Government of **Western Australia**
North Metropolitan Health Service
Women and Newborn Health Service

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Associate Professor Sonia Allan
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Dear Associate Professor Allan,

Thank you for allowing the opportunity for the Women and Newborn Health Service to contribute to the review of the Western Australian *Human Reproductive Technology Act 1991* (the Act) and the *Surrogacy Act 2008*.

The Women and Newborn Health Service is Western Australia's tertiary public obstetrics, gynaecology, neonatal and perinatal mental health service; caring for women of all ages and life stages and newborns. This submission has been prepared by the Women's Health, Genetics and Mental Health Directorate (WHGMH Directorate), consisting of King Edward Memorial Hospital for Women-based and several state-wide programs which address:

Genetic Services of WA;
WA Register of Developmental Anomalies;
Perinatal and infant mental health care;
Allied Health services;
Crisis care and counselling following sexual assault;
Cervical cancer prevention;
Women's health policy and procurement of services for women's health,
Sexual assault and unplanned pregnancy; and
Education on perinatal mental health; Family and Domestic Violence; and Female Genital Mutilation/Cutting.

The views expressed in this submission are those of the Women and Newborn Health Service as part of the North Metropolitan Health Service, and do not necessarily reflect those of other WA Health Service Providers, the Western Australian Department of Health, or the Western Australian Government.

The submission, corresponding largely to the review Terms of Reference and focused primarily on the *Human Reproductive Technology Act*, is outlined below. We have made a total of 23 recommendations. Additional thematic comment relevant to the expertise of the WHGMH Directorate appears throughout and at the end of the submission.

Research and experimentation on gametes, eggs in the process of fertilisation, and embryos
It is clear that a number of prohibited offences under the Act are now being used in experimental international research, which may be relevant or become relevant if adopted within Western Australian research settings.

For example, prohibited offences under the current Act which could be reviewed include:

53G. Offence — creating human embryo other than by fertilisation, or developing such an embryo (p. 97);
53N. Offence — creating chimeric or hybrid embryo (p. 100);
53O. Offence — A person commits a crime if they place a human embryo in an animal (p. 100)
In an international research context, these experimental techniques are being considered to create animals with human tissue which are gestated by an animal, for the purpose of developing compatible saviour organs for transplant – the experimental process of interspecies blastocyst complementation.
53C. Offence — creating human embryo clone (p. 96)
This technique may be used to create stem cell tissue for research.

From a longer-term ethical perspective, these methods of cultivating saviour tissue may protect the interests of children more effectively (i.e. if child is being created simply for the benefit of parental attachment to the sibling, it may be better to not create the child in a time of family crisis and simply cultivate donor tissue using implantation in an animal).

While the above comments do not provide an exhaustive overview of the way Offences under the HRT Act might limit current and future research opportunities, it is useful to demonstrate that many advances in research and technology are currently incompatible with the Act and should be revised in consultation with existing national legislation, guidelines and directions in current and future research.

Recommendation 1:
Amend the overview of Offences in the Act in order to comply with *National Health and Medical Research Council ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research 2007* (NHMRC Guidelines); the *Research Involving Human Embryos Regulations* 2017; and the *Prohibition of Human Cloning for Reproduction Act 2002*.

Genetic testing of embryos, saviour siblings, mitochondrial donation and gene editing technology
Genetic testing of embryos may be relevant and ethically acceptable in some circumstances, given the primacy of the welfare of the child. Consideration should be given to the perceived quality of life, the ability of parents to care for the child, and the extent of social and medical support for the screened condition, as outlined in the NHMRC Guidelines. Ethically-comparative arguments for the termination of pregnancy for the prevention of heritable conditions may be relevant; with additional responsibility and qualifying conditions given that genetic testing takes place prior to embryonic implantation.

In addition, preimplantation genetic testing may be used to select an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling or other relative. Mitochondrial donation should also be permitted, as a process of allowing families with mitochondrial disorders to have healthy children. Traditional methods for testing a pregnancy in the setting of a female having a mitochondrial DNA mutation are complex, accuracy and interpretation is uncertain, is only available for specific mitochondrial DNA mutations and given that all of the children would inherit the mitochondrial DNA mutation from the mother limits these families' choices in having children significantly.

In a similar vein, heritable alterations to the genome may be permissible in some circumstances to prevent genetic conditions or disease, yet these are also considered an offence under the HRT Act:

53L. Offence — heritable alterations to genome (p. 99)

Heritable alterations to the genome would be most suitable in cases where there is evidence to suggest that a child may inherit a serious disease or illness if conceived naturally; or that in lieu of genetic screening or editing, a created saviour sibling would not be a welcomed, respected member of the family unit and the use of PGT will significantly affect the welfare and interests of the person who would be born.

Recommendation 2:
It is the recommendation of the WHGMH Directorate that genetic testing, mitochondrial donation and gene editing (although not at a developmental stage that would be useful for clinical practice in the assisted reproductive technology field), be permitted for use according to NHMRC Guidelines; the *Research Involving Human Embryos Regulations 2017*; and the *Prohibition of Human Cloning for Reproduction Act 2002*; and that the overview of Offences in the Act should be amended in order to comply with NHMRC Guidelines and legislation.

Recommendation 3:
Similar to the above, ensure that the process for granting licenses for exemptions from Offences under that Act is also subject to ethical oversight from the Reproductive Technology Unit and Council in accordance with the above guidelines and legislation.

Recommendation 4:
The WHGMH Directorate supports the current system whereby the Reproductive Technology Council assesses all applications for preimplantation genetic diagnosis, and also the current process where all couples undergoing PGD are seen by a geneticist or genetic counsellor to discuss the aspects of the condition in the context of PGD prior to the application. We do recommend that the geneticist or genetic counsellor be independent of the fertility clinic, that they do not need to be working within genetic services of Western Australia but do need to be qualified, and in the case of the genetic counsellor, either working under the supervision of a geneticist or a HGSA board-certified genetic counsellor.

Posthumous collection, storage and use of gametes and embryos

There are considerable discrepancies between the current WA Reproductive Technology Council Position statement on the posthumous collection and use of gametes, and NHMRC Guidelines on this issue. To that end, the WHGMH Directorate advocates for the responsible collection, storage and use of gametes and embryos, with additional provisos to verify information and justify use of gametes posthumously.

This submission supports the wholesale adoption of NHMRC Guidelines within WA HRT legislation. In the case of non-consensual collection and use of gametes, the WHGMH Directorate particularly supports the spirit and practical application of those clauses which advocate for "some evidence that the dying or deceased person would have supported the posthumous use of their gametes by the surviving partner, or at the very least, there is no evidence that the deceased or dying person had previously expressed that they do not wish for this to occur", and that "the proposed collection and storage has been approved by an appropriate court authority".

Given the alignment of this submission with the paramountcy of the interests of the child, the posthumous collection, storage, and use of gametes and embryos should ideally be undertaken with the knowledge and express written consent of the donor prior to death. In cases where donors have not provided express written consent for their spouse or partner to collect and store gametes, or conceive a

child using their gametes or embryos, the WHGMH Directorate advocates for the surviving spouse or partner to provide evidence of suitability for assisted reproductive technology (ART) implantation procedures aligned with WA surrogacy guidelines. Additionally, corroborative supporting evidence, outlined below, should be submitted if gametes or embryos are to be used in an ART procedure by the surviving spouse or partner.

Recommendation 5:
It is the recommendation of the WHGMH Directorate that the Act (e.g. Section 22.8, p. 46, which is inconsistent with the posthumous use of gametes) be amended to allow for the posthumous collection, storage and use of gametes and embryos in accordance with the NHMRC Guidelines.

Recommendation 6:
In addition, for the posthumous use of gametes from a deceased partner or spouse, that the surviving spouse been assessed by a clinical psychologist or Reproductive Technology Council approved counsellor to be psychologically suitable to be involved in an ART procedure using these gametes; allowing for adequate time to grieve. This assessment will be provided in a written report to the Council, who will approve use.

Recommendation 7:
Furthermore, the surviving spouse provide corroborative, supportive written testimonies from two people who had an extended relationship with both parties that the deceased person intended to have a child with the surviving partner in the period immediately prior to their death.

A final comment relevant to the interests of the WHGMH Directorate is that, in the interests of gender equality, the legislation should be amended so that both stored male and female gametes may be used in posthumous ART (gametes from female donors would require a surrogacy arrangement in order to conceive via posthumous ART).

Rights to storage of gametes and embryos
The WHGMH Directorate has no specific recommendation on the rights to storage of gametes and embryos upon divorce; mental incapacity of an individual or one or both members of a couple; or rights of subsequent partners or family members, beyond a general comment that the storage and use of gametes should remain the exclusive prerogative of the two members of the couple to provide or withdraw consent at any time. In the case of mental incapacitation, regulations similar to those around the posthumous storage and use of gametes should apply, with particular consideration of the wellbeing of resulting children and all parties involved.

The storage of gametes and embryos (storage periods and eligible parties)
Current legislation around the storage of gametes specifies that storage may only be extended beyond the maximum of 10 years with the approval of the Council and meeting additional criteria for the extension of storage. There is little evidence that longer term storage affects the quality and viability of gametes and embryos wholesale, hence if there is no evidence of deterioration, the Act should be amended to allow individual clinics to maintain storage for the period of time agreed between the parties involved; noting that the UK *Human Fertilisation and Embryology (Statutory Storage Period) Regulations 2009* provide a mechanism for successive 10-year extensions of storage, up to a maximum of 55 years.

Recommendation 8:
That the WA HRT Act (e.g. s. 24) be amended to allow individual clinics to determine their own regulations around the duration of the storage of gametes and embryos, provided these are communicated clearly to the parties involved and documented at the time of consent and donation.

On the matter of eligibility for the storage of gametes, the HRT Act currently prescribes that women can only store eggs for medical reasons, and not for social infertility (the personal choice to store gametes). This unduly discriminates against women and increases their personal and medical risks, as currently men can store semen regardless of social or medical infertility. Legislative change would particularly allow women in same-sex relationships and single women to access ART, and means that women in same-sex relationships are not choosing the gestational mother on the basis of medical infertility – with additional invasive testing to determine this and potential health consequences for the mother and child.

Recommendation 9:
That the Act (e.g. s. 23) should be made to allow women who are unlikely to become pregnant other than by ART procedures to both store gametes and access ART therapies, and include the guiding principle that people seeking to undergo ART procedures must not be discriminated against on the basis of their sexual and gender orientation, marital status or religion (aligned with recent South Australian ART review recommendations).

Inconsistent terminology used throughout the Act highlights that greater clarity and standardisation is required around who can access treatment to ensure gender and sexual equality. Furthermore, the terms 'male' and 'female' might apply to the chromosomal sex of a person, but are currently discriminatory from a gender equity perspective. The below examples give some idea of how the sexuality and gender normative terminology could be corrected or standardised throughout the Act:

"a couple who are married, or in a de facto relationship with each other ***whether they are different sexes or both female****"* (p. 41);
"Offence — creating human embryo for purpose other than achieving pregnancy in a ***woman****"* (p. 97)
This discriminates against transsexual men and male couples who are capable of carrying a pregnancy (Note that NHMRC Guidelines state that ART is for "exclusive use of a woman", which is similarly transphobic).

"any persons seeking to be regarded, in applying (a), as members of a couple are — (i) married to each other; or (ii) in a de facto relationship with each other ***and are of the opposite sex to each other****"* (p. 47);
This discriminates against trans men who are capable of carrying a pregnancy, as well as lesbian women who are not married accessing treatment for social infertility. Recent changes to marriage laws which allow same-sex couples to marry might simplify some of this issue, but it still discriminates against lesbian and homosexual couples who are not married.

Recommendation 10:
It is the recommendation of the WHGMH Directorate to revise the Act to ensure consistency of terminology, where not completely necessary from a medical perspective, to reflect developments in gender and sexual equity – i.e. amend gendered terms to more gender neutral forms (person, persons etc.).

The Chief Executive Officer's (CEO) power to issue directions; make a Code of Practice, regulations; and the scope of existing Directions and Regulations under the HRT Act

The current parameters of the CEO's role to issue directions and write a Code of Practice and make regulations are significantly hindered by deficiencies in the existing Act, which will be rectified by updating the legislation as part of this review. It is envisaged that the role of the CEO to interpret and administer the Act will be enhanced by more modern and streamlined legislation.

Recommendation 11:
That the definition and role of the CEO (as the Department CEO) need to be clarified in light of the *Health Services Act 2016*; and that the definition of the Chair of Council and their relationship with the Minister and the CEO is clearly outlined within the legislation. This will address issues with consistent nomenclature and subsequent function of all roles.

Role of the Reproductive Technology Council (RTC):
The RTC is effective in managing legislative differences and/or lacunae in NHMRC Guidelines, provides expert guidance on ethical considerations of ART and individual cases, and is a mechanism for regulation of clinics. However, the RTC could be more inclusive of fertility clinic and researcher views, as the HRT Act currently mandates that:

> *no more than one member of the Council at any time — (i) is a licensee; or (ii) is a person who has a pecuniary or other beneficial interest, other than an interest of a prescribed kind, in the practice of a licensee.* (p. 22).

Recommendation 12:
Remove the above clause (s. 9 (2) d), and include in the membership (s. 8) at least two licensees or experts in reproductive technology to ensure that more consultative, relevant, and expert-led decision-making and regulation takes place within the remit of the RTC.

Recommendation 13:
That the RTC continues as a governance and regulatory body for ethical, clinical and legal issues which arise from the use of ART. Updating the legislation to reflect more modern research and ethical requirements, and expanding the membership of the Council to include clinic and industry perspectives, should hopefully reduce the need to establish a formal appeal mechanism for Council decisions.

The RTC may also consider their role in regulating, or at the least, offering guidance around artificial insemination procedures which occur outside the overview of fertility clinics and therefore the licensing process (i.e. by other health professionals or between individuals privately). This may take the form of entry of the arrangement onto the donor register or the provision of education around safe practices as part of their general business in managing the clinical and ethical landscape of ART.

Management of information on the Reproductive Technology Registers
Access to information for children born of ART, as outlined in the Act, is not currently sufficient to prevent the formation of consanguineous relationships, nor can children born of HRT procedures access their full medical history for the prevention and management of disease and illness later in life. At best, children can only access non-identifying information for medical purposes, and the storage of this information should be prescribed under the Act so that the information is consistent and accessible. Medical histories are also not necessarily provided to all donor-conceived children.

Additionally, psychological matters around parentage and identity, for donors, donor-conceived children, and recipient parents, are not currently catered for under existing information-sharing practices (which prescribe that all information released 'does not identify' the donor). The need for open-disclosure of information around identities and the particulars of ART procedures is strongly recommended.

Currently the information sought or provided to children or donors is not stipulated in the legislation and is open to interpretation. For example:

"Sufficient particulars to identify each such child" (p. 79)
"Such relevant demographic and clinical information, as may have been required to be supplied under this Act" (p. 82)
This information, does not stipulate exactly as to age/sex/number of siblings, contact details for donors etc., necessary to provide a full medical history or prevent consanguineous relationships.

Recommendation 14:
It is the recommendation of the WHGMH Directorate that all parts of the Act are amended to address the existing confidentiality requirements around non-disclosure. Updated legislation should ensure abundant, accurate, and contemporaneous information and contact details are provided to children, donors and recipient parents as a compulsory requirement in all future provision of gametes and ART therapies.

Recommendation 15:
Ensure that the release of gametes or embryos for research purposes is accompanied by de-identified data about the donor (and any children conceived using the gametes or embryos in ART procedures prior to donation for research purposes).

Recommendation 16:
That the number of families conceived using ART procedures from a single individual donor is restricted to four, to prevent the possibility of siblings forming consanguineous relationships given the size and relative density of Western Australia's population.

Recommendation 17:
Funding is to be provided the State Government for the WA voluntary donor register to be immediately digitised and integrated with existing clinic records and Reproductive Technology Registers. The database should be managed by the WA Health data management team with additional resources to ensure its operational integrity. A long-term, stable and sustainable data management plan, with appropriate governance, should be developed by the WA Health data management team, consistent with other WA Health data collection processes for this database.

Recommendation 18:
The WHGMH Directorate recommends the establishment of a similar opt-in, contact/veto system for identifying information outlined in the South Australian ART legislative review. This would apply as an interim measure for donors who have existing gametes in storage, recipient parents that have already undergone ART, or children already conceived using ART. Non-identifying information was recommended for immediate, compulsory disclosure as part of the SA review; which the WHGMH Directorate also supports in this submission.

International surrogacy, international ART procedures, the commercial importation of gametes, and commercial domestic surrogacy

Although the issues in this section are diverse and highly complex, the WHGMH Directorate submission on this topic addresses an overarching, interlinked theme: namely the need to balance commercial inducement to donate gametes and provide surrogacy services in a domestic setting, with the exploitation and potential harm for donors, recipients, and surrogates when accessing ART or surrogacy arrangements overseas.

Each of these scenarios may expose different parties to potential financial, physical and mental exploitation and harm, but the situation can be essentially refined to an understanding of ART legislation and governance adopting either a punitive or regulatory approach. The WHGMH Directorate would like to stress that from a policy perspective, regulation of the industry through greater leniency towards domestic commercial arrangements safeguards both Australians and women and men in developing or overseas nations.

Recommendation 19:

That the RTU/RTC considers developing an ethical framework around international surrogacy, international ART procedures, the commercial importation of gametes, and commercial domestic surrogacy, in order to:

- Ethically evaluate overseas surrogacy arrangements to reduce the exploitation of women's bodies in international settings;
- Explore the possibility of allowing prescribed, limited options permitting domestic commercial surrogacy and gamete donation, to reduce the incidence of unethical or risky overseas surrogacy and ART and the importation of gametes;
- Allow fertility clinical practices which screen commercially-imported gametes/embryos prior to implantation; and
- Any other issues associated with international surrogacy, international ART procedures, the commercial importation of gametes, and commercial domestic surrogacy.

Recommendation 20:

- That the RTU/RTC develops guidelines and education materials around the risks of accessing gametes, surrogacy, and ART from overseas sources.
- That the RTU/RTC develops guidelines and education materials identifying the risks associated with providing commercial surrogacy and gamete donation in a domestic setting.

Sex-selection for non-medical purposes

Recent research from census data around gender preferences indicates that many Australians may favour sex-selection for non-medical purposes, and that sex-selection for non-medical purposes may already be informally taking place through other means. While this is an incredibly sensitive issue which may reinforce harmful preferences for a particular gender; to more fully reflect the wishes of people undergoing ART, an interim measure may be adopted which aligns with NMHRC protocols where sex-selection for non-medical purposes is more permissible in instances for 'family balancing' (where there are two or more children of the same sex, and the opposite sex is selected).

Screening donors and recipients for criminal convictions, lifestyle choices and health factors

The issue of previous criminal convictions, lifestyle choices, and other health factors impacting on the suitability of donors and recipients is an ongoing part of debate around ART procedures. Health and child safety and wellbeing related to these factors may negatively affect the viability of pregnancies and

long-term outcomes for children; so consideration should be given to the primacy of the child in clinical decision-making about whether to proceed with ART therapies.

New knowledge on the heritable and epigenetic influences of particular lifestyle choices resulting in health complications, such as alcohol consumption, illicit drug use, cigarette smoking, and high BMI may also require clinics to screen donors for these factors. Options of counselling to address lifestyle choices may modify patient behaviour and address concerns.

Recommendation 21:
That clinics reserve the right to determine health and lifestyle eligibility criteria for ART procedures which might compromise pregnancy and birth outcomes. This includes support in the legislation for clinicians to regulate ART for pre-existing morbid health conditions to reduce risks associate with pregnancy prematurity, congenital conditions, and heritable epigenetic links, provided that ART is not withheld on any grounds listed in the *Western Australian Equal Opportunity Act 1984*.

Recommendation 22:
Concerning previous criminal convictions of recipients, it is the recommendation of the WHGMH Directorate that all potential recipients and their partners undergo National Police Criminal Record Checks and are free from prior convictions for child sex offences – in a similar process to screening for adoption or foster care arrangements. This will ensure that potential recipients will not 'shop around' for a clinic if they are turned away for a previous criminal conviction and will hopefully reduce the risk of harm for associated child protection issues.

'Maximising outcomes' clause in the NHMRC Guidelines

Should recommendations around clinical practice as a result of this review be adopted from the NHMRC Guidelines, the WHGMH Directorate wishes to comment upon the 'maximising outcomes' clause in the NHMRC Guidelines (3.8). This discusses therapies to maximise the outcomes (i.e. live births) from ART, but does not stipulate a minimisation of harm principle (i.e. that less-invasive therapies should be used before more invasive therapies) which may place recipients at greater risk.

Recommendation 23:
That any clinical consideration (or wholesale adoption of NHMRC Guidelines) should shield those undergoing ART from decision-making which has adverse effects upon their health and wellbeing. E.g. recipients should progress through treatment with less invasive procedures considered prior to more invasive procedures, regardless of considerations to 'maximise outcomes'; and that clinical decision making is used to minimise harm to patients undergoing ART.

Once again, the WHGMH Directorate, on behalf of the Women and Newborn Health Service, would like to thank you for the opportunity to contribute to this legislative review. Should you have any further questions, please do not hesitate to get in touch.

Your sincerely,

Boardley

Graeme Boardley
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