severed at birth.<sup>115</sup> Such an approach would mean that families' reproductive choice to use surrogacy will not inevitably cause them to go through the emotional and economic costs of seeking court approval of parentage transfer. Instead, such families will have the same status and protection as families created using other reproductive methods and the law will reflect all parties' intentions at the time the surrogacy is arranged.

**TABLE: GENETICS IN AUSTRALIAN REGULATION OF EGG DONATION, SURROGACY AND PARENTAGE**

Jurisdiction	Use of donor eggs	Use of surrogacy	Parentage – Donor eggs used	Parentage – Surrogacy used
ACT	NHMRC Guidelines on ART 2007 <ul style="list-style-type: none"> <li>• "gamete provider" defined as "[t]he person who is the biological (that is, genetic) source of the gamete"</li> <li>• "In these guidelines, the term 'donated gametes' is used when the gametes are provided by a third person who, while being the genetic parent of the person born, will not be the social parent"</li> <li>• "genetic parent/offspring/sibling/ material" used but not defined</li> </ul>	NHMRC Guidelines on ART 2007 <ul style="list-style-type: none"> <li>• genetic and gestational surrogacy controversial</li> <li>• notes genetic relatedness considerations in surrogacy debate</li> </ul>	<i>Parentage Act 2004</i> <ul style="list-style-type: none"> <li>• conclusive statutory presumption of motherhood for any woman becoming pregnant other than as result of sexual intercourse</li> <li>• conclusive statutory presumption that egg donor is not child's mother</li> </ul>	<i>Parentage Act 2004</i> <ul style="list-style-type: none"> <li>• parentage order application can be made if inter alia: <ul style="list-style-type: none"> <li>- neither birth parent is a genetic parent</li> <li>- at least one intending parent is genetic parent</li> </ul> </li> <li>• "genetic parent" defined as "a person whose gametes [undefined] were used to create the embryo"</li> </ul>

<sup>115</sup> Exceptional procedures could be introduced to allow for parentage transfer to the surrogate to address those cases where a surrogate changes her mind regarding parenting of the child.

Genes and gestation in Australian regulation of egg donation, surrogacy and mitochondrial donation

Jurisdiction	Use of donor eggs	Use of surrogacy	Parentage – Donor eggs used	Parentage – Surrogacy used
<b>NSW</b>	<i>Assisted Reproductive Technology Act 2007</i> <ul style="list-style-type: none"> <li>• “gamete provider” defined as “in relation to a gamete, means the individual from whom the gamete has been obtained and in relation to an embryo means an individual from whom a gamete used to create the embryo was obtained”</li> <li>• “genetic” not used</li> <li>• “biological parent” used but not defined</li> </ul>	<i>Assisted Reproductive Technology Act 2007</i> <ul style="list-style-type: none"> <li>• “biological sibling” used and defined by reference to “blood”</li> </ul>	<i>Status of Children Act 1996</i> <ul style="list-style-type: none"> <li>• irrebuttable statutory presumption of motherhood for any woman becoming pregnant other than as result of sexual intercourse</li> <li>• irrebuttable statutory presumption that egg donor is not child’s mother</li> </ul>	<i>Surrogacy Act 2010</i> <ul style="list-style-type: none"> <li>• parentage order application to be accompanied by independent counsellor’s report on matters, including “any contact arrangements proposed in relation to the child and his or her birth parent or parents or biological parent or parents”</li> <li>• “genetic parent” not used</li> <li>• “biological parent” used but not defined</li> </ul>
<b>NT</b>	See ACT	See ACT	<i>Status of Children Act 1978</i> <ul style="list-style-type: none"> <li>• any woman who gives birth is child’s mother</li> <li>• egg donor is not mother of any donor-conceived child</li> <li>• does not use “genetic”, “biological” or “gamete provider”</li> </ul>	<i>Status of Children Act 1978</i> <ul style="list-style-type: none"> <li>• general “maternity” provisions mean birth mother is legal mother</li> <li>• no legislation providing for parentage transfer</li> </ul>
<b>QLD</b>	See ACT	See ACT	<i>Status of Children Act 1978</i> See NSW	<i>Surrogacy Act 2010</i> <ul style="list-style-type: none"> <li>• guiding principle that same status, protection and support available to children born as result of surrogacy arrangements regardless of whether there is a genetic relationship between child and any parties to the arrangement</li> <li>• “genetic relationship” used but not defined</li> <li>• independent counsellor’s report required with parentage application but no express requirement regarding discussion of genetic relationship</li> <li>• “genetic” or “biological parent” not used</li> </ul>



Jurisdiction	Use of donor eggs	Use of surrogacy	Parentage – Donor eggs used	Parentage – Surrogacy used
SA	<p><i>Assisted Reproductive Treatment Act 1988</i></p> <ul style="list-style-type: none"> <li>adopts NHMRC Guidelines – see ACT</li> <li>“genetic” or “biological parent” not used</li> <li>“donor of human reproductive material” used, such material defined as including “a human ovum”</li> </ul>	See SA – Use of donor eggs	<p><i>Family Relationships Act 1975</i></p> <ul style="list-style-type: none"> <li>for children conceived following fertilisation procedures, woman that gives birth is mother</li> <li>egg donor is not child’s mother</li> </ul>	<p><i>Family Relationships Act 1975</i></p> <ul style="list-style-type: none"> <li>recognition of surrogacy agreement to enable parentage transfer requires at least one intended parent be genetic parent of child (subject to medical based exceptions)</li> <li>provider of “human reproductive material” (defined to mean sperm or an ovum) used rather than genetic parent</li> </ul>
TAS	See ACT	See ACT	<p><i>Status of Children Act 1974</i></p> <ul style="list-style-type: none"> <li>any woman becoming pregnant other than as result of sexual intercourse is treated as mother</li> <li>egg donor treated as not being child’s mother</li> </ul>	<p><i>Surrogacy Act 2012</i></p> <ul style="list-style-type: none"> <li>same guiding principle as QLD</li> <li>Court may request independent counsellor’s report on matters including “any arrangements proposed for the child to have contact with his or her birth parent or birth parents or a person, other than an intended parent, who has provided some of the child’s genetic material”</li> <li>“genetic relationship / material” not defined</li> </ul>
VIC	<p><i>Assisted Reproductive Treatment Act 2008</i></p> <ul style="list-style-type: none"> <li>guiding principle that “children born as the result of the use of donated gametes have a right to information about their genetic parents”</li> <li>“genetic parents” not defined</li> <li>“donor gametes” includes donor eggs</li> </ul>	<p><i>Assisted Reproductive Treatment Act 2008</i></p> <ul style="list-style-type: none"> <li>surrogacy involving ART provider can only be approved if surrogate’s egg not used or requirement waived by Panel</li> <li>“genetic” or “biological parent” not used</li> <li>surrogacy not involving ART provider has no requirements re genetic parentage</li> </ul>	<p><i>Status of Children Act 1974</i></p> <p>See NSW</p>	<p><i>Status of Children Act 1974</i></p> <ul style="list-style-type: none"> <li>“genetic” or “biological” parent not used</li> <li>can transfer parentage where ART provider involved, only if PRP pre-approved ART procedure</li> <li>“other” relevant considerations can be taken into account by court</li> <li>if ART provider not involved in surrogacy, parentage transfer can occur regardless of genetic link between surrogate and child</li> </ul>

Genes and gestation in Australian regulation of egg donation, surrogacy and mitochondrial donation

Jurisdiction	Use of donor eggs	Use of surrogacy	Parentage – Donor eggs used	Parentage – Surrogacy used
WA	<p><i>Human Reproductive Technology Act 1991</i></p> <ul style="list-style-type: none"> <li>• “genetic parents” used but not defined</li> <li>• “biological parent” used and defined by reference to “genetic parent” as: “a biological parent is a person who: (a) is the source of a human egg or human sperm used in an artificial fertilisation procedure; and (b) is the genetic parent of a human embryo developed, or of a child born, as a consequence of that procedure”</li> </ul>	<p><i>Surrogacy Act 2008</i></p> <ul style="list-style-type: none"> <li>• pre-approval of arrangement requires, inter alia, signed written agreement by “any other person (a donor) whose egg ... is to be used for conception of the child”</li> </ul>	<p><i>Artificial Conception Act 1985</i></p> <ul style="list-style-type: none"> <li>• birth mother is mother of child</li> <li>• donor of “genetic material” has no status as parent</li> <li>• “genetic material” not defined</li> </ul>	<p><i>Surrogacy Act 2008</i></p> <ul style="list-style-type: none"> <li>• parentage transfer requires pre-approval of surrogacy arrangement</li> <li>• court can dispense with certain requirements including surrogate’s consent if: - surrogate is not a genetic parent and - at least 1 arranged parent is a genetic parent</li> <li>• “genetic parent” defined for these purposes as “a person from whose egg or sperm the child is conceived”</li> </ul>