Submissions on the General Scheme of the Assisted Human Reproduction Bill

1. Alliance for the Defence of the Family and Marriage, p2
2. Caroline Langley, p4
3. Dr. Andrea Mulligan, p5
4. Dr. Brian Tobin, p20
5. Dr. Ciara Staunton and Professor Frank Barry, p31
6. Dr. Katherine Wade, p35
7. Dr. Lydia Bracken, p45
8. Dr. Lucy Frith, p51
9. Emma O'Friel and Dr Joanna Rose, p52
10. Families Through Surrogacy, p60
11. Fiona Duffy, p67
12.
13. Hayley Mulligan, p79
14. Human Life International Ireland, p89
15. Irish Cancer Society, p92
16. Irish Clinical Embryologists, p96
17. Irish Fertility Counsellors Association, p100
18. Irish Fertility Society, p103
19. Institute of Obstetricians & Gynaecologists, p130
20. John Duffy, p145
21. LGBT Ireland, p151
22. National Infertility Support and Information Group, p156
23. National Women's Council of Ireland, p165
24. Professor Deirdre Madden, p186
25. Professor Martin Clynes, p198
26. Repromed, p205
27. Stop Surrogacy Now, p207
28. The Iona Institute, p209
29. Transgender Equality Network Ireland, p215
30. Virtus Health, p217
31. Waterstone Clinic, p223
32. LGBT Ireland, p237
33. Ann Bracken, p253

1: Alliance for the Defence of the Family & Marraige

Submission to the Oireachtas Joint Committee on Health

on the General Scheme of the Assisted Human Reproduction Bill 2017

by Séamas de Barra,

Why the Joint Committee on Health should reject the General Scheme

of the Assisted Human Reproduction Bill 2017

Reasons to Reject the General Scheme

1) [Head 10 of PART 2 GENERAL PRINCIPLES, pp. 26–27] The General Scheme ignores the Constitution and statute law, as they are at present, in relation to the status of the human embryo. While it is true that the Supreme Court in *Roche –v- Roche & ors* [15/12/2009] ruled that the 'unborn' of Article 40.3.3° does not protect human embryos conceived *in vitro*, that is 'on glass', and only protects human embryos indeed starting from implantation. However, their ruling is no longer the law of the land, as the statute law has been changed significantly since then, with the passing of the Criminal Justice (Forensic Evidence and DNA Database System) Act 2014 [the 2014 Act].

2) In **Interpretation 2.** (1) of the 2014 Act the human foetus is recognized as a human person. Not only that, but that Act endorses the well-established practice of DNA testing. The DNA of the individual human being is set down at fertilization. That means that the State, since 2014, has recognized, not only that the human foetus is a human person, but as individual human life begins at fertilization, **the human being is a human person starting from fertilization**.

3) The DNA test is practically 100% accurate in pinning a crime on a particular culprit, and to my knowledge, **not one** such **culprit has ever been acquitted by claiming that he/she is a human being, but not a human person**. Such a claim would be absurd.

4) Approximately 96% of all human embryos conceived *in vitro* are wasted in the process of *In Vitro* Fertilization [Nicholas Tonti-–Fillipini, 'Reproductive Technology Outcomes in Australia: Analysing the Data', *Bioethics Research Notes* (March 2003, **15**: 1, 2)]. **Such wastage is foreseen**, and in Irish law, according to the late Mr Justice Adrian Hardiman, Lord rest his soul, what is foreseen is considered to be deliberate. He gave this legal opinion, while still a young barrister, during a talk he gave to the Anti‑Amendment Campaign in Carrick Hall, Orwell Road, Rathgar, Dublin 6, during the Referendum campaign of 1982–83, a Referendum that gave us the 8th Amendment on September 7, 1983. Putting that in context, Professor Fergal Malone, Master of the Rotunda, said at the meeting on October 11, 2017, of the Oireachtas Joint Committee on the Eighth Amendment of the Constitution, that about 30% to 40% of all human conceptions will end in a miscarriage. In other words, nature is much less profligate than IVF.

5) Irish law, at present, permits the deliberate destruction of unborn human life only in the circumstances set out in sections 7, 8, 9, of the Protection of Life During Pregnancy Act 2013 [the 2013 Act]. **Destruction of unborn human life**, outside of these circumstances, **is still a crime** [see section 22].

6) Furthermore, the deliberate destruction of unborn human life, refers to human life 'after implantation' [see the word 'unborn' in **Interpretation 2.** (1), in the Protection of Life During Pregnancy Act 2013]. In other words, there is **no endorsement in Irish law of the deliberate destruction of human life before implantation**. Accordingly, there is **no endorsement in Irish law of destructive research on 'supernumerary' human embryos. That would be permitted until the 14th day after fertilization**, if this General Scheme is accepted. **[PART 7 EMBRYO AND STEM CELL RESEARCH, pp. 143–152]**

7) Unlike the Supreme Court ruling in *Roche ---v– Roche & ors* [15/12/2009], **the 2014 Act does not discriminate between human embryos implanted in the natural way, and those implanted following *In Vitro* Fertilization**. The Courts for years have challenged the Oireachtas to define when human life begins, or at least to define from what point the law begins to protect human life. In the 2014 Act, as explained, the State did precisely that. As the 2014 Act enjoys the presumption of Constitutionality, as it was passed after the introduction of the 1937 Constitution, if the Constitutionality of the 2014 Act were challenged, it probably would be endorsed by the Supreme Court. For decades now the dominant opinion of the Supreme Court has been that that Court should leave the work of legislation to the Oireachtas; that the Court's role is just to interpret the law.

8) [Head 49, pp. 123–124] This General Scheme is very disrespectful of those poor unfortunates who act as donors in the context of IVF. **It completely ignores the advice of a majority of the Supreme Court in 2014 [7/11/2014] in their ruling on the Government appeal against the ruling of Mr Justice Henry Abbott in the High Court on the 'Surrogate Mother' Case [5/3/2013], that the genetic/biological mother be recognized in law as a legal mother**. After all, traditionally every mother has been the biological/genetic mother of her children. The General Scheme makes, in effect, a reproductive slave of the poor unfortunate surrogate mother. That is inhuman. It allows for 'justified expenses' for the surrogate mother, but bans so–called 'commercial surrogacy', a distinction that is without reality **[HEAD 4, p. 102]**. In this General Scheme the donors have to give up their rights as natural parents when they finally agree to a Parental Order.

9) IVF/AHR do nothing to cure infertility, unlike technologies such as NaProTechnolgy. IVF/AHR ignore the causes of infertility and subfertility. NaProTechnology costs a fraction of what IVF/AHR cost, and doesn't involve gravely unethical practices. The success rate for NaProTechnology is between 40% and 60% after one year [Dr Phil Boyle, practitioner].

10) How ironic that the Government saw fit to start this discussion in the middle of the week that they decided that the Report recommending the Repeal of the Eighth Amendment should be discussed by the Dáil and Seanad. **Abortion itself can lead to infertility**. Infertility, or subfertility are caused, in part, by delaying having children until the couple is in early middle age.

11) That delay, in part, is caused by economic factors. What is the Government doing to encourage young couples to start their family when they are young and still fertile? That would involve ensuring a living wage, and fertility–friendly work practices, for young women especially. It also would involve the control of house prices in a fertility–friendly way. **There is an ecology of the human body, and not just of the environment**.

12) There are significant cutbacks to funding for IVF through the UK NHS [Stephen Matthews, 'County that pioneered IVF 40 years ago becomes the latest to scrap the fertility treatment for free on NHS' *MailOnline*, September 6, 2017]. Yet Minister Simon Harris, in the Republic of Ireland, at a time of 'unprecedented cash crisis' in the HSE, intends to make IVF, and the like, available to people, at the taxpayers' expense, without regard to income.

2: Caroline Langley

I am a Barrister in 4 jurisdictions and a former scientist, specializing in AHR. I would like to appear before the Health Committee's hearings regarding the AHR Bill.

I have attached some excerpts from one of my papers:
"The government is to be applauded for stepping up to its responsibilities to address AHR which many countries have circumvented by simply declaring a blanket ban on all AHR procedures and surrogacy ...

In September 2016 world's first baby was born using the DNA from three people in a technique known as 'mitochondrial DNA transfer' ("mtDNA")... Now, further advances have been made and the human genome can to be easily edited using the CRISPR-Cas9 (clusters of regularly interspaced short palindromic repeats) technique and 6 CRISPR babies have now been born in the USA ... We must understand the science and have stringint regulations and enforcement for ethical AHR procedures and research to protect those future generations who cannot consent to the editing of their genome."

I have also attached my C.V. I would like the opportunity to speak with your directly before the hearings and I can be reached on 085 863 1090.

Sincerely,

C. Langley

3: Dr Andrea Mulligan

Submission to Joint Committee on Health on the General Scheme of the Assisted Human Reproduction Bill 2017

Dr Andrea Mulligan BL

LL.B, LL.M(Harv.) PhD, Barrister-at-Law

23 February 2018

I. Introduction

I am an Assistant Professor at the School of Law, Trinity College Dublin, where I lecture in Medical Law and Ethics, and Law and Bioethics. I am also a practising barrister in the fields of medical law and public law, and I have represented commissioning parents in surrogacy arrangements as they attempt to establish legal parentage in proceedings before the courts.

My specialist academic research area is the regulation of assisted human reproduction, and I completed my PhD thesis in this field, under the title 'Fundamental Rights and Organising Principles in the Regulation of Assisted Human Reproduction in Ireland'. My thesis and my subsequent research in the area have produced a substantial body of peer-reviewed academic articles in Irish and international law journals.[1] I am a co-author of the recently published textbook *Medical Law in Ireland* (Bloomsbury, 2017), which addresses the Irish law on assisted reproduction in some depth. I specialised in the study of assisted human reproduction and constitutional law during the course of my Masters in Law, which I completed at Harvard Law School as a Fulbright Scholar.

This submission highlights a number of aspects of the General Scheme of the Assisted Reproduction Bill 2017 (the "**General Scheme**") that raise issues which I believe need to be considered by the Joint Committee on Health (the "**Committee**"), potentially with a view to making changes to the approach adopted in the General Scheme.

[1] Mulligan: "Identity Rights and Sensitive Ethical Questions: The European Convention on Human Rights and the Regulation of Surrogacy Arrangements" (2018) *Medical Law Review;* "Article 8 and the Right to Respect for the Decision to Have or Not to Have a Child" (2014) 4 European Human Rights Law Review 378; "Constitutional Parenthood in the Age of Assisted Reproduction" (2014) 48(1) Irish Jurist 90; "From *Murray v Ireland* to *Roche v Roche:* Re-Evaluating the Right to Procreate in the Context of Assisted Reproduction" (2012) 35 Dublin University Law Journal 261; "Tortious Liability for Mistakes in IVF: Duty of Care, Public Policy and the Non-Identity Problem in *A(A Minor) and B(A Minor) v A Health and Social Services Trust*" (2011) 34 Dublin University Law Journal 256; "Frozen Embryo disposition in Ireland After *Roche v Roche"* (2011) 46(1) Irish Jurist 202.

At the outset, I should say that I believe that the General Scheme is an excellent piece of work which addresses a wide range of issues and activities in the field of assisted human reproduction ("**AHR**"), an area which has been in dire need of regulation for some time. For the sake of efficiency, this submission will not generally highlight aspects of the General Scheme which are commendable – though there are many such aspects - and will focus instead on areas where there is the potential for problems to arise. In some instance, the problem may simply arise from the fact that this is a General Scheme rather a draft bill and is therefore necessarily lacking in detail. Where that is the case, I hope that my recommendations can provide some assistance on how that detail is to be filled in.

An important preliminary point which I believe the Committee should consider is the regrettable fact that Parts 2 and 3 of the Children and Family Relationships Act 2015 (the "**2015 Act**") have not yet been commenced. These are the parts which apply to assisted human reproduction, governing parental status in donor assisted human reproduction, and prohibiting the anonymous donation of eggs and sperm. It is entirely unacceptable that the legislation has not been commenced almost two years after its passage. Given the interdependence of the General Scheme with the 2015 Act, I presume that the intention is that the 2015 Act will be commenced imminently. The Committee should highlight the need for this to take place as soon as possible.

At the outset it should be noted that the right to procreate has been recognised as an unenumerated personal right under the Irish Constitution, including in the context of assisted human reproduction, in the case of *Roche v Roche*.[2] The right to decide to become a parent has been recognised as a facet of the Article 8 protection for the right to respect for private and family life, under the European Convention on Human Rights,[3] and it too includes access to medical assistance in reproduction. While neither right is absolute, the State must take care in the limitation of rights of access to reproductive technologies to ensure that such limitation is proportionate.

II. Executive Summary

This submission addresses the following issues:

- In respect of **Part 2 - General Principles** this submission calls for the interests of both male and female AHR patients to be recognised, calls for clearer guidance on the welfare of the child principle, and recommends that a 'mutual contemporaneous consent' rule is adopted in respect of further actions concerning cryopreserved embryos.

[2] *Murray v Ireland* [1985] IR 532, *Roche v Roche* [2010] 2 IR 321. See analysis of this in Mulligan "From Murray v Ireland to Roche v Roche: Re-Evaluating the Right to Procreate in the Context of Assisted Reproduction" (2012) 35 Dublin University Law Journal 261.

[3] Evans v UK (application 6339/05) Judgment of the Grand Chamber 10th April 2007, SH v Austria (Application no. 57813/00) Decison of the First Section, 15th November 2007.
Admissibility decision.

- In respect of **Part 3 – Gamete and Egg Donation** this submission observes that the rules in respect of the payment of reasonable expenses for eggs and sperm are extremely restrictive and may mean that there is little or no development of a domestic supply of donor eggs and sperm.
- In respect of **Part 4 – Posthumous Assisted Reproduction** this submission recommends that the legislation adopt the rule and/or clarify the rule that posthumous reproduction is only permitted where the child is born with 36 months of the parent's death, and argues that posthumous reproduction should be permitted in combination with altruistic surrogacy.
- In respect of **Part 5 - Pre-Implantation Genetic Diagnosis and Sex Selection** this submission highlights the need to clarify the definitions of "serious genetic disease" and the significant ethical implications arising from pre-implantation genetic diagnosis, especially in respect of the rights of persons with disabilities. It also emphasises the need for the regulator to be provided with very clear guidance as to how to identify diseases to be the subject of PGD as a matter of constitutional law.
- In respect of **Part 6 - Surrogacy** this submission recommends that the prohibition on the provision of legal services is overbroad and potentially unconstitutional, and that the advertising of altruistic surrogacy services should not be prohibited. This submission applauds General Scheme's protections for the child's right to access information concerning a surrogate, but counsels that there is a need for those provisions to be supplemented by a regime which promotes a genuine culture of openness. The submission also observes that the General Scheme makes no provision for retrospective recognition of surrogacy arrangements entered into before the legislation commenced, in contrast to the 2015 Act. Finally, the submission highlights the fact that the General Scheme makes no provision for the regularisation of the legal status of children born through illegal surrogacy arrangements and argues that at least in respect of cross-border surrogacy, this may breach the State's obligations under the European Convention on Human Rights.

III. Recommendations to the Committee

i) Recommendations on Part 2: General Principles

a) Recipients of AHR: Children, Women and Men

Head 5(1) states:

> *(1) In all decisions regarding the provision of assisted human reproduction (hereafter referred to as AHR) treatment, due regard shall be given to the health and wellbeing of children born as a result of such treatments and to women who receive such treatments.*

Head 5(1) focuses on the health and wellbeing of the child born as a result of assisted human reproduction, an emphasis which is entirely appropriate.[4] As well as children, this provision mentions women who are the recipients of AHR treatment, but conspicuously fails to mention men who are the recipients of such treatment. This is a strange omission. While IVF treatment is more invasive and carries higher physical risks for women than for men, this does not mean that the men involved in AHR do not have interests which need to be protected. In many cases it is male infertility that leads couples to AHR. The exclusion of men from this section fails to recognise that the risks of AHR are not only physical, they may be emotional, social or psychological as well. It is essential to recognise that people who seek AHR treatment – whether they are men or women – are often rather vulnerable, dealing as they may be with the pain of infertility. Responsible AHR must take account of the interests of both male and female commissioning parents.

The Committee should perhaps also consider the fact that this section makes no reference to donors or surrogates, categories of persons whom the General Scheme seems eager to protect. Responsible AHR requires proper protection of these parties, as well as protection of commissioning parents and resulting children.

b) Need for Legal Certainty as to Welfare of the Child Principle

Head 7(1) provides that "*A person shall not be provided with AHR treatment unless account has been taken of the welfare of any child who may be born as a result of such treatment.*" Treatment is to be refused unless account is taken of the welfare of the child. The Committee should be aware that the welfare principle (also known as the best interests principle) is a flexible, somewhat vague concept.[5] In the interests of legal certainty, it is advisable to provide more detail on what precisely the threshold for non-provision of AHR is to be. By requiring the provision of written explanations where treatment is refused, the General Scheme acknowledges that the decision not to treat is a very significant one, involving a potential infringement of the fundamental rights of the individual. As such, the circumstances in which treatment is to be denied must be clearly enumerated. This is of additional relevance in circumstances where the treatment is provided by a public institution, as a decision not to treat would be subject to judicial review on the part of the person who is refused treatment.

Furthermore, the explanatory note to subhead 2 states the consensus of the Irish Fertility Society (**"IFS**") that "w*here there is objective evidence of significant risk of harm to any child that may be conceived through fertility treatment there should be a presumption*

[4] Though this is not uncontroversial in academic discourse. See for example: John A. Robertson, "Procreative Liberty and Harm to Offspring in Assisted Reproduction", 30 AM. J.L. & MED. 7, 16 (2004)

[5] On the problems with best interests see: Jon Elster, "Solomonic Judgments: Against the Best Interest of the Child" (1987) 54(1) University of Chicago Law Review 1, Parker, "The Best Interests of the Child – Principles and Problems" (1994) 8 International Journal of Law and the Family 26.

against treatment." It states that a similar view was taken by the Commission on Assisted Human Reproduction ("**CAHR"**). The position of the IFS and CAHR is in fact quite different to the statement in Head 7(1). The IFS position specifies an express threshold below which treatment will not be provided, ie. where there is objective evidence of significant risk of harm. The Committee should consider if this is the threshold that should be adopted, and if so, this should be set out expressly in the legislation. Head 7(1) as it is currently drafted does not implement the position of the Irish Fertility Society and the Commission on Assisted Reproduction. It merely requires that "account be taken" of the welfare of the child, rather than that the AHR provider consider whether there is objective evidence of serious risk, and refuse treatment if such a risk exists.

Consent to Future AHR Procedures the Importance of Mutual Contemporaneous Consent

Head 9 is designed to govern consent to treatment and the possibility of differences of opinion arising in the future between the commissioning parents. This is particularly important in the context of cryopreserved embryos. In the course of fertility treatment, many couples create surplus (supernumerary) embryos. It is important that the law provides for what should happen to those embryos in the event that the couple separates and/or cannot agree what to do with them. Unfortunately, disputes about the fate of frozen embryos are not uncommon. The Committee may be aware that the leading case on AHR in Ireland *Roche v Roche*[6] arose from a dispute as to whether the female partner was entitled to have frozen embryos implanted in her uterus against the wishes of her estranged husband.

Head 9(d) attempts to address this problem and states that the consent form filled in at the time of treatment will specify what will happen if there is a difference of opinion in the future. On my reading, it appears that the General Scheme envisages that consent form being binding on the parties in the event of a disagreement in the future, even though one party may at the later point have entirely changed their mind about what they believe should happen. Head 9 seems to require a formal revocation of consent, rather than a contemporaneous provision of consent. As such, unless that revocation has taken place, it seems that one partner could proceed to take an action in respect of the embryos without the contemporaneous consent of the other partner.

This is especially problematic where the action to be taken is to use those embryos to attempt to have a child, whether through implantation by a female partner in her own uterus, or through the use of a surrogate by a male partner. It would be highly undesirable for the law to allow for the use of cryopreserved embryos in the absence of the contemporaneous consent of one of the parents. This could potentially result in the birth of a child against the wishes of one of its parents. Under the General Scheme and the 2015 Act, it seems that that parent would be a legal parent of the child.

[6] *Roche v Roche* [2010] 2 IR 321

The better approach is to require that in advance of any procedure – even where there was agreement in place in the past - each person must provide contemporaneous consent. This is the rule adopted in the United Kingdom under the Human Fertilisation and Embryology Acts 1990-2008, and upheld by the European Court of Human Rights in *Evans v UK.*[7] Sometimes called the "mutual contemporaneous consent" rule, this rule ensures that consent is provided at the time when the relevant action is taken. So, under the UK regime, no action can be taken in respect of a frozen embryo without the consent of both parents.

It may be that the intention of the General Scheme is to enshrine the mutual contemporaneous consent approach. In any event, it is strongly recommended that the Committee adopt this approach.

ii) Recommendations on Part 3: Gamete and Embryo Donation

a) Payment of Reasonable Expenses of Gamete and Egg Donors

The General Scheme adopts an extremely restrictive approach to the payment of donors of eggs and sperm. **Head 19** provides that reasonable expenses only may be paid, defined as (i) travel expenses, (ii) medical expenses, (iii) counselling expenses, and (iv) any legal expenses arising in relation to the donation process. In reality, this means that there is absolutely no incentive for a person to act as an egg or sperm donor. This may be the policy which the Committee – and ultimately the Oireachtas – wishes to adopt, but it should be conscious of the risk that this will stifle any development of the donation of eggs and sperm to Irish clinics. Currently, donor eggs and sperm used in Irish AHR treatments almost always are obtained from outside the country. There is little to no practice of domestic donation.

The approach adopted in the General Scheme is even stricter than other relatively strict regimes. The UK, for example, allows only the payment of reasonable expenses. However, this is defined as £35 per visit for sperm donors,[8] and £750 per donation cycle for egg donors.[9] In each case donors can claim additional expenses for travel, accommodation and childcare. So while the scheme is ostensibly based around "reasonable expenses," in reality donors are paid a fee, but the fee is very strictly capped. These modest sums would not be available under the proposed regime in the General Scheme.

Furthermore, the General Scheme also prevents the payment of "other reward" to donors. This would presumably prohibit schemes under which patients can donate their own eggs or sperm to others in return for a deduction in their treatment fees. Such

[7] Evans v *UK* (application 6339/05) Judgment of the Grand Chamber 10th April 2007
[8] https://www.hfea.gov.uk/donation/donors/donating-your-sperm/
[9] https://www.hfea.gov.uk/donation/donors/donating-your-eggs/

schemes are called egg and sperm "sharing" schemes and these have operated successfully in the UK.[10]

It is not clear from the General Scheme whether the importation of eggs and sperm from abroad – which is currently permissible – will be prohibited by the AHR legislation. One can assume that in the great majority of cases these gametes are obtained in return for the payment of more than reasonable expenses. If the import of these gametes is prohibited, and if a very strict regime for the payment of egg and sperm donors is adopted, it could well be the case that the availability of DAHR procedures in Ireland will be extremely limited. Again, perhaps this is a policy that the Committee will wish to adopt. If so it must recognise that there will be a significant risk that patients will travel abroad to circumvent such a prohibition, and seek treatment in a neighbouring jurisdiction.

iii) Recommendations on Part 4: Posthumous Assisted Reproduction

a) Time Limits for Posthumous Reproduction

The General Scheme does not appear to establish a time limit within which posthumous reproduction must take place, although it does specify a minimum period of 1 year from the time of death. It furthermore provides that the deceased person will only be recognised as the child's parent if the child is born within 36 months of the death.

The Committee should consider whether this 36 month period was intended to limit the period in which posthumous reproduction should take place. If not, the Committee should consider what the parental status of a child conceived outside of that period will be. To clarify this matter, it may be advisable to confine posthumous reproduction to the 36 month period. It would seem to be highly undesirable to permit posthumous reproduction in circumstances where the deceased parent will not be legally recognised as the child's parent.

b) Prohibition of altruistic surrogacy in context of posthumous reproduction

Head 24 only allows for posthumous reproduction where the surviving partner can, herself carry the pregnancy. It is not permissible to use a surrogate for the purposes of posthumous reproduction. There is no discernible principled basis for this. The General Scheme allows for altruistic surrogacy. It is not clear why, therefore, altruistic surrogacy in the case of posthumous reproduction is not permitted.

The result of this is that a surviving male partner who was in possession of frozen embryos would be unable to use them to have a child, even if his deceased partner had expressly consented to this. This seems to be a wholly unfair result. Similarly, a surviving female partner who had contributed an egg to create an embryo but was unable to

[10] *https*://www.hfea.gov.uk/donation/donors/egg-sharing/

gestate the pregnancy, would be excluded from posthumous reproduction. The General Scheme clearly accepts that altruistic surrogacy is permissible – if so, there is no principled reason to prohibit it in this context.

iv) Recommendations on Part 5: Pre-Implantation Genetic Diagnosis and Sex Selection

a) Pre-Implantation Genetic Diagnosis and the Definition of Serious Genetic Disease

Head 30(1) provides that pre-implantation genetic diagnosis (PGD) "*shall be permitted in cases where there is a significant risk of a child being born with a serious genetic disease that is included in the list to be established and maintained by the Regulatory Authority."* The Committee should note that this head refers to a "serious genetic disease" but the definition in **Head 29** refers to a "genetic disease." **Head 30** omits reference to "life limiting disease" even though this is defined in **Head 29.** There may be an unintentional discrepancy here, and this should be clarified.

Due to this lack of clarity it is difficult to assess how narrow the category of diseases which will be included actually is. It is not clear whether the disease must entail *all of* a "short life expectancy, serious physical or mental disability or illness and poor treatability" or just one of them.

From an ethical perspective, it is important that the circumstances in which PGD can be used are clearly prescribed. Analysis of this issue engages important debates about disability rights, and the appropriate attitude of the State to disabilities. The effect of PGD – if used widely – would ultimately be to eradicate certain disabilities. This is a delicate matter of social policy which must be carefully considered, both by reference to the people who would seek to use PGD, to the interests of members of the disabled community, and to the interests and values of society more broadly.

b) Identification of Conditions and the Constitutional Constraint of Article 15.2

Head 30 appears to delegate identification of the specific diseases which may be lawfully diagnosed to the Regulatory Authority. Constitutional issues may arise if too much discretion is afforded to the regulator, in circumstances where that discretion is not adequately controlled by the Oireachtas. Article 15.2 of the Constitution confines the power to make laws for the State to the Oireachtas.[11] It may only delegate powers if it provides sufficient principles and policies to guide the decision maker such that the decision maker is merely giving effect to the statute rather than making law itself. As such, for this legislation to meet the constitutional requirements, it must sufficiently set out for the regulator the criteria defining what types of condition will be sufficiently serious to be subject to PGD.

[11] *Cityview Press v An Comhairle Oiliúna* [1980] IR 381

v) Recommendations on Part 6: Surrogacy

Context: Surrogacy in Ireland

Before turning to the provisions of the General Scheme which address surrogacy, it may be of assistance to the Committee to briefly consider the reality of surrogacy practice in Ireland today. It would appear that within Ireland the practice of surrogacy is very rare.[12] This is not to say that Irish people are not engaged in surrogacy arrangements. When Irish people seek surrogacy services, they generally look overseas. Countries such as the United States, and Ukraine are attractive destinations. As certain countries crack down on the practice of international surrogacy – India, Nepal and Thailand, for example – Irish business necessarily moves elsewhere. Currently therefore, when we talk about surrogacy in Ireland, we primarily mean surrogacy arrangements entered into by Irish people overseas which those Irish people seek to have recognized in Ireland. We can only assume that the vast majority, or even all, of these agreements are made on a commercial basis where the surrogate is paid for her services.[13] This reality must be recognized as a key facet of the regulatory challenge in making law for surrogacy in Ireland.

a) Prohibition on Provision of Professional Services including Legal Advice

Head 36 sets out the conditions for the form of surrogacy which is to be permitted under the legislation. Only altruistic surrogacy which meets the criteria set out in the legislation will be permitted. Head 36(2) provides:

> *(2) Subject to subhead (3), it is prohibited for any person to intentionally provide a technical, professional or medical service that is to facilitate or give effect to a surrogacy agreement not permitted under subhead (1).*

This subsection is explained as follows:

> *Subhead (2) states that the provision of any technical, medical or professional service that would help to facilitate surrogacy which is not permitted under subhead (1) is prohibited, which would include providing legal or practical advice on a professional basis to people seeking to engage in surrogacy abroad or in commercial surrogacy.*

It is clear therefore that Head 36(2) is intended to prevent the giving of legal advice which would "facilitate or give effect to" surrogacy arrangements which fall outside the legislation. While this section pursues a reasonable goal – discouraging lawyers from assisting in the circumvention of the law on surrogacy - it is far too broad in scope.

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[12] Note, however, that the surrogacy arrangement in *MR v An t-Árd Chláraitheoir* [2013] IEHC 91, [2014] IESC 60 did take place in Ireland.

[13] This view is necessarily anecdotal.

This Head appears to prohibit the provision of legal advice or legal services to people who have already had a child through a prohibited surrogacy arrangement. The purpose of legal advice and/or services given in those circumstances would likely be to advise the commissioning parents on their legal position, and to provide advice as to how they may regularise the legal parentage of the children at Irish law. Such advice would likely be illegal under the General Scheme, as at least in relation to the legal status issue, it could be construed as a service "intended to facilitate or give effect to" a prohibited surrogacy arrangement.

From the perspective of the children, such a wide-ranging prohibition on the provision of legal advice is undesirable. The result would have a negative impact not just on commissioning parents, but also on the children, as there would be no mechanism under which legal advice could be sought to assist in the establishment of their parentage as a matter of Irish law. Arguably, the commissioning parents would not even be entitled to seek legal advice to assist them in clarifying their position, and to allow them to make a decision as to what steps to take to attempt to regularise the legal position of the child.

If there is a concern that lawyers may be involved in enabling commissioning parents to circumvent the law on surrogacy, the better approach may be to establish a legal requirement that lawyers do not engage in the promotion of surrogacy arrangements which fall outside the permitted regime. This would leave lawyers free to provide neutral advice on the legal consequences of such arrangements. As discussed below, there is a significant risk that due to the extremely restrictive nature of the surrogacy regime there will be substantial numbers of Irish people who will persist in travelling abroad to avail of commercial surrogacy services. If such arrangements will be rendered illegal, lawyers must be entitled to advise people as to their legal position both before they enter into such an arrangement (with a requirement to provide only neutral advice) and afterwards.

The freedom to provide neutral legal advice is essential to the role of the lawyer in society. Furthermore, the entitlement to provide such advice is arguably protected by the constitutional protection for the right to freedom of speech under Article 40.6.1, which comprises the right to express convictions and opinions, including the facts on which those opinions are based.[14] The constitutional protection also protects the right to give and receive information,[15] thereby potentially engaging the right of the commissioning parent to be advised on his or her legal position. While these rights would, of course, be subject to proportionate limitation, the restriction proposed in the General Scheme is not proportionate.

Ultimately, all surrogacy regimes struggle with the problem of how to address cases of people who deliberately or inadvertently circumvent the law, without negatively affecting the innocent child who is a product of those actions. This is discussed further below. In

[14] *Murphy v IRTC* [1998] 2 ILRM 360.
[15] *Kivlehan v RTE* [2016] IEHC 88

respect of Head 36(2), the General Scheme fails to give proper weight to the best interests of the child, and to the role of the lawyer in society.

b) Advertising of Surrogacy Services

Head 42 provides that it will be illegal to advertise the availability of surrogacy services of a particular person, or to advertise that one is seeking a surrogate. It seems that it would still be permissible for a fertility clinic to advertise that it provided medical surrogacy services in respect of altruistic arrangements already in place, but it could not advertise assistance in finding a surrogate. These provisions appear to be designed to avoid the growth of a surrogacy marketplace in which surrogates and intended parents could make contact and potentially enter into illegal commercial arrangements. If that is the purpose, however, the section may potentially overreach its intent. Altruistic surrogacy is permitted under the General Scheme, but if one cannot publicly advertise in respect of altruistic surrogacy arrangements, then presumably the only arrangements which will occur are those where the intended parents and the surrogate already know each other. There does not seem to be any principled basis for prohibiting advertising in respect of altruistic arrangements. It is possible that a woman may altruistically wish to carry a pregnancy for strangers, and therefore would need a way to make contact with them. To the extent that Head 42 prevents such arrangements being made – by preventing the development of a forum in which the relevant parties could make contact - it would seem to go too far. In reality, altruistic 'advertising' would likely consist of online fora where potential surrogates and intended parents would be able to make contact.

c) Access to Information Concerning the Surrogate and the National Surrogacy Register

Perhaps the most distinctive aspect of the General Scheme is that it makes extensive provision for the recording of information about the surrogacy arrangement and for ensuring that the resulting child will have access to information concerning the surrogate, issues that are addressed in **Heads 44, 50 and 51.** This aspect of the Irish regime will be different to that which operates in many other jurisdictions, but this is not necessarily a negative feature. Irish law provides a higher level of protection for the right to identity in assisted reproduction than that found in most other jurisdictions. The 2015 Act establishes a regime under which the anonymous donation of eggs and sperm is prohibited, and whereby donor-conceived people have access to identifying information on their donor. There is also an interaction between the National Donor Conceived Persons Register and the register of births to facilitate a person seeking a copy of their birth certificate being informed that they are donor conceived. The General Scheme adopts an approach to surrogacy which is wholly consistent with the 2015 Act. It should be applauded in taking the view that access to information concerning one's gestational mother is as important as information concerning one's genetic parents. This accords an appropriate level of respect to the gestational aspect of motherhood.

However, it should be emphasised that while it is appropriate to provide for an interaction with the register of births, so as to address situations where the person is never informed that they were surrogate-born or donor-conceived, finding out this kind of information from the office of the Chief Registrar is hardly ideal. It is essential that a culture of openness is created in Irish fertility to ensure that the vast majority of children are told about their status by the commissioning parents.

d) Surrogacy Arrangements Falling outside the Legal Regime

The General Scheme is silent on the status of children and parents who enter into surrogacy arrangements which fall outside the category of permissible arrangements. This silence is not unusual – legal regimes across the world struggle with the question of how to cope with these situations.[16] There is a fundamental tension arising from the fact that the commissioning parents have circumvented the law, but the child is a wholly innocent party. In the great majority of cases, the best interests of the child are served by remaining in the care of the commissioning parents, given that it is highly unlikely that there is anyone else who wants to be recognized as its parents. Clarke J adverted to this problem in *MR,* commenting:

> *Whatever form of regulation is considered appropriate to prevent abuse, exploitation or other practises which may be considered to be undesirable, there is always the risk that a child will come into existence in circumstances which are a breach of those regulations. Such a situation will not be the child's fault. The law will have to deal with that child as that child is. Any legislation needs not only to deal with the proper regulation of practise and methodology in this area but also the proper recognition of the status of children who result from advances in modern science. In the context of new advances in science the law will have to deal with the problem of what to do in circumstances where, in breach of whatever regulation may be put in place, a new human being has come into the world.*[17]

The General Scheme, whether deliberately or inadvertently, fails to tackle this issue. It establishes no procedure through which the best interests of the child born through a prohibited surrogacy arrangement may be protected.

A further issue for the General Scheme is the fact that it is expressly directed at surrogacy arrangements which take place in Ireland. Permissible surrogacy

[16] Fenton Glynn has explored the difficulties the English courts have experienced in relation to children born through international, commercial surrogacy arrangements which are illegal as a matter of English law. C Fenton Glynn, 'The Regulation and Recognition of Surrogacy Under English Law: An Overview of the Case Law' (2015) 27 Child and Family Law Quarterly 83, C Fenton-Glynn, 'Outsourcing Ethical Dilemmas: Regulating International Surrogacy Arrangements' (2016) 24(1) Medical Law Review 59.

[17] *MR v An t-Árd Chláraitheoir* [2013] IEHC 91, [2014] IESC 60, Clarke J at §2.21.

arrangements include only domestic surrogacy arrangements,[18] and surrogates must be habitually resident in Ireland. It seems therefore that the legislation will not regulate surrogacy arrangements entered into abroad by Irish people, and more importantly will not regulate the legal status of those parents and children when they return to Ireland. Given that such foreign surrogacy arrangements currently constitute the vast majority of "Irish" surrogacy arrangements, this would seem to be a significant lacuna. This omission may also fail to vindicate the rights of the child under the European Convention on Human Rights, as discussed below.

e) Absence of Retrospective Procedure

The General Scheme appears to make no provision for the making of parental orders in respect of surrogacy arrangements concluded prior to the enactment of the legislation. This is in contrast to the 2015 Act which does establish a limited regime for the retrospective recognition of parental status.[19] This seems unjust as it makes no allowances for the recognition of parental status even where the surrogacy arrangement in question was an altruistic one. Admittedly, it may well be the case that there have been few if any such arrangements in Ireland, but in principle it would seem to be unfair not to make any provision for arrangements which would have fallen within the regime, if enacted earlier.[20]

f) State Obligations under the European Convention on Human Rights

The General Scheme makes no provision for the recognition of the parentage of children birth through surrogacy arrangements falling outside the regime. This may be problematic from the perspective of the State's obligations under the European Convention on Human Rights.[21] In recent years the ECtHR has decided a number of cases concerning cross-border surrogacy, and the State's obligations respect of the rights of persons concerned when they return to their country of origin.[22] While it is clear that States are entitled to maintain domestic prohibitions on surrogacy, they may have obligations in respect of children born abroad. The leading case on this is *Mennesson v France*,[23] which concerned a French couple that entered into a surrogacy agreement in

[18] Defined as "a surrogacy agreement undertaken by a surrogate and an intending parent who are habitually resident and where the embryo transfer is carried out in this State." General Scheme Head 35.
[19] Sections 20-22, Children and Family Relationships Act 2015.
[20] At the very least, the applicants in *MR v An t-Árd Chláraitheoir* [2013] IEHC 91, [2014] IESC 60, the leading case on surrogacy in Ireland, seem to fit the criteria, and surely should be entitled to retrospective recognition.
[21] For a more in-depth discussion of this case law see Mulligan, 'Identity Rights and Sensitive Ethical Questions: The European Convention on Human Rights and the Regulation of Surrogacy Arrangements' (2018) Medical Law Review (Advance access: https://academic.oup.com/medlaw/advance-article-abstract/doi/10.1093/medlaw/fwx066/4838884?redirectedFrom=fulltext)
[22] *Mennesson v France* App no 65192/11 (ECtHR, 26 June 2014), *Labassee v France* App no 65941/11 (ECtHR, 26 June 2014), *Paradiso and Campanelli v Italy* Appl no. 25358/12 (ECtHR, 27 January 2015, Second Chamber) (ECtHR, 24 January 2017, Grand Chamber).
[23] *Mennesson v France* App no 65192/11 (ECtHR, 26 June 2014),

California with a Californian surrogate, which led to the birth of twins. The commissioning father was the genetic father, but the commissioning mother had no genetic link. Surrogacy was illegal as a matter of French law.[24] The French authorities refused to record the legal relationship between the parents and children in the French register of births, marriages and deaths, on the basis that it was contrary to the principles of French law "to give effect, in terms of the legal parent-child relationship, to a surrogacy agreement".[25] While the legal relationship between the parents and the children was not recognized as a matter of French law, the parents enjoyed full legal responsibility for the children, granted on the basis of the US civil status documents. The parents challenged this refusal to recognize the legal parent-child relationship, arguing that it violated the right to private and family life of both the parents and the children, as protected by Article 8 of the Convention.

The applicants were ultimately successful in this challenge, and the Court identified a breach of the children's right to respect for private life arising from the refusal of the French authorities to recognize the children as the children of their biological father, and as French citizens by reason of that relationship. This conclusion was premised on the existence of that genetic link, with the court commenting:

> *It cannot be said to be in the interests of the child to deprive him or her of a legal relationship of this nature where the biological reality of that relationship has been established and the child and parent concerned demand full recognition thereof*.[26]

As is clear from this quote, the welfare of the children was central to the Court's conclusions.

It is not clear precisely what effect *Mennesson* will have on the obligations of Member states in the surrogacy arena more broadly, but what does seem to be clear is that Member States have some obligation to recognize the legal relationship between a child born through cross-border surrogacy and its biological father, even where surrogacy is itself illegal as a matter of domestic law.[27] It is also important to note that the surrogacy arrangement in Mennesson appears to have been a commercial one, but this had no bearing on the Court's analysis. It seems therefore, that the obligation to recognize the parental relationship arises even where the child is born through a surrogacy arrangement which is illegal as a matter of domestic law. This may arguably apply to surrogacy arrangements carried out within the home state which are in breach of domestic law, as well as those entered into abroad.

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[24] French Civil Code, Civil Code, Article 16-7. This prohibition addressed altruistic as well as commercial surrogacy agreements.

[25] *Mennesson,* para 27, quoting the decision of the Court of Cassation of the 6 April 2011.

[26] *Mennesson,* para 100.

[27] Note that the ECtHR has been significantly less sympathetic to surrogacy related claims where there is no biological relationship *Paradiso and Campanelli v Italy* Appl no. 25358/12 (ECtHR, 27 January 2015, Second Chamber)

The General Scheme makes no provision for children born outside of the proposed regime, whether at home or abroad. The ECHR case law on surrogacy raises the prospect that a failure to make provision for these children may constitute a breach of the Convention, at least where there is a genetic link with the commissioning father. The Committee should explore the extent to which the legislation can accommodate the State's obligations in this regard.

4: Brian Tobin

Submission to the Oireachtas Joint Committee on Health on the General Scheme of the Assisted Human Reproduction Bill 2017

Dr Brian Tobin*

Introduction

I am a Lecturer (Above the Bar) in Law at NUI Galway, and I specialise in the areas of Family and Child Law, Assisted Human Reproduction and the Law, and Emerging Family Forms.[1] In 2014, I was invited to Leinster House to make an oral presentation to the Joint Committee on Justice, Defence and Equality regarding a related piece of legislation, the General Scheme of the Children and Family Relationships Bill.[2] In 2017, my work on parental rights for same-sex couples was cited and discussed in the Seanad.[3] I have been invited as the Irish national expert to present a paper on the surrogacy proposals contained in the General Scheme at the "Families through Surrogacy" conference at Croke Park in Dublin on 11th March 2018.[4] I have published numerous peer-reviewed papers in the areas of surrogacy and donor-conceived children and presented my findings at national and international conferences.[5]

A Critique of the Hybrid Model for Regulating Surrogacy proposed in Part 6 of the General Scheme of the Assisted Human Reproduction Bill 2017[6]

Part 6 of the General Scheme provides for the regulation of surrogacy in Ireland through what would appear to be a 'hybrid' model. The proposed regulatory model contains elements of both the 'pre-birth State approval' and 'post-birth Parental Order' models.[7]

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[1] See http://www.nuigalway.ie/business-public-policy-law/school-of-law/staff/briantobin/

[2] http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/DebatesWebPack.nsf/committeetakes/JUJ2014040900002?opendocument#A00100

[3] http://oireachtasdebates.oireachtas.ie/debates%20authoring/debateswebpack.nsf/takes/seanad2017053000002?opendocument#A00300

[4] http://www.familiesthrusurrogacy.com/dublin-expert-speakers/

[5] Brian Tobin (2016) Surrogacy Legislation, the Child's Constitutional Rights and the Irish Judiciary. [International Refereed Conference], *Society of Legal Scholars Annual Conference*, Oxford, U.K , 09-SEP-16

[6] See further Brian Tobin, "The General Scheme of the Assisted Human Reproduction Bill 2017: A Hybrid Model for the Regulation of Surrogacy in Ireland?" (2017) 4 Irish Journal of Family Law 83: https://www.academia.edu/35759031/The_General_Scheme_of_the_Assisted_Human_Reproduction_Bill_2017_A_Hybrid_Model_for_the_Regulation_of_Surrogacy_in_Ireland

[7] For a discussion of these models see generally Brian Tobin, "Forging a Surrogacy Framework for Ireland: The Constitutionality of the Post-birth Parental Order and Pre-birth Judicial Approval Models of Regulation" (2017) 29 (2) *Child and Family Law Quarterly* 133:

In Part 8, the General Scheme provides for the setting up of an Assisted Human Reproduction (AHR) Regulatory Authority that must, among its many functions, approve a surrogacy agreement before any treatment in a clinic will be permitted to go ahead. However, if Part 6 is ultimately enacted, the AHR Regulatory Authority's 'approval' of the surrogacy agreement between the intending parent(s)[8] and the surrogate will be limited to the approval of treatment, *not* parentage. Thus, Part 6 does not propose to sanction any 'pre-birth State approval' of parentage. This limited form of 'pre-birth State approval' is quite remarkable for a variety of reasons.

First, according to Head 38, before the surrogacy agreement can be submitted to the AHR Regulatory Authority for this 'prior approval' process, the surrogate must be medically and psychologically 'assessed and approved as suitable to act as a surrogate by a registered medical practitioner and also by a counsellor'. This rigorous process should help to ensure that the surrogate has the physical and mental capacity to consent to the agreement. Further, to ensure that her consent to the agreement is a free and fully informed one, under Head 43 the surrogate is required to receive *independent* legal advice, that is, legal advice independent from that received by the intending parents, about the legal implications of the surrogacy agreement before it can be submitted to the AHR Regulatory Authority.[9] Therefore, if the medical and psychological assessments are sound and the surrogate has received the requisite *independent* legal advice and is content to proceed with the arrangement, surely she should be deemed capable of consenting to a clause in the surrogacy agreement which stipulates that *immediately* upon the birth of the child, legal parentage rests with the intending parents? In other words, the surrogate should be able to consent to, and the provisions of the General Scheme should enable the AHR Regulatory Authority to approve, as part of the 'prior approval' process, legal parentage in favour of the intending parents once the child is born. At present, Head 45 only enables a surrogate to consent to treatment – why not parentage?

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https://www.academia.edu/35759028/Forging_a_surrogacy_framework_for_Ireland_the_constitutionality_of_the_post-birth_parental_order_and_pre-birth_judicial_approval_models_of_regulation

[8]The intending parents are the couple that commissions the surrogacy arrangement. The General Scheme also allows for there to be a *single* intending parent in a surrogacy situation: see Head 39 of the General Scheme of the Assisted Human Reproduction Bill 2017.

[9]See Head 43 of the General Scheme of the Assisted Human Reproduction Bill 2017.

Second, the General Scheme only proposes to regulate gestational surrogacy in Ireland, where the surrogate does not use her own genetic material but instead carries an embryo formed from the genetic material of others. Gestational surrogacy is also regulated under Californian law and there the surrogate is referred to as a 'gestational carrier', which clearly acknowledges that she is *not* the child's genetic parent.[10] Thus, it is unclear as to why Part 6 of the General Scheme does not propose to settle the issue of parentage in favour of the intending parents at the 'pre-birth State approval' stage, especially when one considers that, according to Head 39, *at least* one of the intending parents must contribute gametes to the formation of the embryo(s). Thus, in all domestic surrogacy scenarios, *unlike the surrogate*, one of the intending parents will *always* be genetically related to the child. Indeed, in practice, it is not unusual for *both* intending parents to contribute their genetic material to the formation of the embryo(s), because surrogacy is most often availed of by heterosexual married couples in situations where the wife's gametes may be suitable for IVF, but she is unable to carry a child to term.[11]

Post-birth Parental Orders, Surrogate's Consent and Article 42A

Head 44 provides that, at birth, the surrogate will be the child's legal mother. This might be more understandable in the case of a traditional surrogate who is in fact the genetic mother of the child. However, despite the rather selfless role she undertakes, an altruistic gestational surrogate has no genetic connection to the child The intending parents can only apply to the court seeking a Parental Order that will transfer legal parentage from the surrogate to them six weeks after the birth of the child, and only then if the surrogate consents to this. Part 6 makes it clear that the parties' surrogacy agreement may not be used as evidence of the surrogate's consent to a Parental Order. However, Part 6 does provide some potential relief for intending parents where the surrogate refuses to consent to a Parental Order. Head 48 (2) provides that the court can *waive* the requirement for the surrogate's consent in certain circumstances, including where

[10]Gestational or "carrier" surrogacy is estimated to account for 95% of surrogacy in the U.S. See further, Diane S. Hinson and Maureen McBrien, *"Surrogacy across America"* (2011) 34 (2) *Family Advocate* 32, at p 33. In the U.S., California, New Hampshire, Nevada, Connecticut, Delaware and Maine, have legislated for gestational surrogacy. Greece, Portugal and Israel similarly recognise only gestational surrogacy in their respective AHR legislation.

[11]Carol Coulter, "Why Surrogacy has nothing to do with Same-Sex Marriage", *Irish Times*, 27 April 2015, p.14.

she is (a) deceased, (b) lacks capacity, (c) cannot be located, or (d) 'for *any* other reason the court considers to be relevant.' (Emphasis added)

Situations a-c are highly unlikely and, while subsection (d) offers a potential life-line to intending parents where the surrogate refuses to consent, and might in practice prevent the kind of unfortunate outcome that occurred in the recent case of *Re AB (Surrogacy: Consent)*[12] in the U.K., it is nonetheless a broadly drafted provision that leaves far too much to judicial discretion in each individual case.

It is submitted that a better provision than (d), and one that would be more cognisant of the constitutional rights of the child under Article 42A, would be a provision equivalent to that contained in section 31 of the Adoption Act 2010, as amended by section 14 of the Adoption (Amendment) Act 2017. Section 31 allows the High Court to dispense with the need for the natural mother's consent where she fails, neglects or refuses to give her consent to the making of an adoption order. However, the High Court must have regard to:

The rights, whether under the Constitution or otherwise, of the persons concerned (including the natural and imprescriptible rights of the child);

(See section 31 (4) (a) (iv) of the Adoption Act 2010, as amended)

An identical provision should be included under Head 48 (2) because Article 42A protects the natural and imprescriptible rights of *all children* and statute should expressly provide that the constitutional rights of a surrogate-born child can factor into the court's decision on whether to waive the need for the surrogate's consent to the granting of a Parental Order. Indeed, Geoffrey Shannon has suggested that a child may enjoy a "natural constitutional right to family life pursuant to Article 42A.1".[13] There is much to suggest that, *where possible*, a child has a natural constitutional right to family life with its genetic parents.[14]

[12][2016] EWHC 2643 (Fam). In this case the surrogate and her husband refused to consent to a Parental Order in favour of the intending parents, and there was no possibility for the court to waive their consent as the U.K. Human Fertilisation and Embryology Act 2008 does not make provision for this. For an analysis of this case, see Brian Tobin, "A Critique of Re AB (Surrogacy: Consent): Can Ireland learn from the UK Experience?" (2017) 20 (1) *Irish Journal of Family Law* 3: https://www.academia.edu/35759022/A_Critique_of_Re_AB_Surrogacy_Consent_Can_Ireland_Learn_from_the_UK_Experience

[13] Geoffrey Shannon, *Child Law* (Thomson Round Hall, 2nd edn, 2010) at p 36.

[14] *G v An Bord Uchtála* [1980] IR 32, 67-68 (Walsh J.). Walsh J. suggested that among the child's natural rights is an entitlement "to be supported and reared by its parent or parents, who are the ones responsible for its birth".

Under the surrogacy regime proposed in Part 6, if a gestational surrogate refused to consent to a Parental Order in favour of the intending parents, it could be argued that she is breaching the child's natural constitutional right to family life under Art.42A. Since surrogacy is most often availed of by heterosexual married couples who both provide the genetic material that forms the embryo(s), by refusing to consent, and thus remaining the legal mother, a gestational surrogate could arguably be denying the child *its constitutional, familial right*s in relation to its genetic, married parents.[15] This would appear contrary not only to the 'Children's Amendment', Article 42A, but also the rights of the married family under Article 41 because there is a constitutional presumption that, *where possible*, the welfare of a child is best secured with its natural, married parents.[16] Therefore, an amendment/addition to Head 48 (2) that acknowledges the constitutional rights of the surrogate-born child and the other parties in the context of Parental Orders is crucial.

My Proposal: Pre-birth State Approval Model for Ireland

The proposed regulatory approach is at odds with the 'pre-birth State approval' model. This model operates in Ontario and British Columbia in Canada, and in certain States in the U.S. such as California, Delaware and New Hampshire, which permit intending parents in a gestational surrogacy arrangement to obtain a *pre-birth* court order determining the child's legal parentage *before* he/she is born. A similar model operates in Greece in the EU. In Greece, once the court has approved the surrogacy arrangement and given permission for treatment, there is a statutory presumption of maternity and a presumption of paternity in favour of the intending parents *as soon as the child is born*. Although the Greek model only embraces heterosexual intending parents, a similar model in Ireland could encompass same-sex intending parents with a statutory presumption of 'parentage' once the child is born.

In a surrogacy/donor-assisted human reproduction situation, the intending parents are the ones responsible for the child's birth, because it is they who initially *conceived of the notion of having the child* before even engaging the surrogate/gamete donor. In addition, Article 7.1 of the United Nations Convention on the Rights of the Child (UNCRC) provides that a child has "from birth… as far as possible, the right to know and be cared for by his or her parents".

[15]See Brian Tobin, "Forging a Surrogacy Framework for Ireland: The Constitutionality of the Post-birth Parental Order and Pre-birth Judicial Approval Models of Regulation" (2017) 29 (2) *Child and Family Law Quarterly* 133, 141.

[16] See *Re JH* [1985] I.R. 375, and *N v Health Service Executive* [2006] 4 I.R. 374. Indeed, the marital family is the only family form recognised under the Irish Constitution.

- From the intended parents' perspective, there is a high degree of certainty in relation to their post-birth parental status, and no need to worry about a post-birth parental order being made subject to the surrogate's consent. Where the intended parents are a married couple this approach, if adopted in Ireland, would surely help to prevent any 'attack' on their constitutional family by a non-consenting gestational surrogate following the child's birth.[17]

- From the child's perspective, its natural constitutional right to family life with its intended and, in many cases, genetic, married parents would be ensured pre-birth.[18] The child will only ever have *one* legal mother and there will be no need for expensive, time-consuming post-birth court proceedings to transfer legal parentage. Efie Kounougeri-Manoledaki praises the *child-centred* nature of the Greek model, as it enables "the child to have the woman who wants it as its mother from the moment it is born, without the intervention of judicial proceedings and with no legal connection at all with any other 'mother'."[19]

There is no apparent reason why a similar model could not be put in place in Ireland. The General Scheme could be amended to provide that once the AHR Regulatory Authority has approved the surrogacy agreement and given permission for treatment to go ahead, then a statutory presumption of parentage operates in favour of the intending parents *as soon as the child is born*. This would not conflict with the surrogate's right to manage her pregnancy in the same way as any other pregnant woman, as provided for under Head 41 (2), because the statutory presumption of parentage would only commence from the time of the child's birth, *and not before*. This 'pre-birth State approval' model achieves the best possible balance between the legal and constitutional rights of the gestational surrogate, intending parents and, *most importantly*, the surrogate-born child.

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[17] Brian Tobin, "Pre-birth Judicial Approval could be Surrogacy Answer", *Irish Times*, Dublin, 21 March 2016: https://www.irishtimes.com/opinion/pre-birth-judicial-approval-model-could-be-the-surrogacy-solution-1.2580783

[18] In the *MR & Another v An tArd Chláraitheoir* (surrogacy) case, the Supreme Court did caution the Oireachtas in relation to the regulation of surrogacy because, in his judgment, Clarke J frequently referred to "constitutionally permissible" legislation and cautioned that "*[w]ithin constitutional bounds* it is *largely* a question of policy for the Oireachtas to determine the precise parameters of [surrogacy] regulation." (Emphasis added)

[19] Efie Kounougeri-Manoledaki, "Surrogate Motherhood in Greece" (2005) *International Survey of Family Law* 267, at p 274.

Why has the Department of Health drafted proposals supporting a "Post-birth Parental Order" Model?

The General Scheme's proposal to allocate parentage via a "post-birth Parental Order" model is also baffling because in the U.K., the *Surrogacy UK Working Group on Surrogacy Law Reform* recently advocated in its report for a move away from this model, and for the law to instead move towards the *pre-authorisation* of surrogacy arrangements so that legal parenthood can be conferred on intended parents at birth in that jurisdiction.[20] In 2005 the Commission on Assisted Human Reproduction recommended in its report that a child born via surrogacy in Ireland should be *presumed* to be that of the intending parents.[21] The Commission appeared to envisage some form of *pre-birth* approval of legal parentage by the regulatory body that it proposed should be set up in Ireland to regulate AHR, a body akin to the Assisted Human Reproduction Regulatory Authority that is provided for in Part 8 of the General Scheme. This approval was to be based on "the 'intent of reproduction', *i.e.* what all parties intended from the outset of the arrangement."[22] Pre-birth State approval of parentage provides a greater incentive to intending parents to choose surrogacy as a viable means of assisted human reproduction, as their parental rights in relation to the child can be established and secured early on in the process.[23] There is less risk involved for intending parents. Further, with a pre-birth approval of parentage there is no need to apply to the court for a Parental Order post-birth, so there should be less cost involved for intending parents.

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[20] *Surrogacy in the UK: Myth Busting and Reform – Report of the Surrogacy UK Working Group on Surrogacy Law Reform* (Surrogacy UK, 2015) at p 39: https://www.surrogacyuk.org/Downloads/Surrogacy%20in%20the%20UK%20Report%20FINAL.pdf

[21] *Report of the Commission on Assisted Human Reproduction* (Department of Health, 2005) at p 53. Available at: http://health.gov.ie/wp-content/uploads/2014/03/Report-of-The-Commission-on-Assisted-Human-Reproduction.pdf . In March 2000 the Commission on Assisted Human Reproduction was established by the then Minister for Health and Children, Micheál Martin. Its role was to examine how assisted human reproduction services, including surrogacy, might be regulated in Ireland. The Report of the Commission on Assisted Human Reproduction was published in 2005. Among its 40 recommendations was a proposal that AHR, including surrogacy, should be regulated by a regulatory body established by the Oireachtas.[21]

[22] *Report of the Commission on Assisted Human Reproduction* (Department of Health, 2005) at p 52.

[23] Brian Tobin, "Surrogacy Proposals would make Process Costly, Time consuming and Frustrating", *TheJournal.ie*. Available at: http://www.thejournal.ie/readme/opinion-surrogacy-proposals-would-make-process-costly-time-consuming-and-frustrating-3666377-Oct2017/

Confusion regarding the Supreme Court's Pronouncements on Surrogacy

The Department of Health's basis for adopting the hybrid "pre-birth State approval/post-birth Parental Order" model for regulating surrogacy seems to have emanated from a clear misunderstanding of the Supreme Court's decision in the surrogacy case of *MR & Another v An tArd Chláraitheoir* in November 2014. This confusion was evident both when the General Scheme was being prepared and when department officials appeared before the Joint Committee on Health on 17th January 2018. Indeed, at the drafting stage, department officials responded to my email queries claiming that:

> "[t]he proposed legislation will take cognisance of the 2014 Supreme Court judgment in the *MR & Another v An tArd Chláraitheoir* (surrogacy) case, which found that the birth mother, rather than the genetic mother, is the legal mother."[24]

This is a complete misreading of the *MR* case. The Supreme Court did *not* find that the birth mother of the child is the legal mother. Denham CJ actually found that the principle of *mater semper certa est* "mother is always certain" is ***not*** part of the common law of Ireland:

> "It appears to me that in fact the maxim *mater semper certa est* was not part of the common law of Ireland. *It was a statement which recognised the medical and scientific fact that a birth mother was the mother of the child.* The common law of Ireland has not addressed the issue of motherhood in a surrogacy situation."[25]

The Supreme Court only quashed the High Court declaration that the twins' genetic mother was entitled to be registered on their birth certificates instead of the birth mother on the grounds that it was for the Oireachtas, ***not the courts***, to determine in a surrogacy scenario "the issue of who is the mother for the purpose of registration of the birth".[26]

[24]Email from Paul Ivory, Bioethics Unit, Department of Health, to author (16 November 2016).
[25][2014] IESC 60, at para [88]. Emphasis added.
[26][2014] IESC 60, at para [117].

Denham CJ held that:

> "**Such lacuna should be addressed in legislation and not by this Court** ... [u]nder the current legislative framework it is not possible to address issues arising on surrogacy, including the issue of who is the mother for the purpose of registration of the birth. *The issues raised in this case are important, complex and social, which are matters of public policy for the Oireachtas*."[27]

Thus, the Supreme Court made it quite possible for the Department of Health to draft legislation allowing for *pre-birth* approval of parentage in surrogacy situations, and the General Scheme can be amended by the Oireachtas so that the ultimate legislation that is enacted provides for *pre-birth* State approval.

In light of the true reading of the *MR* case, the deference shown to the Latin principle of *mater semper certa est* when department officials appeared before the Joint Committee on Health on 17th January was entirely misplaced:

Ms Geraldine Luddy: Yes. In cases of surrogacy, the scheme does not change the law about who is the mother on the birth of the baby. In this country, the birth mother is the mother. That is not changed in surrogacy cases in the scheme. The surrogate must transfer her right. If she does not do so, she remains the mother.

Dr. Tony Holohan: The scheme clearly provides that at the point of birth, the Latin principle is *mater semper certa est*, or motherhood is always certain. The birth mother is the mother until such time as she goes through or consents to the parental order process through the courts as I described earlier.

Therefore, the department's reason for including the complex hybrid model in Part 6 of the General Scheme appears to be rather misguided - it is hoped that this part of the General Scheme will be revised significantly on its passage through the Houses of the Oireachtas.

[27] [2014] IESC 60, at para [116-118]. Emphasis added.

Part 6 and the Screening of Intending Parents

In order to prevent a situation like that which arose in the 'baby Gammy' case, where the genetic father of twins born to a Thai surrogate was found to have child sex convictions, the General Scheme could be revised to require that intending parents disclose any previous convictions/agree to some form of Garda vetting prior to treatment being approved. Permission for treatment could be refused by the Assisted Human Reproduction Regulatory Authority where the nature of any previous convictions indicates that allowing a child to be born via surrogacy and ultimately parented by the intending parents may prove to be contrary to the best interests of the child. Indeed, it is stated clearly in the "Introduction" that the General Scheme has "a number of objectives, most importantly, protecting the *health and safety* of children born through AHR".[28]

Conclusion

The General Scheme of the Assisted Human Reproduction Bill 2017 proposes a complex, hybrid pre-birth and post-birth approval model for domestic surrogacy arrangements. Given that only gestational surrogacy will be regulated, the requirement for a genetic link between the child and at least one intending parent, and the rigorous statutory requirements that must be fulfilled before the parties can submit their surrogacy agreement to the AHR Regulatory Authority for 'approval', there is no apparent reason as to why the regulatory body's 'approval' at the pre-birth stage should really be limited to an approval to proceed with treatment in a clinical setting, and not to an approval of legal parentage. The hybrid model appears to have emerged from the policy-makers' clear misunderstanding of the Supreme Court's decision in *MR & Another v An tArd Chláraitheoir* in late 2014.[29]

The hybrid model proposed by Part 6 of the General Scheme arguably discourages surrogacy because so many criteria must be fulfilled before the parties' agreement can be submitted to the AHR Regulatory Authority for 'approval', and such 'approval' does not then secure the intending parents' parental rights *pre-birth*. If ultimately enacted, the hybrid model could also prove potentially frustrating for intending parents where the surrogate's consent is not forthcoming after the birth of the child, and it could involve expensive, time-consuming,

[28] See "Introduction to the General Scheme" of the Assisted Human Reproduction Bill 2017. (Emphasis added.)
[29] [2014] IESC 60.

heart-wrenching court proceedings to seek to have the surrogate's consent waived. Given the amount of time, planning and financial and emotional expenditure involved in seeing a surrogacy arrangement through to fruition, these are huge risks that many Irish intending parents may be quite unwilling to take. The policy underlying Part 6 of the General Scheme and the provisions contained therein need to be substantially revised because, if enacted, rather than facilitating domestic surrogacy arrangements, Part 6 of the General Scheme is far more likely to discourage them.

Recommendations to the Committee

• Replacement of the hybrid model for regulating surrogacy in Part 6 with the pre-birth State approval model;

• Introduction of the pre-birth State approval model is entirely compatible with the Supreme Court's decision in *MR & Another v An tArd Chláraitheoir*;

• The pre-birth State approval model achieves a better balance between the constitutional rights of the child, the gestational surrogate and the child's intending, married parents;

• This would require substantial redrafting/deleting of parts of Head 35, 39, 41, 43, & 44-49, and even an amended definition of 'surrogate' in Head 2.

• If hybrid model is to remain, amend Head 48 (2) to allow the constitutional rights of the child under Article 42A to factor into the court's decision on whether to waive the need for the surrogate's consent to a Parental Order;

• Consider screening/Garda vetting of intending parents in light of international surrogacy scandals such as the 'baby Gammy' case in 2014.

5: Dr Ciara Staunton and Professor Frank Barry

Submission to the Joint Health Committee by Prof Frank Barry and Dr Ciara Staunton

Authors

Dr Ciara Staunton is a lecturer in law at Middlesex University. She completed her post-doctoral research at the Centre for Medical Ethics and Law at Stellenbosch University, Cape Town. She completed her PhD at the School of Law in National University of Ireland, Galway. Her thesis, funded by the Irish Research Council, was entitled *The Regulation of Stem Cell Research in Ireland.* She has published widely on the regulation of stem cell research in Ireland, and has conducted empirical research with scientists on this topic. She is currently engaged in research examining the regulation of embryo research and testing in Europe, and has been requested by the Government of Bahrain to advise on the introduction of stem cell research regulations in Bahrain.

Frank Barry is Professor of Cellular Therapy at the Regenerative Medicine Institute (REMEDI), National University of Ireland Galway. Here he directs a large team of researchers who focus on the development of new repair strategies in stem cell treatment in musculoskeletal diseases. He also has an interest in the development of advanced manufacturing platforms for cell therapy products. He has worked in leading research centres in the US, UK and Canada, including the Kennedy Institute of Rheumatology, London, Shriners Hospital for Children, Florida and Case Western Reserve University, Cleveland. He is currently Senior Scientist at the Arthritis Programme, Toronto Western Hospital, is a Senior Fellow of the International Cartilage Repair Society and was recently a recipient of the Marshall Urist Award for excellence in tissue regeneration research from the US Orthopaedic Research Society.

Introduction

There has been marked global interest in stem cell therapy in recent years and many investigators hold the view that this new technology will have a transformative impact on the practice of medicine. Stem cell therapy is based on the principles of regeneration, rather than replacement, of tissues damaged as a result of disease or trauma, thereby providing new treatment modalities for serious diseases for which there are currently no effective options. It is likely that stem cell treatments will become part of the routine practice of medicine in the future and will have a strongly positive impact on the quality of life of patients and their families as well as providing significant efficiencies in healthcare delivery.

Classification of Stem Cells

Stem cells are commonly classified in terms of their source and method of preparation. Adult stem cells (also referred to as tissue stem cells) are derived from adult or neonatal tissues, for example bone marrow, fat tissue or umbilical cord. These cells are being tested in clinical studies to determine their effectiveness in wound repair and in conditions where there is tissue degeneration, such as arthritis and chronic back pain. They are also being tested, and have shown very promising results, in conditions where modulation of the immune system is needed, such as inflammatory diseases. Although there is still much work to be done, the testing of tissue stem cells in clinical studies is progressing at a fast pace and shows a great deal of potential.

Embryonic stem (ES) cells are derived from unimplanted embryos 5 days after in vitro fertilization. This is referred to as a blastocyst and is generated in protocols for assisted human reproduction. The embryonic stem cells are taken from a particular group of cells in the blastocyst referred to as the inner cell mass. A milestone in this research was attained in 1998 when the first report was published which demonstrated the derivation and maintenance of human ES cells in laboratory

culture. Many experts believe that ES cell therapy provides unprecedented and remarkable opportunities for treating patients. This enthusiasm arises because of two properties of the cells, (1) they are pluripotent and can differentiate into cells of every tissue in the body and (2) they can be maintained indefinitely in laboratory culture. Therefore these cells represent an inexhaustible supply of every cell type for tissue regeneration therapy.

In recent years newer technologies were developed which have also had a dramatic impact. In 2006 research was published which showed the generation of embryonic-like stem cells from adult cells. In this approach normal and easily available adult cells (for example taken from a skin biopsy or a blood sample) can be modified by genetic manipulation so that they attain the properties of ES cells. Like ES cells, these cells are pluripotent and can be maintained indefinitely in culture. They are termed induced pluripotent stem cells (iPSCs).

Status of Research in Stem Cell Therapy

ES cells, iPSCs and tissue stem cells are all undergoing clinical testing and many clinical trials - conducted to provide evidence on whether these therapies are successful or not - are either registered, active or completed. At this time tissue stem cells are at the forefront of this effort and several such studies are taking place in Ireland. The results of these inevitably represent a mixture of outcomes: in some studies there has been dramatic success and in others no useful outcome has been observed. The clinical testing of ES cells and iPSCs is less advanced but still continuing apace. There is a view that these cells may well represent a superior option compared to adult stem cells in treating specific severe conditions such as diseases of the retina and spinal cord and peripheral nerve injury.

Approaches to Stem Cell research in Ireland

*A*s the Committee is aware, the Commission on Assisted Reproduction (CAHR) published a comprehensive report in 2005 on assisted reproduction and associated research. In 2008, the Irish Council for Bioethics (ICB) issued a report that examined stem cell research in Ireland and made a series of recommendations that were broadly in line with the CAHR. In the intervening years there has been no legislative response and we welcome the publication of the General Scheme of this Bill, as well as the opportunity to comment on specific aspects.

Since the publication of the CAHR report there have been considerable legal, ethical and scientific developments. In Ireland, the Supreme Court in *Roche v Roche* clarified that the embryo *in vitro* is not protected under Article 40.3.3. The Court declined to state what status the embryo has in law, rightly believing this to be a matter for the Oireachtas, but did state that the embryo is deserving of 'respect'. This decision clarified the constitutional matter, but the lack of a legislative response meant that the embryo *in vitro* was without any protection in law in Ireland.

Certain research institutes in Ireland (University College Cork and Trinity College Dublin) published guidelines for their research ethics committees on how to consider research proposals involving human ES cells. The guidelines were broadly in line with those of the CAHR and ICB. It emerged, however, that a directive from the Department of Health to the funding agencies Science Foundation Ireland and Health Research Board indicated that financial support should not be provided for research in Ireland involving human ES cells.

In April – June 2017, one of us (CS) conducted qualitative interviews with scientists, regulators and funders based in Ireland to examine the impact that the lack of a regulatory framework has on science in Ireland. The main points of the study can be summarised as follows:

1. There was universal criticism of the failure of successive governments to engage on this topic. Many of those interviewed believed that the lack of a regulatory framework and the *de facto* ban on ES cell research has had a negative impact on career progression and scientific advancement.
2. Research involving IPSCs is actively pursued in Ireland and many investigators have the view that this research is strengthened if ES cells are available for comparative studies.
3. Many of those interviewed referred to a confused or inconsistent approach in Ireland whereby the procurement and use of human embryonic *stem* cells is strictly curtailed while the procurement and use of embryonic *kidney* cells is not. Human embryonic kidney (HEK) cells, widely used in life sciences research, were originally isolated from foetal tissue

A number of recommendations emerged from this analysis, and some of these are worth noting:

1. There is a clear need for clarity and transparency in this area of scientific research
2. The regulations that apply in Ireland should be consistent with international practice
3. An independent regulatory body capable of responding to future technological, scientific and ethical developments is proposed

Head 63

Head 63 requires an application to the Regulatory Authority to create, collect, store or use ES cell lines *and* iPSC lines. Head 63 thus puts the same regulatory burden on both, despite that fact that the former are derived from blastocysts and the latter from adult cells. This strikes us as being illogical from a scientific, legal and ethical perspective.

The ethical concern with ES cell research rests on the *origin* of the cells. The potential *use* of the research is relatively uncontroversial and will be subject to the same licensing requirements as other cell therapies. The ethical concern with the use of an embryo in research arises because the status of the embryo is uncertain: Some view the moral status as that of a human being and it can never be destroyed; others view the embryo as an entity that gradually develops into a foetus that eventually results in the birth of a child. Agreement on these points will be elusive, but it is the legal status of the embryo that is the focus of this Committee. The Irish Supreme Court in *Roche* noted that the embryo is worthy of 'respect' and for this reason there must be some protection in law. Thus, by restricting the use of embryos for research to only the most serious of diseases and having clear oversight of the research, this Bill ensures that the embryo is respected and finally confers protection on the embryo *in vitro* in law in Ireland.

As iPSCs differ from ES cells in their origin and do not necessitate the destruction of the embryo, iPSC research does not raise the same ethical concerns. It is standard practice internationally that research that involves embryos or ES cell research is subject to specialised review. IPSC research is not included in such a review and in its most recent guidelines, the International Society for Stem Cell Research have recommended the following:

> 'All research that (a) involves preimplantation stages of human development, human embryos, or embryo-derived cells or (b) entails the production of human gametes in vitro when such gametes are tested by fertilization or used for the creation of embryos shall be subject to review, approval, and ongoing monitoring by a specialized human embryo

research oversight (EMRO) process capable of evaluating the unique aspects of the science. The derivation of human pluripotent stem cells from somatic cells via genetic or chemical means of reprogramming (for example, induced pluripotent stem cells or iPSCs) requires human subjects review but does not require specialized EMRO as long as the research does not generate human embryos or entail sensitive aspects of the research use of human totipotent or pluripotent stem cells as outlined in this section.'

It is clear that all research that involves clinical application of cell-based therapies, irrespective of the origin of the cell, should undergo a review and be monitored by a Research Ethics Committee. The ethical concerns in the future use of such therapies are distinct from the concerns over the origin of the cells: these concerns relate to the protection of research participants and include issues relating to informed consent, the benefit-risk ratio as well as confidentiality and privacy. Putting an extra review process on IPS research simply because of its potential would be inconsistent in the treatment of adult stem cells, out of step with international best practice and lacking in legal or ethical foundation.

Proposed Regulatory Authority

The proposed Regulatory Authority is a welcome development and, provided it is adequately staffed, will ensure that there is appropriate ethical and scientific oversight of proposed research and services under the Bill. However, due to the restrictive scope of the Bill, the Regulatory Authority will not be in a position to respond to technological change in this area and the Bill risks being outdated before it has become an Act. We urge the Committee to give greater authority to the Regulatory Authority to ensure that there they have the power to respond to technological change.

Recommendations

1. The unnecessary review for IPS research must be removed to bring Ireland in line with international best practise.
2. The Bill must confer greater power to the proposed Regulatory Authority to be proactive in the regulation of these new and emerging technologies.

6: Dr Katherine Wade

Submission on the General Scheme of the Assisted Human Reproduction Bill 2017

My name is Dr Katherine Wade. I am a Lecturer in Law at the University of Leicester. I hold a BCL from the National University of Ireland, Galway, and an LLM and PhD from University College Cork. Prior to my appointment, I was a Post-Doctoral Research Associate at the Centre of Medical Law and Ethics at King's College London, where I worked on a Wellcome Trust project entitled "The Donation and Transfer of Human Reproductive Materials" and was module leader for Medical Law. My research and teaching interests lie in the areas of medical law and ethics, family law, children's rights, human rights and research ethics. My current focus is on the area of surrogacy. I am examining this issue from a children's rights perspective. I have published research in leading journals in my areas, such as the Medical Law Review, the Child and Family Law Quarterly and the European Journal of Health Law. I have been a visiting scholar at a number of institutions in Europe and the US including the Brocher Foundation, Geneva, St Louis Law School, Missouri and Emory Law School, Atlanta. In March 2014, I was a Yale-Hastings Visiting Researcher. I have also been invited as an expert to conferences on bioethics and children's rights at the Council of Europe in 2015 and 2016.

The Right to Know One's Origins: Heads 50-56

The General Scheme of the Bill takes a clear stance on the issue of children knowing their origins. In relation to surrogacy using donor gametes, it is clear that a person can find out non-identifying information about their donor before the age of 18 and identifying information after the age of 18.[1] In relation to surrogacy, they can also find out the identity of their surrogate mother at the same age.[2] (This is subject to the relevant person making the case not to release such information on safety grounds).[3] It is clear from the Bill that children are entitled to know of the manner of their birth, and their genetic and biological origins. Head 50(3) provides that a "National Surrogacy Register" will keep records of every surrogacy arrangement in the State. The Register will record the identity of the surrogate, intending parents and any relevant donor, as well as information about any Parental Order which was made. Such information is then recorded on a child's birth certificate (Head 49). I

[1] Head 53, *General Scheme of the Assisted Human Reproduction Bill 2017.*
[2] Head 54, *General Scheme of the Assisted Human Reproduction Bill 2017.*
[3] Head 54, (2), *General Scheme of the Assisted Human Reproduction Bill 2017.*

support this approach. It goes further than the law in England and Wales. While access to identifying information about donors is permitted, there is no indication from a child's birth certificate which would alert them to the availability of such information They therefore rely on parental disclosure of the use of donor gametes in their conception.[4] However, one recommendation can be made. The law should permit access to such information before the age of 18. This is not to say that there is a requirement that children should be told at a certain age about their genetic and/or biological origins, but that such information should at least be available if parents want to share this information with their child during their childhood.

John Tobin argues that since current research indicates the importance of openness with children in the context of donor assisted reproduction, it is difficult to justify legal regimes which deny access to identifying information about donors until a child turns 18.[5] There is a growing recognition of the importance of telling children about their origins at an *early age* so that they develop an integrated narrative sense of self.[6] Donor-conceived individuals advocate oneness at an early age, to avoid mistrust and poor self-perception which can occur from being told at a later stage.[7] Some case law from the European Court of Human Rights (ECtHR) has engaged with the right of a child to know their genetic origins *during childhood*. In *Mikulić v Croatia* it was held that the failure by domestic courts to require the putative father of the five-year-old applicant to undergo a paternity test amounted to a violation of her right to respect for private and family life under Article 8 of the *European Convention on Human Rights* (ECHR). While this case is about the right to know whether a *particular person* is or is not one's parent, the court held that people have a 'vital interest, protected by the Convention, in receiving the information necessary to uncover the truth about an important aspect of their personal identity'.[8] The *Convention on the Rights of the Child 1989* also contains a right to "know one's parents" under Article 7(1). The Committee on the Rights of the Child has been critical of States which preclude access to information about

[4] The law is slightly different in the case of surrogacy, since the child's original birth certificate will contain the name of the surrogate.

[5] See J Tobin, 'The *Convention on the Rights of the Child:* the rights and best interests of children conceived through assisted reproduction' (Victorian Law Reform Commission, 2004), at p 144.

[6] Nuffield Council on Bioethics, *Donor Conception: Ethical Aspects of Information Sharing* (Nuffield Council on Bioethics, 2016), at pp 13 and 64.

[7] For a discussion, see D Madden, *Medicine, Ethics and the Law*, 3rd ed, (Dublin: Bloomsbury, 2016) at 208-212, citing O Van den Akker, "A Review of Family Donor Constructs: Current Research and Future Directions" (2006 12(2) *Human Reproduction Update* 91.

[8] Application No 52176/99) (2002) 11 BHRC 689, at para 64.

children's biological origins.[9] Since the CRC concerns people under the age of 18, it is clear that the right to know one's parents is relevant during childhood, and not only when one turns 18. Therefore, it has been argued that the law should be changed to allow parents to have access to identifying information about donors so that they can share this with their child at a time when they deem appropriate, in line with the child's development and evolving capacities.[10] I agree with this approach. The General Scheme of the Bill and its Explanatory Notes are clear that the aim of many of the provisions are to "protect the child's right to ascertain his or her identity by ensuring that s/he will be informed that s/he was born under a surrogacy agreement".[11] However, allowing access to identifying information about donors and surrogates at the age of 18 focuses not on the right to identity of *children,* but rather on the right to identity of the adults they become.

In order to follow the approach set out above, the Children and Family Relationships Act 2015 would have to be amended to allow parents to have access to identifying information about donors. This is beyond the scope of the current consultation. In relation to the right to know one's surrogate mother, the General Scheme of the Bill could be amended to reflect this position. This would require a change to the operation of the Surrogacy Registry. It would mean that it could operate in such a way that parents have access to information about the surrogate mother, so they can tell the child before they reach the age of 18. However, it should be noted that this issue may not be particularly relevant in the surrogacy context. Since the Bill proposes that all surrogacy arrangements are done through "surrogacy agreements", it most likely that the surrogate mother is known to the intending parents. Indeed, in the case of surrogacy, surrogates and intending parents are in usually in regular contact throughout the pregnancy, not least because of the payment of reasonable expenses to the surrogate mothers. In the UK, surrogate mothers and intending parents often forge a bond throughout the pregnancy, with surrogate mothers sometimes keeping in contact with the child.[12]

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[9] It has urged States Parties to ensure that adopted children can access information about the identity of their biological parents and to eliminate anonymous birth. See K. Wade, "The Legal Regulation of Surrogacy in the UK: A Children's Rights Perspective" (2017) 29(2) *Child and Family Law Quarterly* 113 at 123-124.

[10] See J Appleby, 'Regulating the provision of donor information to donor-conceived children: is there room for improvement', in S Golombok et al (eds), *Regulating Reproductive Donation* (Cambridge University Press, 2016), at pp 334–351.

[11] Explanatory Notes to Subhead 6, *General Scheme of the Assisted Human Reproduction Bill 2017.*

[12] See, for example, V. Jadva, S. imrie and S. Golombok, "Surrogate mothers 10 years on: a longitudinal study of psychological well-being and relationships with the parents and child" (2015) 30(2) *Human Reproduction* 373.

However, the recording of the surrogacy arrangement serves other purposes than recording information about gamete donors and surrogate mothers. Head 50(3)(a) provides that the surrogacy arrangement also records the same information for the intending parent(s). Head 54(1)(a) aprovides that a child may request birth and contact details of intending parent(s).[13] The agreement also records whether an application was made to the court for Parental Order and the outcome of this decision. This means that if a Parental Order was not granted to the intending parents, the child still has a way to access information about their intending parents. On the one hand, this is commendable, since it protects the child right to know their origins. On the other, there may be concerns about the child's welfare, depending on the reasons for the refusal of the Court to grant the Parental Order. This type of situation may be very rare, particularly given the focus on welfare before the birth of the child (Head 6(1)), the counselling requirements for intending parents (Head 8) and the assessments of surrogate mothers (Head 38(1)(b)). Indeed in the UK, disputed surrogacy arrangements are very rare.[14]

The Right of the Child to Know Their Origins and Counselling Requirements: Head 6

The concept that all intending parents wishing to undergo assisted human reproduction services be required to attend counselling is commendable. The Explanatory Note to Head 8, Subhead 1 states:

> Such counselling would provide an opportunity to discuss the possible medical and social implications of the proposed treatment for the intending parents, any child who might be born as a result of that treatment or for the intending parent's existing children, if any. Counselling could also provide advice in relation to additional supports or services available.

It is important that such counselling includes information to parents regarding the importance of children knowing about their genetic and biological origins.[15] The Bill is committed to the child's right to know their genetic origins in relation to donors and their biological origins relating to their surrogate mother. As noted above however, the restriction on accessing identifying information about either surrogates or egg donors until the child is 18 does not reflect a children's rights perspective. It should be open to parents to be able to

[13] The singular, i.e., "parent" is used in Head 54(1)(a).
[14] N Gamble, 'A better framework for United Kingdom surrogacy?' in S Golombok et al (eds), *Regulating Reproductive Donation* (Cambridge University Press, 2016), at p 148 citing *Re N* (2007) EWCA Civ 1053, *Re TT (2011)* EWHC 33 Fam and *H v S (Surrogacy Agreement)* (2015) EWHC 36 Fam.
[15] See K. Wade, "The Legal Regulation of Surrogacy in the UK: A Children's Rights Perspective" (2017) 29(2) *Child and Family Law Quarterly* 113 at 127.

tell their children identifying information about their biological or genetic parents during their childhood. This would require changes in the law on gamete donation under the *Children and Family Relationships Act 2015* to allow parents to access identifying information about donors on the birth of their child. This Bill could allow access to information about the surrogate so parents could inform children of the nature of their birth during their childhood. Again, it is extremely unlikely that the parents will not know the identity and contact details of the surrogate mother, due to the nature of the surrogacy agreement.

Nonetheless, parents may wish to refrain from telling them of the nature of their birth through surrogacy and/or that they were conceived with the use of donor gametes. Counselling for intending parents should include information about the importance of the right of the child's know their origins, in line with the above arguments made on this point. **It should also be noted then that surrogate mothers should receive information regarding the importance of a child's right to know their genetic and biological origins and that the child will have information about their identity on turning 18. Provision could also be made in the Act for AHR treatment providers to provide counselling to children relating to the manner of their birth through surrogacy and/or gamete donation.**

The Ban on International Surrogacy: Head 36(1)(a) and Head 36(2)

The issue of inter-country surrogacy raises difficult legal and ethical concerns. Certain countries will allow certain practices which are not permitted under this Bill. For example, certain countries allow anonymous gamete donation, while others allow commercial surrogacy. It is not clear from the General Scheme of the Bill if procurement of surrogacy services abroad and the provision of information about such services are criminal offences. It states in Head 36 that only domestic surrogacy arrangements are permitted. In addition, Head 36 (1) (2) states that it is "prohibited for any person to intentionally provide a technical, professional or medical service that is to facilitate or give effect to a surrogacy agreement not permitted under subhead (1)". In the UK framework, it has been recommended that international surrogacy should not be prohibited, noting that such a prohibition would be extremely difficult to enforce.[16] Nonetheless, serious ethical issues arise in relation to

[16] See K Horsey et al, 'Surrogacy in the UK: myth busting and reform: Report of the Surrogacy UK Working Group on Surrogacy Law Reform' (Surrogacy UK, 2015) at 38.

potential exploitation of surrogates and intending parents. Moreover, there are concerns about safety of the procedures used and the use of anonymous gamete donation.[17]

There are also difficult legal issues relating to legal parenthood arising from inter-country surrogacy arrangements, some of which have been documented in recent cases before the ECtHR. These cases involve intending parents who go abroad to avail of surrogacy services and when they return to their home country (where surrogacy is illegal) there are issues around the legal recognition of parenthood in relation to the child.

The following principles arise from these cases:

1. Refusal to recognise the parenthood of a genetic parent in relation to children born through surrogacy in another country was held to be a violation of the children's right to private life under Article 8 of the *European Convention on Human Rights* (ECHR). It was held that the right to respect for private life comprises the right to establish details of one's identity, including the legal parent-child relationship.[18]
2. The removal of a child from intending parents who partook in surrogacy from another country where there was no genetic link to either of them did not amount to a violation of their private life under Article 8 of the ECHR.[19]

The principles set out above from the case law of the *European Court of Human Rights* (ECtHR) need to be taken into account in relation to the ban on international surrogacy arrangements.

In addition, **if international surrogacy is not permitted, then this needs to be made known to the public. Public information about the potential disadvantages of inter-country arrangements needs to be made known.[20] The details of such a scheme may be outside the ambit of this Bill.**

[17] Hague Conference on Private International Law Permanent Bureau, *A Study of Legal Parentage and the Issues Arising from International Surrogacy Arrangement*, Prel. Doc. No 3 C March 2014 , at 84. See also Conference on Private International Law Permanent Bureau 2015, *The Parentage/Surrogacy Project: An Updating Note*, Prel. Doc. No 3A, February 2015.
[18] See *Labassee v. France*, App no. 65941/11, 26 June 2014 and *Mennesson v. France*, App no. 65192/11, 26 June 2014.
[19] See Paradiso and Campanelli v Italy, App No. 25358/12, 24 January 2017.
[20] See K. Wade, "The Legal Regulation of Surrogacy in the UK: A Children's Rights Perspective" (2017) 29(2) *Child and Family Law Quarterly* 113 at 127.

Parental Orders: Head 47

Under the General Scheme of the Bill, legal parenthood of the child would be transferred to the intending parents after the child through a Parental Order. There is a similar system in operation in the UK. However, there have been calls to change the system to one based on pre-authorisation of parenthood. Under such a system, the intending parents would be approved by a Court as the legal parents of the child.[21] **I support the introduction of a system of pre-authorisation of parenthood and believe this could be introduced in this Bill.** The argument for changing the law to such a system is that parental orders do not reflect the intentions of the parties in the majority of cases. The surrogate mother's intention is usually to give the child to the intending parents.[22] As Gamble notes, the current system is also disadvantageous to surrogates and their partners, who could be burdened with legal responsibility for a child they did not wish to have.[23]

Therefore, it is argued that the law should reflect the intentions of the parties and allow the intending parent to become the legal parents before the child's birth. It can also be argued that a pre-authorisation system recognises the autonomy of individuals in the surrogacy arrangement and reflects the fact that women can make autonomous decisions to enter into surrogacy arrangements. A pre-approval system can also be argued to be in the best interests of children. Any dispute about parenthood at the time of the child's birth should cause psychological distress to infants and could also cause distress to children if they find out about the dispute at a later stage. This point was made in the Brazier Report in 1998. It states:

> The welfare of the child, who may in infancy be the subject of protracted legal proceedings, and later come to know of the disputed custody and separation from his or her genetic parent(s), must be a matter of concern.[24]

Of course, it can be argued that any disputes or conflict in a child's life at this early stage and have deleterious effects and the law cannot seek to avoid this. However, it can be argued that if a pre-approval system is likely to facilitate a successful arrangement, in which all of the parties are in agreement at the time of the child's birth and thereafter, this is to be commended.

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[21] See K Horsey et al, 'Surrogacy in the UK: myth busting and reform: Report of the Surrogacy UK Working Group on Surrogacy Law Reform' (Surrogacy UK, 2015) and N Gamble, 'A better framework for United Kingdom surrogacy?' in S Golombok et al (eds), *Regulating Reproductive Donation* (Cambridge University Press, 2016), at p 152.

[22] See N Gamble, 'A better framework for United Kingdom surrogacy?' in S Golombok et al (eds), *Regulating Reproductive Donation* (Cambridge University Press, 2016), at p 152. She cites only three cases involving a dispute over parenthood.

[23] N Gamble, 'A better framework for United Kingdom surrogacy?' in S Golombok et al (eds), *Regulating Reproductive Donation* (Cambridge University Press, 2016), at p 146.

[24] *Surrogacy: Review for Health Ministers of Current Arrangements for Payments and Regulation: Report of the Review Team* (Her Majesty's Stationery Office, 1998), at p 26.

It should be noted that pre-authorisation of parenthood does not necessarily mean that there must be enforceability of surrogacy agreements. In Israel, where there is a pre-approval system, surrogates can withdraw from the agreement to relinquish the child if it is found that there has been a 'change of circumstances' which justifies the withdrawal of her consent, and that this is not likely to have an adverse effect on the child's welfare.[25]

However, it must be noted that if such a system is brought into effect the right of the child to identity must be protected. **This would mean that there must nonetheless be documentation of the surrogacy agreement in a way which allows for the child to know of the nature of their birth through surrogacy and their surrogate mother.** The pre-authorisation of parenthood , along with the identity of all parties could be documented and stored by the Surrogacy Registry. There would have to be a system of notification to An tArd Chláraitheoir in order for the birth certificate of the child to be annotated to contain a reference to the existence of the pre-approval form.

The Requirement for a Genetic Link with One Intending Parent: Head 39(3)(b)

Head 39(3)(b) of the General Scheme of the Bill states that every surrogacy agreement shall involve "an embryo which was or will be created using a gamete from an intending parent". This means that there is a requirement for one intending parent to have a genetic link to the child. Such a requirement can be criticised.[26] The rationale for such a requirement appears to be that it is needed to 'legitimise the relationship'[27] and to protect against parents 'commissioning' children for adoption.[28] However, it is difficult to justify this requirement in surrogacy.[29] In Ireland, a woman can avail of donated eggs and sperm (double gamete donation) or embryo donation.[30] In these cases, a woman can give birth to a child with no genetic link to her or her partner, and these individuals will automatically be the legal

[25] §13(a) *Surrogate Motherhood Arrangements Act 5756-1996*. See K. Weisberg, *The Birth of Surrogacy in Israel* (Gainesville: University press of Florida, 2005), at p 198.
[26] See K. Horsey et al, 'Surrogacy in the UK: Myth Busting and Reform: Report of the Surrogacy UK Working Group on Surrogacy Law Reform' (Surrogacy UK, 2015).

[27] See K Horsey et al, 'Surrogacy in the UK: Myth Busting and Reform: Report of the Surrogacy UK Working Group on Surrogacy Law Reform' (Surrogacy UK, 2015), at para 4.4.

[28] *AB and Another v Minister of Social Development as Amicus Curiae: Centre for Child Law* (40658/13) [2015] ZAGPPHC 580 (12 August 2015).

[29] For arguments pertaining to the UK context, see N Gamble, 'A better framework for United Kingdom surrogacy?' in S Golombok et al (eds), *Regulating Reproductive Donation* (Cambridge University Press, 2016), at p 152.
[30] S. 4(b) and (c), *Children and Family relationships Act 2015.*

parents. Such practices recognise the acceptability of parenthood which is not based on genetic links.

Another reason why such a requirement should be abolished is that precludes single people and couples who cannot produce gametes from entering surrogacy arrangements. For example, a single woman who in unable to gestate and does not have viable eggs would not be able to avail of surrogacy. A couple who cannot produce viable gametes and who cannot gestate a child also cannot do so. An equivalent requirement in South African law was found to be unconstitutional.[31] It was held to be an encroachment on the human dignity of such individuals, as it prohibited such people from exercising their right to autonomy and also reinforced the profound negative psychological effects of infertility.[32] It was also held that the argument that the welfare of the child was best served by a requirement for a genetic link with one intending parent was 'an insult to all those families that do not have a parent–child genetic link'.[33] On the latter point, it should be noted that studies show that a genetic link to their parents does not appear to be crucial to the realisation of children's well-being. It is the quality of parenting which is thought to be central, as opposed to the existence of genetic links. [34] **Therefore, the requirement for a genetic link with one intending parent should be removed and Head 39(3)(b) of the General Scheme of the Bill omitted.**

Summary of Recommendations

1. The General Scheme of the Bill could be amended to ensure parents have access to identifying information about the surrogate mother from the Surrogacy Registry, so they can tell the child before they reach the age of 18.

2. Counselling for intending parents should include information regarding the importance of children knowing about their genetic and biological origins. Surrogate

[31] *AB and Another v Minister of Social Development as Amicus Curiae: Centre for Child Law* (40658/13) [2015] ZAGPPHC 580 (12 August 2015), at para 76.

[32] Ibid.

[33] Ibid, at para 84.

[34] See S Golombok et al, 'The European Study of Assisted Reproduction Families: the transition to adolescence' (2002) 17(3) *Human Reproduction* 830; S Golombok et al, 'Parenting infants conceived by gamete donation' (2004) 18(3) *Journal of Family Psychology* 443; S Golombok et al, 'Non-genetic and non-gestational parenthood: consequences for parent–child relationships and the psychological well-being of mothers, fathers and children at age 3' (2006) 21 *Human Reproduction* 1918; E Ilioi and S Golombok, 'Psychological adjustment in adolescents conceived by assisted reproduction techniques: a systematic review' (2015) 21(1) *Human Reproduction Update* 84.

mothers should receive information regarding the importance of a child's right to know their genetic and biological origins and that the child will have information about their identity when they turn 18. Provision should also be made for AHR treatment providers to provide counselling to children relating to the manner of their birth through surrogacy and/or gamete donation.

3. If international surrogacy is not permitted, then this needs to be made known to the public. Public information about the potential disadvantages of inter-country arrangements needs to be made known. The details of such a scheme may be outside the ambit of this Bill.

4. A system of pre-authorisation of legal parenthood should be introduced and the system of parental orders removed. Under such a system, the intending parents would be approved by a Court as the legal parents of the child before the birth.

5. Under a system of pre-authorisation of parenthood, there should be documentation of the surrogacy agreement in a way which allows for the child to know of the nature of their birth through surrogacy and their surrogate mother.

6. The requirement for a genetic link with one intending parent should be removed and Head 39(3)(b) of the General Scheme of the Bill omitted.

7: Dr Lydia Bracken

Submission by Dr Lydia Bracken, School of Law, University of Limerick

Dr Lydia Bracken

Submission on General Scheme of the Assisted Human Reproduction Bill 2017

Dr Lydia Bracken, School of Law, University of Limerick

About the Author

Dr Lydia Bracken is a lecturer in law and Director of Clinical Legal Education at the School of Law, UL. She is a graduate of UCC (BCL, 2010; LLM, 2011; PhD, 2015) and the Honorable Society of King's Inns (Barrister-at-Law, 2012). Her PhD thesis, which was funded by a Department of Children and Youth Affairs research scholarship, examined the implications of the best interests principle in the context of same-sex parenting in Ireland. This research focused on the pathways to parentage available to same-sex couples in Ireland, with extensive focus on donor-assisted human reproduction and surrogacy. Lydia's current research concentrates on child and family law and European human rights; she has published nationally and internationally in these areas. In particular, Lydia's research examines the legal recognition of "non-traditional" families and explores how such recognition can be provided in a manner that respects the rights and interests of children.

As a lecturer in child law at the University of Limerick, Lydia's work focuses on building awareness of children's rights through teaching, academic outputs and community engagement. She also has experience of working directly with young people and advocating on their behalf as part of her previous advocacy volunteer role with the Irish Society for the Prevention of Cruelty to Children (ISPCC) and currently as a member of the Board of Gaisce. Lydia has a strong track-record of publications in high-ranking legal journals and has been successful in a number of funding competitions. She is committed to legal and policy reforms that ensure that the best interests of children and young people.

Selected Publications Relevant to the Submission:

PEER REVIEWED JOURNALS

- Lydia Bracken, "The Assisted Reproduction Bill 2017: An Analysis of Proposals to Regulate Surrogacy in Ireland" (2017) 68 *Northern Ireland Legal Quarterly* 577 (accessible at: http://nilq.qub.ac.uk/index.php/nilq/article/view/65)
- Lydia Bracken, "Assessing the best interests of the child in cases of cross-border surrogacy: inconsistency in the Strasbourg approach?" (2017) 39 *Journal of Social*

Welfare and Family Law 368 (accessible at: http://www.tandfonline.com/doi/full/10.1080/09649069.2017.1344393)

- Lydia Bracken, "Challenging Normative Constructions of Parentage in Ireland" (2017) 39 *Journal of Social Welfare and Family Law* 316 (accessible at: http://www.tandfonline.com/doi/abs/10.1080/09649069.2016.1272224)
- Lydia Bracken, "The Role of the Best Interests Principle in Regulating Parentage in Surrogacy in Ireland" [2017] *International Family Law* 115
- Lydia Bracken, "In the Best Interests of the Child? The Regulation of DAHR in Ireland" (2016) 23 *European Journal of Health Law* 391 (accessible at http://booksandjournals.brillonline.com/content/journals/10.1163/15718093-12341400)

SELECTED CONFERENCE PROCEEDINGS

- Lydia Bracken, "Assessing Best Interests in Assisted Reproduction: Benchmarking Ireland's Blank Canvas", Society of Legal Scholars Annual Conference 2017, 5th September 2017
- Lydia Bracken, "Assessing the Best Interests of the Child in Assisted Reproduction" Contemporary Issues in Family Formation, 1st September 2017
- Lydia Bracken, "Challenging Normative Constructions of the Family", 7th World Congress on Family Law and Children's Rights, 5th June 2017
- Lydia Bracken, "The Recognition of Modern Family Relationships in Ireland", UL Law Society Family Law Conference, 11th March 2016
- Lydia Bracken, "Legislating for Surrogacy: The Advantages of the South African Approach", Irish Society of Comparative Law Conference 2015, 6th June 2015
- Lydia Bracken, "When *mater certa semper est* is not always certain: Rethinking parentage in surrogacy" Annual Socio-Legal Studies Association Conference 2014, 10th April 2014

Submission: Allocation of Parentage in Surrogacy

In favour of a pre-conception model of parentage

The 2017 Bill proposes to introduce a "delayed" or "post birth" model of parentage in cases of surrogacy. The Bill provides that the surrogate will be recognised as the legal mother upon the birth of the child (and if she is married to a man, her husband is recognised as the legal father). The General Scheme provides that following the birth of the child, the surrogate will be required to provide her consent to the child living with the intending parent(s). Thereafter, the intending parent(s) (or the surrogate) can apply to the court for a parental order to transfer parentage from the surrogate to the intending parent(s). This application cannot be made earlier than six weeks and not more than six months after the child's birth, and the consent of the surrogate (and her husband, if she has one) is required before the parental order can be granted. This requirement can be waived in certain circumstances, such as where the surrogate is deceased or cannot be located.[1]

A major difficulty that arises with this delayed model of parentage is that, at the time of the child's birth, at least one of the intended parents will not be recognised as a legal parent. This is because the woman who gives birth to the child (the surrogate) will always be regarded as the child's legal mother; if she is married to a man, her husband is presumed to be the legal father (though this can be rebutted); otherwise, the genetic father of the child will typically be regarded as the legal father. As such, a non-genetic intended father or a non-gestational intended mother is not recognised as a legal parent upon the birth of the child under the model of parentage proposed in the 2017 Bill. As a result, one of the intended parents will not have any automatic legal rights and responsibilities towards the child. This is such notwithstanding that the child will be taken into the care of the intended parents at birth.[2] The child is therefore left in a vulnerable position as the intended parents may have limited legal powers to care for the child in the first weeks of life, for example, in relation to medical decision-making.

Thus, the delayed model of parentage does not respect the reality of the child's intended upbringing. In failing to do so, the model deprives the child of the security and protections that would flow from automatic legal recognition of the role of the intended parents. Prior to

[1] Heads 47 and 48 of the General Scheme of the Assisted Human Reproduction Bill 2017.
[2] Head 46 of the General Scheme requires the surrogate to provide her consent to the child living with the intended parents following his or her birth.

the making of the parental order, the intended parents would have limited capacity (or in some cases, no capacity) to exercise decision-making powers in respect of the child. Instead, these powers would be bestowed upon the surrogate who may live in a different part of the country. This has the potential to jeopardise the child's best interests.

The model of parentage that is set out in the 2017 Bill is broadly similar to that which applies in England and Wales under the Human Fertilisation and Embryology Act 2008. Under this Act, the surrogate is automatically regarded as the legal mother upon the birth of a child. The intended parents may then apply for a parental order to transfer legal parentage to them. Similar to the General Scheme, this order cannot be made for the first six weeks after the child's birth, but it must be made within six months of the birth and the surrogate's consent is required for the order to be granted.

The regulation of surrogacy in England has been widely criticised as out-of-step with the reality of surrogacy arrangements. It is notable that both intended parents and surrogates have called for reform of the delayed model of parentage that currently operates in that country. In a 2015 study published by Surrogacy UK, for example, 70.1 per cent of intended parents who responded indicated that the surrogacy laws in England and Wales are in need of reform, while 65.7 per cent of surrogates expressed the same sentiment. Of the surrogates who responded to the survey, 64.9 per cent said that they thought that the intended parents should be the legal parents of a child, "whether genetically related or not", while 68.5 per cent did not believe that the surrogate should have the right to change her mind about giving the baby to the intended parents.[3]

The delayed model of parentage set out in the 2017 Bill suffers from the same difficulties as the English regulation with the added burden of pre-authorisation. The pre-authorisation requirement has no impact on the allocation of parentage: it is simply a pre-requisite to the medical procedure taking place. The pre-authorisation requirement essentially means that the surrogacy agreement must be approved twice: before conception by the Regulatory Authority and after birth by the courts. A much simpler (and cheaper) process would be to allow for pre-conception court orders that provide approval of the surrogacy arrangement *and* determine the parentage of the child before conception takes place. This approach would allow the surrogate to give her consent to the transfer of parentage in advance of the

[3] Surrogacy UK, *Surrogacy in the UK: Myth Busting and Reform: Report of the Surrogacy UK Working Group on Surrogacy Law Reform* (Surrogacy UK 2015) accessible at: https://www.surrogacyuk.org/Downloads/Surrogacy%20in%20the%20UK%20Report%20FINAL.pdf

conception with the effect that the intended parents acquire full parental responsibilities and rights at birth and the surrogate is never recognised as a legal parent. This approach would also provide certainty, as the parties would know who the child's legal parents are at the outset and there would be no need for post-birth litigation to establish who the legal parents are or should be.[4]

Pre-conception court orders

It is submitted that parentage in surrogacy should be determined by pre-conception court orders. Such orders allow for the child's legal parental status to be determined prior to conception. As such, the intended parents are automatically recognised as legal parents on the birth of the child and are immediately given all of the necessary legal tools to protect that child upon birth. In this model, the surrogate is not recognised as a legal parent. It is submitted that the use of such orders better respects the best interests of the child than the delayed model of parentage as it recognises and respects the reality of the child's intended upbringing. These orders are used in many countries such as California, South Africa and Greece.

A pre-conception model of parentage has the potential to alleviate many of the difficulties associated with the delayed model that were outlined above. Furthermore, it would bring Ireland's potential surrogacy legislation into line with the regulation of donor assisted human reproduction (DAHR). DAHR, as provided for in the Children and Family Relationships Act 2015, allows for parentage to be allocated on the basis of the intention of the parties. Therefore, in cases of donor insemination, a sperm donor or egg donor does not acquire any status as a parent but instead the woman's spouse or partner is deemed to be the child's second legal parent.[5] Parentage in surrogacy should similarly be based on the pre-conception intentions of the parties.

It is further submitted that the 2017 Act should allow for double gamete donation (use of donated sperm and egg in the same procedure) in surrogacy arrangements. At present, the Bill stipulates that one of the intended parents must have a genetic connection to the child. By contrast, in DAHR, double gamete donation is permitted under the Children and Family Relationships Act 2015. It is argued that requiring one of the intended parents to have a

[4] See: Lydia Bracken, "The Assisted Reproduction Bill 2017: An Analysis of Proposals to Regulate Surrogacy in Ireland" (2017) 68 *Northern Ireland Legal Quarterly* 577.
[5] Children and Family Relationships Act 2015, s 5.

genetic connection to the child in cases of surrogacy is discriminatory against infertile couples and so the requirement should be removed.[6]

Number of Parents

The final part of this submission addresses the legal recognition of multiple parents. This is a matter that is of relevance not only in surrogacy but also in cases of DAHR and potentially in other areas.

Head 47(3) of the General Scheme states that there cannot be more than two intending parents involved in the application for the parental order. It is submitted that consideration should be given to recognising more than two intended parents in some circumstances. For example, the surrogate or a donor could be given the opportunity to opt into parentage in circumstances where this is agreed before conception and where it is in the best interests of the child to do so. The Children and Family Relationships Act 2015 allows for more than two persons to be appointed as guardians of the same child. As such, it is submitted that allowing for more than two persons to be recognised as *legal parents* in cases of donor-assisted human reproduction or surrogacy should also be considered for its potential to promote the best interests of the child.[7]

Key Recommendations

1. The delayed model of parentage in surrogacy does not operate in the best interests of the child and should not be adopted in Ireland.
2. Parentage in surrogacy should be determined before conception by court order.
3. The intended parents should be recognised as legal parents on the birth of the child.
4. The surrogate should not be recognised as a legal parent.
5. The requirement that one of the intended parents must have a genetic connection to the child is discriminatory against infertile couples and should be removed from the Bill. Double gamete donation should be allowed in cases of surrogacy as it is in cases of DAHR.
6. Consideration should be given to the possibility of allowing for more than two persons to be recognised as legal parents in cases of donor-assisted human reproduction or surrogacy.

[6] Lydia Bracken, "In the Best Interests of the Child? The Regulation of DAHR in Ireland" (2016) 23 *European Journal of Health Law* 391
[7] See: Lydia Bracken, "Challenging Normative Constructions of Parentage in Ireland" (2017) 39 *Journal of Social Welfare and Family Law* 316

8: Dr Lucy Frith

Dr Lucy Frith

I am a bioethicist and social scientist and have conducted research into the ethical and social aspects of donor conception for a number of years.

Key provisions in information giving and parentage in donor conception are included in 2015 Children and Family Relationships Act. Having two pieces of legislation addressing different aspects of the same issue is not ideal and the 2017 Assisted Human Reproduction Bill is an opportunity to develop a cohesive piece of legislation in this area.

I would like to make a submission primarily about the birth certification – although this is covered by the 2015 Act. If it is accepted that there will be some annotation of the birth certificates of those who are donor-conceived, how this is handled in practice, when the people affected become 18, is a key issue that needs to be addressed in the legislation and any regulations that follow from this.

How birth certificates are annotated is a complex issue. Any proposal must safeguard the privacy of the donor-conceived person, the bureaucracy and cost must be proportionate and it should not place an undue burden on any particular party. Safeguarding the privacy of the donor-conceived person is of crucial importance and providing them with documentation that can be used for administrative purposes without unnecessary disclosure of their donor status is imperative. This raises questions of what aspects of the birth certificate should be a matter of public record, and I would argue that the donor conception aspect should not be a matter of public record.

The second aspect is how the donor-conceived person is supported when applying for their birth certificate at 18. Support mechanisms and the offer of specialist counselling should be made available, so that if there person is finding out they are donor-conceived via this mechanism, they have some structure of support to draw on. How this could be organised both practically and how this support should be offered and what it should consist of, should be a matter that is explored before enacting legislation in this area. Further, funding for this support should also accompany any legislative change, so that it can be practically delivered.

9: Emma O'Frield and Dr Joanna Rose

Submission to the Health Committee regarding AHR legislation: Emma O'Friel and/or Dr. Joanna Rose. February, 2018

1. Area of expertise

Dr. Joanna Rose, Biography

Dr Joanna Rose has completed a PHD thesis titled: A critical analysis of sperm donation practices: The personal and social effects of disrupting the unity of social and biological relatedness for the offspring (http://eprints.qut.edu.au/32012). She has written and presented papers internationally over the last twenty years, particularly addressing issues affecting donor offspring, identity, kinship, ethics and law.

Dr Rose was conceived from anonymous sperm donation in London in the early 1970's, and has been personally and politically active in campaigning for an end to donor anonymity, recognition and services to help address the difficulties created for those created in this way. She took a High Court test case against the HFEA and Department of Health in 2002 and won. The judicial review judgment established that **a right to one's identity** is integral to respect for private and family life found in **Article 8** (OHCHR, 1989). Justice Scott-Baker ruled that the donor offspring's information about a biological parent "goes to the very heart of their identity, and to their makeup as people", "an **AID child is entitled to establish a picture of his [her] identity as much as anyone else.**" ("Rose and Another v. Secretary of State for Health and Human Fertilisation and Embryology Authority," 2002.).

Dr. Rose has drawn from other experiences of kinship loss, such as adoption and the Australian stolen generations. She posits that the reproductive industry has evaded the lessons learnt from such human experiences. Dr Rose urges for the children's best interests to be paramount in practices that affect them, and for laws to support the notion that children should only be removed from their genetic kin for reasons of child protection and not for child production. She speaks of living with a sense of loss all her life, of wanting to know her genetic family but that this was denied her by doctors who offered a service to desperate parents for financial gain.

On 6th March 2018, Dr. Rose will speak for The European Centre for Law and Justice at the United Nations, Geneva on 'Reproduction and Human Rights'.

Emma O'Friel (M.Psych.Sc.) Biography

Emma received a First Class Masters in Psychological Sciences, following a First Class degree in Psychology. She is commencing a position as Assistant Psychologist with the HSE. She is age 51, with one teenage child. She has a particular interest in family psychology.

Emma studied Medicine for two years and continues to have an interest in this field,

Over the last two years, Emma has been researching DAHR (donor assisted human reproduction) practices in Ireland. Her research was the basis of Paul Cullen's article in the Irish Times 'Who are Ireland's Donor children', July 22, 2017 in which she had a bye-line.

She is currently liaising with the Children's Research Centre, TCD (Prof. Trevor Spratt) with a view to conducting a PhD on DAHR and the long-term consequences for DC people.

Emma is in the process of founding Donor Offspring Ireland, as part of the existing Donor Offspring Europe network of donor-conceived people. This group are concerned at their lack of human and social rights, the lack of oversight in the fertility industry who have traded in their lives before conception, and that children are now products of an industry.

Contribution to discussion on AHR

Both Emma and Joanna regularly liaise with world-wide organisations of donor-conceived people (see list at end of document) and individuals. Joanna in particular has decades of research and personal experience in this area. She is a widely respected speaker on DAHR and an expert on human rights and issues of fractured identity and kinship.

DC people are the party most at risk of being harmed or disadvantaged by this practice. They are the party objecting to the suffering it causes. It would be wrong not to place them at the centre of discussions.

Q**uestions of urgent and primary concern** in discussion on DAHR are:

1. When is it acceptable to remove a child from his/her genetic family, to be raised by a non-related parent?
2. What assessment has been done to evaluate whether donor-conceived people are being harmed or disadvantaged by this practice?
3. The commercial nature of DAHR.
4. The reluctance to learn from history, where children removed from their kin have suffered and sought redress (Adoptees in Ireland, Stolen Generation Australia).

Another very pressing issue is to determine why the Government has delayed commencing Parts 2 and 3 of the Children and Family Relationships Act (April 2015), the only parts that pertain to DAHR and that ban donor anonymity. It is necessary to commence these parts before even considering the AHR Bill, 2017.

It is of some concern that most people in Ireland (including doctors and nurses in mainstream medicine) do not realise that the ban on donor anonymity has not commenced. There also seems to be a lack of knowledge of what really is involved in AHR and what 'donating' future children really entails.

DAHR is a practice that profoundly and intrinsically alters the lives of the people it creates. It allows medics and scientists determine who is or isn't a child's parent, who will rear them, whether they have a right or not to know their genetic parent, and allows a non-related person's name on their birth certificate. In discussions much weight is given to the view of fertility specialists who have clear vested interests. Significantly less weight is given to first-hand accounts of DC people. Medical and scientific fertility specialists are experts in precisely this: medicine and science. They are not experts on the psychological and emotional impact of this practice on DC people.

Fertility clinics explicitly state that their primary concern is their clients (see Sims website and brochure). Fertility clinics have no contact with DC adults nor do they engage with organisations of DC people to form a complete understanding of the results of their practices.

2. Useful facts

a) Research on the impact of DAHR on DC people

There is currently no research in Ireland on the impact of third-party reproduction on DC people. DC people are virtually invisible in society. The reasons for this are several. Firstly, DAHR is relatively new in Ireland (most clinics opened in this millennium) so most DC people are still minors. For example, Dr. Waterstone's four fertility clinics were founded in 2002. The same year, Sims began using donor eggs and sperm. Secondly, due to the secrecy and lack of disclosure surrounding DAHR it is not visible in our society, either in records in terms of DC people knowing their origins and in terms of society knowing who are and who are not DC. There is still an element of uncertainty in accepting this in our society and arguably an instinctive reluctance to accept a practice that transfers ownership of a child before its birth.

Most studies world-wide have been parent-focussed or conducted by stakeholders. For example Susan Golombok, in the Centre for Family Research, U.K. actively advocates for gay and lesbian rights to have a child, even if it isn't theirs. Dr. Maggie Kirkman of the University of Melbourne's expertise is in the psychosocial aspects of female reproduction (specifically infertile women). This research is adult-centric, focussing on women's experiences and attempts to rear a child (any child). Kirkman has a child using a donor and a surrogate). Likewise Ken Daniels' of the University of Canterbury, New Zealand has focussed his two decades of research on parents' experiences of raising donor-children and their reports of donor-children's well-being.

Studies that engage directly with DC people provide invaluable insight. Turner and Coyle (2000) interviewed sixteen DC adults and found profoundly distressing impact of being severed from genetic kin, including feelings of abandonment. Marquardt, Glenn and Clark (2010) surveyed adults from a pool of one million Americans - DC, adoptees and biological offspring - to examine personal well-being. DC adults fared worse in mental health. The vast majority answered that their donor parent is 'half of who I am", were uncomfortable with the financial aspect of being sold as a gamete and lived in a kind of limbo unsure of where they belong, saying that if they saw somebody they slightly resembled they wondered if they were related.

Dr. Joanna Rose's doctorate (mentioned above) on the loss of kinship and biological and social relatedness is a unique reflection on the impact of DAHR on actual lived experiences. Rose has personal experience and speaks of decades of carrying loss and anger.

Testimonials from across the world are shouting loud and clear that they have been profoundly and negatively impacted by being created in this way, from loss of family and loss of identity. Who are they really, they want to know? Where have they come from? Why have they been intentionally and discriminately denied access to family? Bill Cordray, an active campaigner and support in the DC community, writes about the unbearable longing to know his father, how he thought it may have been his mother's doctor (as was often the

case) and how for years he would spy on this doctor just to be close to him and try to know something of him.

b. Psychology; childhood, identity, belonging

Children's development occurs in stages. For example, it is only in late-primary school that abstract reasoning develops. Independent thinking, reflection, and questioning one's place in the wider community occurs much later, often beginning in teenage years. Awareness of one's human and civil rights, of the political world is not something that occurs at a specific point in time, but certainly only a rudimentary knowledge occurs in childhood – and this knowledge is often learnt through doctrinal teaching from adult sources. It is well accepted in the field of developmental psychology that psychological development continues throughout life. It is therefore incomplete to assess a DC child's well-being and equate it to being happy with being conceived in this way, and reared by a non-related parent/s.

Another central understanding in modern developmental psychology is the importance of the relationship between the individual and society in affecting personal development. In Ireland we know too well that the circumstances of our birth can have lifelong implications. How our society and its institutions treat the individual, whether they respects their rights, afford them dignity, do not discriminate against them, do not abuse the power they hold over them all affect an individual's well-being. As a society we cannot allow a questionable practice and then say that good parenting and love is all a child needs. This passes the buck.

Identity formation is now understood as occurring across the lifespan. In adolescence a more profound step towards independent thinking and living often commences, but is by no means complete. Around this time, but often later, critical and reflective thinking develop, when questions are asked about 'who I am', judgements are made, opinions formed, parents and those in authority and in the wider community are challenged. Some developmental psychologists posit that while 18 may be the widely accepted age when adulthood is reached, many are not ready at this age, and early adulthood may in fact, be more akin to late teenage development.

These issues are important when assessing the well-being of DC children. It is misleading to state (as Golombok, and fertility specialists do) that DC children are doing fine. Golombok goes so far as to 'prove' that DC children are in fact "doing better than non-DC children". These results are misleading because firstly, questionnaires are often completed by parents' observations on their child's well-being and secondly because assessing children when their identity formation is far from mature, and when they have not reached an adequate stage of critical thinking, is simply wrong. Studies by Golombok that report DC children's development as being "no different" to non-DC children is correct in terms of cognition, social interaction, but gives a very incomplete picture. The difficulties of being DC only surface later. The end product of DAHR is not the baby/child.

First-hand accounts are arguably the only evidence we have of the well-being of DC people – beyond childhood. Accounts are plentiful on sites such as www.anonymousus.org. Personal stories, including individuals bringing their cases to court are becoming more frequent. DC people are increasingly grouping together demanding an end to this practice, which many view as a form of trafficking. Such groups and organisations (listed below) are growing each

year. Personal stories of profound loss, of emotional and psychological pain and grief must be heeded.

Part of psychological well-being and identity is belonging; to parents, family, social groups. It matters who we are in space and time, where we have come from and who we have come from. Indeed it is this urge for genetic continuity that is the basis of the despair of infertile couples. Yet, removing a person from their genetic kin is offered as an immediate solution to an infertile person's inability to have genetic kin. One's person's pain is replicated in a baby's because they cannot object for decades to come, and if the secret is kept, they can never object.

The society that is being shaped by the use of DAHR may be well expressed in Charles Handy (economist, author, philosopher) words as "clamouring for rights without accepting responsibilities". It is adult-centric, desire-based instead of child-centred and rights and needs-based, and evidence is clear that it is not putting the best interests of the child first.

c. Fertility industry

Certain aspects of this industry must be addressed – its commercial nature, the power it is afforded over the identities of children, their motives.

Discourses: The discourses used by the industry need urgent scrutiny. The terms 'donors, donations' are misleading and arguably are used for PR and advertising purposes. By usurping terms that are used for altruistic, non-profitable giving (organ donation, charitable donation) the industry aligns DAHR with other genuinely altruistic practices. It is incorrect. Donors do not give without reward. They receive 'compensation' or comparable advantage. It is misleading for a clinic to tell clients that donors do this "to help" and not for financial gain (see Sims brochures). How do clinics know this? It seems part of a donor's questionnaire is to answer the question "are you happy to help an infertile person?"

Misrepresentation of DAHR as a benign solution to infertility. DAHR is not a solution to infertility. It does not solve infertility. It simply transfers an unrelated child to a person who could not otherwise have a child. Take for example what happens with a heterosexual couple where the woman is infertile. A clinic arranges for the man to have a child with another woman. The clinic ensures that the mother of this child will not know that she has a child, and will ensure that the child never knows the identity of its mother. They will ensure that a non-related woman gives birth to this child (or a surrogate) and that there is no evidence of the biological mother on the child's birth certificate.

'Frankenstein' syndrome: 'we do it because we can'. Mary McNeaney a psych-counsellor imported the first human sperm into Ireland in 1979 (by registering it in customs as cattle sperm). She tells this story as an amusing anecdote (see RTE's 'Going it Alone'). DAHR began simply because it could, with nobody to questions the ethics of it or to explore the potential for harm or disadvantage. This stance remains. Legislation is being pursued after the act, when the act itself is of questionable function and benefit.

Donors. Irish clinics import sperm from Denmark. Cryos is the main provider. Their suppliers receive E200 per supply. Donors have openly said they do so for the money. A donor on RTE's 'Going it Alone' admitted his motives were monetary and said the children born of his sperm were 'not my concern'. TV3's documentary 'Making Babies' heard one donor woman explain that with three children she was doing this for money. What clinics are profiting from and promoting are two rather base aspects of human nature 1) desperation, need for money, 2) flippancy and shirking responsibilities for offspring

Secrecy Mary McNeaney has said that most parents keep the child's origins a secret from the child. This is openly encouraged by clinics who see it as an adult's 'right' to privacy. In this instant they take 'privacy' as the right to partake in the clinics' supply of egg/sperm.

Trade and commerce; of offspring Due to the commercial nature of DAHR, DC people are in essence a third-party beneficiary in a commercial transaction. The other parties are the supplier (donor), agent (clinic) and consumer (clients). Money passes between the hands of these three parties. Ownership of the 'product' is transferred via the legal vehicle of contract law. Sims clinics write that a donor cannot "track down" their child because "it would be a breach of contract law". Contract law is the basis of trade and commerce, whereby ownership of a good is transferred from one party to another. Fertility clinics are unique in their use of contract law to transfer of ownership of a child.

Questionable practices include
Why do clinics offer their clients information on donors (medical history, family history, personal details) in increments – the more you pay, the more information they get?

What is the purpose of offering clients who opt for the 'Deluxe' package (Sims call it their 'Select' Programme as opposed to their 'Simple' programme)?

3. Recommendations to the Committee

1. Legislation on DAHR should not be driven by medical/clinical parties. Given the growing number of DC organisation world-wide, the discontent among the DC community, it must be seriously questioned whether DAHR has any place in a humane and just society.
2. Fertility clinics must as a matter of urgency cease use of anonymous egg and sperm.
3. Parts 2 and 3 of the Children and Family Relationships Act, 2015 MUST be commenced without further obfuscation from the Minister for Health.
4. DAHR is not a solution to infertility. It does not solve infertility. It simply transfers an unrelated child to a person who could not otherwise have a child. To outsource a child is not a solution.
5. "Nothing about us, without us". DC adults must be consulted as primary stakeholders.
6. Any legislation should be child-centric. At present the fertility industry and DAHR is adult-centric, driven by adults for adults.
7. Creating children as a commercial business must stop.

8. It is essential that fertility clinics do not have a role in overseeing their own industry. It must be overseen and regulated by parties that do not have vested interests. For instance at present the Ombudsman for Children cannot "investigate actions of private businesses", which includes fertility clinics. Some independent body should oversee.
9. This is the perfect opportunity to put words into actions and implement the lessons we swore, as a society, to have learned from adoption experiences. No institution, we vowed, will ever have the power to remove children from their genetic kin, unless absolutely necessary. No institution, we promised, will ever again have the power to trade in children. No institution with such involvement in children's lives shall go without oversight and regulation.

International Laws on Human rights for consideration

10. Nobody, man or woman, black or white, able-bodied or disabled, gay or straight, of any religion, race, minority group, marital status has the right to intentionally sever anyone from their genetic kin.

11. The right of every child to be known and cared for by one's[genetic] parents (Article 7 of the United Nations Convention on the Rights of the Child (UNCRC)

12. The rights of every child to an [authentic] identity, an authentic nationality and family relations (Article 8 of the UNCRC). Birth certificates must not be falsified.

13. The human right not to be separated from our parents against our will (Article 9, UNCRC). That this right is removed from a person before they are even born is discriminatory and is playing legal loopholes.

14. That the President of the Irish Fertility Society, John Waterstone (whose members comprise the majority of private fertility clinics in Ireland) has stated that a donor-conceived child's right to know their genetic identity is "utterly meaningless" (Irish Times, July 2017) should sound alarm bells. The lives of children should not be in their hands. Fertility clinics have threatened to take legal action against a ban on donor anonymity as they say it threatens the privacy of their clients, their businesses and they say it will result in job losses for their staff. How are they allowed put their business interests before the rights of the child?

15. The IFS must answer the question: in what way is it alright to put children/adults into the world who do not know who is or isn't their family, who is or isn't their brother or sister, who is or isn't their mother or father, aunt, uncle, grandfather, grandmother? Dr. Waterstone's justification that 2.5% of children are born from extra-marital affairs and are being raised, unknowingly by non-related fathers implies that replicating an unfortunate circumstance in life is what he is happy to do.

16. The Council of Europe's Convention against Trafficking on Human Organs (Treaty no. 216) and their Convention on Human Rights and Biomedicine (Treaty no. 164) forbid financial gain from the sale of body parts. They state that it is a "criminal offence where a living donor, or third party receives financial gain or comparable advantage". Why are donors allowed to receive compensation for selling their gametes? Research shows that the majority of donors to so for money.

17. The EU Charter of Fundamental Rights (Article 3), ratified by Ireland through the Treaty of Lisbon, 2009, forbids financial gain from the sale of body parts.

18. This is a matter of conscience when evaluating a practice that produces children in such circumstances as DAHR does. Questions must be asked: are these children been treated with humanity, compassion and respect by creating them through DAHR. Is it right to put laws in place that allow a child's biological parents "donate" them, before their birth, to an unrelated couple, to rear. Whose interests are being served by this practice?

This submission is for the Health Committee of the Oireachtas, in pre-legislation consideration of the AHR Bill, 2017.

Some organisations of donor-conceived people

Anonymous Us, (USA)
Coalition Against Reproductive Trafficking (U.S.A.)
Donor Offspring Europe
International Donor Offspring Alliance (UK)
Donorkinderen (Belgium)
Procreation Medicalement Anonyme (PMAnonyme, France)
Spenderkinder (Germany)
Stichting Donorkind (Netherlands)
Tangled Webs (UK, Australia)
Them Before Us (U.S.A.)
We are Donor Conceived
…. Et al.

Personal accounts (all now actively involved in campaigning for an end to DAHR)

Bill Cordray,	Christine Whipp,
Emma Cresswell*,	Stephanie Raeymaekers,
Olivia Pratten *	Vincent Brel,
Lindsay Greenwalt	Suzanne Ariel*
Tom Ellis	Audrey Kermalvezen*,
Joanna Rose*	Damian Adams*
Nicholas Isel *	….. and many more

(* = engaged in legal challenges/court cases)

10: Families through Surrogacy

Recommended Considerations in an Effective Assisted Human Reproduction Bill Framework for Ireland

INTRODUCTION

Families Through Surrogacy was founded in August 2013 and since that time has convened over 22 best practice conferences and seminars focused on surrogacy education, four of them in Ireland.

As the Director of this organisation and the founder of Surrogacy Australia, I have dealt closely with the barriers to intended parents engaging in surrogacy for over seven years. My research articles in the Medical Journal of Australia & the Australian and New Zealand Journal of Obstetrics & Gynaecology have detailed the barriers consumers report to engaging in surrogacy domestically.

Australian states have detailed legislation and regulations which allow for altruistic surrogacy arrangements, yet the majority of Australians still chose to engage in international surrogacy. As an educator and public health researcher who has seen hundreds of surrogacy cases globally over recent years I have developed a detailed understanding of the legislative factors which enhance and deter access to both domestic and cross-border surrogacy.

My comments below are intended to provide for a domestic surrogacy structure which is accessible and workable for both intended parents and surrogates. These comments are premised on the assumption that Ireland would like to encourage its citizens to engage in domestic rather than international surrogacy where possible.

Research shows that domestic surrogacy arrangements are more likely to result in an ongoing relationship between the surrogate and the family she assists. Domestic arrangements are also more likely to involve known rather than anonymous egg donors, which has benefits in relation to disclosure to the child

FACTUAL INFORMATION

Counselling

ANZICA (Australia & New Zealand) best practice counselling standards in relation to surrogacy arrangements mandate that both parties in a couple attend counselling together to be eligible for legal parentage. This ensures that the complex social, ethical and medical issues are adequately discussed.

Traditional Surrogacy

Over 50% of UK surrogates, more than 60% of New Zealand surrogates and increasing numbers of Australian surrogates carry using their own eggs, often after being an egg donor for other couples. The academic research into the psychological outcomes for surrogates and children from traditional surrogacy arrangements has shown that such arrangements do not lead to any greater risk of attachment where surrogates are counselled and have completed their own families. (Golombok S).

Expense reimbursements

A Medical Journal of Australia study showed 46% of intended parents considering altruisitic arrangements were concerned about the unfair exchange associated with such arrangements (Everingham et al, 2014).

Ban on Advertising for parties to a surrogacy arrangement

Much altruistic surrogacy legislation in international jurisdictions (such as Australian states) was written assuming only close family members or friends would carry altruistically. That assumption has proven not to be the case. Surrogacy Australia research shows that in over 50% of altruistic cases in Australia, surrogates meet intended parents via online forums.

Transfer of parentage in Surrogacy

In thirty years of altruistic surrogacy arrangements, the evidence shows surrogates, where well counselled prior, very rarely decide to keep the child and if they do so, this is a pre-birth decision.

Both intended parents and surrogates in overseas jurisdictions which mandate a transfer of parentage through the court system post birth, must go through an expensive and time-consuming transfer of legal parentage from the surrogate to the intended parent(s). This process inconveniences all parties and leaves the child in a situation where there is no legal parent residing with them in the five to six months required for the transfer of parentage.

In contrast, some Canadian provinces which have many years of experience of legislated altruistic surrogacy (eg Ontario and British Columbia), have introduced streamlined transfer of parentage processes that have no need for a court application or judicial approval post birth. The surrogate signs a statement of intent saying that she never intended to be the mother and that the Intended Parents are meant to be the only parents.in British Columbia, the parents obtain legal parentage in the hospital immediately. That form is filed with vital statistics and a birth certificate is issued within two to four weeks. In Ontario, parentage may be obtained a few days after filing the application. Birth certificates are usually issued within several days.

Domestic surrogacy arrangements require many months of preparation, legal advice and counselling to ensure informed consent. Failing to respect that groundwork by insisting that the surrogate is the legal parent post birth is not in the best interests of the child.

In Australian states, clauses which award legal parentage post birth to the surrogate discourage a large number of intended parents and surrogates from engaging domestically. This should not be the result of new legislation intended to facilitate access to domestic surrogacy.

One of the key recommendations of the Surrogacy UK Working group on Surrogacy Law Reform was that Parental orders should be pre-authorised so that legal parenthood is conferred on intended parents at birth (Horsey et al, 2015 p7).

Evidence from other jurisdictions with altruistic surrogacy such as Australia, Canada, Greece and US states, have shown that the required counselling processes prior surrogacy as well as pregnancy attempts and pregnancy provide an ample 'cooling off' period for the surrogate to change her mind regarding custody.

Genetic Connection in Surrogacy

There are increasing numbers of altruistic surrogacy cases globally where neither the intended father's sperm, nor the intended mothers eggs can be used. Other countries such as the US, Canada and Greece allow Irish citizens to engage in surrogacy where neither parent is able to provide their biological material.

In most Australian states altruistic surrogacy legislation allows for legal parentage to be transferred in the absence of a genetic connection to either intended parent[1]. There have been no reported adverse consequences of these provisions.

RECOMMENDATIONS

a) Head 8 - Counselling

This Head provides that:

(1) All intending parents wishing to undergo AHR treatment shall be provided with counselling from a counsellor who delivers services on behalf of the AHR treatment provider.

(2) When AHR treatment is to be provided to a couple, pre-treatment counselling shall be offered to the intending parents either individually, together or both.

Having seen surrogacy counselling for altruistic arrangements over more than five years, I would strongly recommend that Australia counselling standards be adopted which mandate that both parties in a couple attend counselling together to be eligible for legal parentage. This ensures that the complex social, ethical and medical issues are adequately discussed.

B) Head 36 Gestational surrogacy

[1] Surrogacy Act 2010 Qld, Surrogacy Act 2010 NSW, Assisted Reproductive Treatment Act 2008, Surrogacy (Consequential Amendments) Act (TAS) 2011

(1) Surrogacy may be permitted under the following circumstances

(a) it is domestic surrogacy

(b) it is gestational surrogacy,

It is recommended that Head 36 (b) be widened to include traditional surrogacy, as is the case in dozens of other jurisdictions in Australia, the US and United Kingdom.

c) Head 41 – Surrogacy agreements and reasonable expenses

(5) The "reasonable expenses" associated with the pregnancy or birth in subhead (4) include the following:

(a) any pre-natal or post-natal medical expenses associated with the pregnancy or birth,

(b) any travel or accommodation expenses associated with the pregnancy or birth,

(c) the expense of reimbursing the surrogate for a loss of earnings as a result of unpaid leave taken by her, but only for the following periods:

(i) a period of not more than two months during which the birth happened or was expected to happen;

(ii) any other period during the pregnancy when the surrogate was unable to work on medical grounds related to pregnancy or birth.

(6) The "reasonable expenses" associated with entering into and giving effect to a surrogacy agreement in subhead (4) include the following:

(a) the expenses associated with the surrogate receiving counselling in relation to the surrogacy agreement (whether before or after entry into the agreement);

(b) the expenses associated with the surrogate and the surrogate's husband, where applicable, receiving independent legal advice in relation to the surrogacy agreement or a parentage order related to the surrogacy agreement;

(c) the expenses, including the reasonable travel and accommodation expenses, associated with the surrogate and her husband, where applicable, being a party to proceedings in relation to making a parentage order as a consequence of the surrogacy agreement.

Many intended parents are put off engaging in domestic surrogacy if they or believe that they cannot pay for surrogacy-associated expenses such as babysitting of surrogates' child(ren), maternity clothes and cleaning. As a result we recommend that Clause 6 above include provision for reimbursement of *any* surrogacy-related expenses.

D) Head 42 – Advertisements for surrogacy

This Head provides that:

(1) A person shall not publish or cause to be published any advertisement, statement, notice or other material that—

(a) states or implies that a person is or may be willing to enter into or arrange a surrogacy agreement,
(b) seeks a person willing to act as a surrogate,
(c) states or implies that a person is or may be willing to act as a surrogate, or
(d) is intending or is likely to induce a person to act as a surrogate.

The current wording of Head 42 bans intended parents from even posting in social media groups about their need for a surrogate. In the absence of not-for-profit professional matching, many intended parents and surrogates rely on such forums. The current wording criminalises such online discussion. This should not be the intention of the Act and would force those without friends or families members who offer to engage offshore. Head 42 should not criminalise unpaid advertising or statements for the purposes of surrogacy arrangements

The Bill should also address the need for an Irish NGO to facilitate screening and matching of Irish surrogates and intended parents, to provide both peace-of-mind, and the professional screening available in other countries such as the US, Ukraine and Georgia.

e) Head 44 – Information to be provided to and recorded by the Regulatory Authority in relation to a surrogacy agreement

(1) Prior to giving his or her consent to the surrogacy agreement, the surrogate and each intending parent involved shall be informed

(a) that the surrogate will be the legal mother of any child born as a result of the surrogacy agreement

(b) that the surrogate's husband, if she has one, will be presumed to be the legal father of any child born as a result of the surrogacy agreement unless the contrary is proven on the balance of probabilities as set out in section 46 of the Act of 1987, and a declaration under section 35 of the Act of 1987 that he is not that child's father is granted

(c) that an intending parent will not automatically be the legal parent of any child born under the surrogacy agreement,

Defining the legal parent post birth as the surrogate and her husband, while seemingly supporting 'keeping the door open' for the surrogate to change her mind and keep the child, in practice is a significant deterrent to both altruistic surrogates and intended parents.

It is appropriate that a new Irish Bill incorporate best practice learnings from other jurisdictions, rather than repeating the oversights of outdated legislation than has been demonstrated as

flawed. It is recommended that a simple and immediate process of transferring parentage be instigated post birth, as in the British Columbia altruistic legislation.

f) Head 46 - Consent to child born under a surrogacy agreement to live with an intending parent

1. *Following the birth of a child under a surrogacy agreement, in order for the home of that child to be with an intending parent, the surrogate shall provide her consent.*
2. *Where applicable, the surrogate and an intending parent shall comply with Part IVB of the Childcare Act 1991.*

Explanatory Note

The surrogate will be the legal mother of any child born to her. As such, Head 46 states that following the birth of a child under a surrogacy agreement the surrogate must consent in order for the child to live with the intending parent(s). That consent must be informed and must be in writing.

***Subhead (2)** clarifies that if allowing the child to live with the intending parent(s) would be classed as a private foster arrangement, the surrogate and the intending parents must comply with Part IVB of the Childcare Act, 1991.*

I raised concerns about the issue of the surrogate remaining the legal parent of a child born via altruistic, regulated surrogacy post birth in Head 44 above. It is recommended that Ireland's legislation should instead adopt the more recent best-practice legislation which British Columbia have in place, which makes the intended parents the legal parents immediately following birth. This will obviate the need for the surrogate being required for some months to provide permission to the intended parents for living arrangements, medical treatment and a range of other day-to-day decisions

g) Head 47 – Application for a Parental Order

(4) An application under this Head shall be accompanied by evidence that the embryo from which the child to whom the application relates was born—

(a) was not created using an egg from the surrogate,

It is recommended that Head 47 (4) be widened to include traditional surrogacy, as is the case in dozens of other jurisdictions in Australia, the US and United Kingdom.

(b) was created using a gamete from at least one intending parent of that child.

Forcing Irish citizens in this situation to offshore surrogacy where donors are often anonymous is not in the best interests of the child nor the intended parents. This clause should be excluded from the Irish legislation

(6) An application under subhead (1) shall be made no earlier than six weeks and no later than six months after the day on which the child was born.

Mandated delays in transfer of legal parentage, as discussed under Heads 44 & 46 above, are an unnecessary deterrent to engaging in domestic rather than overseas surrogacy. As per the British Columbia legislation, transfer of parentage should occur immediately following birth without the need for additional court time and costs, resources which are better spent on adversarial family law matters.

(8) Notwithstanding subhead (1), an application for a Parental Order in respect of a child shall only be made if the application also includes any living sibling who was born as a result of the same pregnancy.

This would be problematic in relation to rare cases such as cited here, where one child of a twin pregnancy is genetically related to the surrogate and one is not. See for example https://www.sciencealert.com/extremely-rare-case-us-woman-pregnant-already-baby-superfetation As a result, this clause needs to be modified to allow for such exceptions.

Sam Everingham

11: Fiona Duffy

PATRICK F O'REILLY & CO.
SOLICITORS

Submission to The Joint Committee on Health regarding the
General Scheme of the Assisted Human Reproduction Bill 2017

PRELIMINARY OBSERVATIONS:

1. I note that **Part 6** contains no provision for the retrospective assignment of parentage in the case of children born through surrogacy and living in this jurisdiction. It is not possible to state precisely how many children are involved. The Department of Foreign Affairs would have access to this information based on applications for travel papers to permit a child born through surrogacy in countries such as Ukraine or India, to travel to Ireland. This information might not however be as freely available in respect of children who were born in either Canada or America. Such children are, by virtue of their birth, Canadian or American citizens and will have travelled to this jurisdiction on their Canadian or American passport. I understand that in many cases parents of children born in either of those two jurisdictions may not have taken the appropriate steps to regularise their relationship with that child under Irish law on the expectation that legislation would be enacted.

   A previous Scheme drafted in 2014 contained provision in Head 13(6) for an application to be made to the Court,

   > "in relation to a child born through a pre-commencement surrogacy arrangement may be made not more than two years after the commencement of this Head unless the Court is satisfied that there are special circumstances, and it is in the best interests of the child or children concerned in which case the Courts may extend the time for the making of an application."

   It is my view that the legal position of such children needs to be protected. The possibility of making an application for a Parental Order is completely ruled out in the current Scheme, thus making those children less equal than those born after legislation is enacted.

   I strongly recommend that this be revisited and that these children and their intending parents be afforded the opportunity to regularise their relationships with each other so that a parental relationship with the female or second intending parent can be established.

2. The purpose of the legislation is to provide for the regulation of Assisted Human Reproduction. Parts 2 and 3 of the Children and Family Relationships Act 2015 contain provisions relating to donor conception which overlap with this Scheme. Those Parts have not yet been commenced. While I would like to see Parts 2 and 3 commenced sooner rather than later I recommend that the proposed AHR legislation would contain all appropriate provisions relating to donor assisted human reproduction, rather than that it be spread over different pieces of legislation. I say this for the following reasons:-

(i) That it is envisaged that the functions set out in Sections 33 to 42 of the 2015 Act would be performed by the regulatory authority proposed under this legislation.

(ii) It would be greatly in ease of any person or indeed organisation trying to consider the legislation if all is incorporated in one Act.

PART 1 - PRELIMINARY AND GENERAL

Head 2- Interpretation

"embryo" is described as a human embryo formed by the fertilisation of a human egg by a human sperm. In the context of this specific legislation where it is anticipated that human reproduction will be assisted and conception will take place in a laboratory this definition should exclude the possibility of including an embryo formed in utero.

"gamete" The definition of is too complex. A simple description that it is a human sperm or a human egg would be simpler.

"surrogate" I recommend that the definition be reconsidered.

A surrogate is a woman who carries a pregnancy for another person or persons in pursuance of an agreement with the intention that the intending or commissioning parent or parents will be the parents of the child. By including the words:-

"…who is the legal mother of any child born under a surrogacy agreement"

negates the purpose of the arrangement. It is clear from my dealings with surrogacy arrangements over many years that no surrogate who undertakes a pregnancy on behalf of another or others does so on the basis that she is the legal mother of the child. Indeed in all cases the surrogate mother does not wish to be the legal mother nor does she wish to have any parental obligations or responsibilities in relation to the child.

Head 6 - Provision of AHR treatment

I note that it is proposed that AHR treatment shall not be provided to:-

(3) persons under the age of twenty one years and

(4) in the case of a woman shall only be provided if she is aged forty seven or under.

It would seem that these age limits are quite restrictive for the following reasons:-

- In some cases it is well known that a person may never be in a position to parent a child. Why therefore should such person be precluded from accessing fertility treatment purely on age grounds?
- The justification for imposing an upper age limit of forty seven years for a woman appears to be linked to the clinical assessment of the woman in question. One wonders whether it would be more appropriate to permit the proposed regulatory authority to regulate for such matters. I suggest flexibility based on clinical assessment.

Head 10 - Embryo Transfer

Sub-head (1) seeks to limit the amount of embryos which can be transferred during any treatment cycle.

Best clinical practice in this area is constantly changing with advances in medical science. Some years ago it would have been perfectly acceptable for multiple embryos to be transferred. Current best practice is that where possible only one embryo should be transferred during any treatment cycle. The particular circumstances of the person involved in the treatment are relevant factors, for example, previous unsuccessful cycles, or the age of the mother. Consideration might be given to such matters being the subject of regulation.

PART 3- GAMETE AND EMBRYO DONATION

Heads 12, 13 and 14

Provisions in these Heads touch on and cross over much of the provision contained in Parts 2 and 3 of the Children and Family Relationships Act, 2015 and concern the donation of gametes and resulting parentage. I recommend that the related provisions in the 2015 Act and these Heads be consolidated (see Observation above).

PART 4 - POSTHUMOUS ASSISTED REPRODUCTION

Head 24 – Posthumous and Assisted Reproduction (PAR)

It is noted that PAR would only be available to a female capable of carrying a child. This excludes the possibility of the embryo being used in a surrogacy arrangement, or by a new female partner of the surviving partner. The facts in the case of *MR and DR (suing by their father and next friend O.R.) & Others -v- An t-Ard-Chláraitheoir & Others* in which the Supreme Court delivered Judgment on 7th November 2014, is a case in point. The couple in that case were both able to provide gametes from which embryos were created. The female

partner however was unable to carry a pregnancy which meant that surrogacy was the only option open to them. By excluding surrogacy as an option in PAR the male in that case would, under these proposals, be deprived of the opportunity to father a child or children if his partner died before the jointly created embryos were used in the intended surrogacy procedure. Indeed the embryos in that case would not qualify for PAR as no donor gametes were used.

Head 27 – Recognition of the Deceased Person as a Parent of the Child

It is proposed that a child born within 36 months of the person's death, as a result of a PAR procedure, would be deemed to have been born in the lifetime of the deceased and as having survived him/her. It is also proposed that the deceased is the child's parent.

The explanatory note for **Head 27(3**) anticipates that the child would obtain certain rights, for instance, inheritance rights. However, there does not appear to be any specifics as to what these rights would be.

On a practical level it would be impossible for a personal representative to distribute an estate until he was sure that a child had not been born through PAR. This would be particularly relevant with regard to an intestacy situation or a will where a bequest is made to 'my children' without naming them or stating that they should be alive at the death of the testator.

Another issue would arise with regard to section 117 of the Succession Act, 1965. An application must be made within 12 months of the date of Grant. An efficient solicitor might have a Grant within 4 months of the date of death. Accordingly a child born after sixteen months in that example would not be able to make a section 117 claim.

Under section 117(1) on application by or on behalf of a child of a testator, the court is of opinion that the testator has failed in his moral duty to make proper provision for the child in accordance with his means, whether by his will or otherwise, the court may order that such provision shall be made for the child out of the estate as the court thinks just. Notwithstanding consent for PAR that it would seem that failing to provide for a child who may or may not come into existence goes beyond the scope for which this section was originally intended.

Apart from the thirty six month timeframe within which parentage is to be presumed, there is no limit for the use of the gametes in which case is it intended that the limits set out in **Head 22(8)** will apply.

PART 6 – SURROGACY

The proposals in relation to surrogacy are in my view very restrictive. They seem to pre-suppose the exploitation of women who agree to act as surrogates. Surrogacy is permitted in Ukraine, where comprehensive legislation and regulation has been on the statute books for many years. Surrogacy is also permitted in the UK, certain States in the USA and in Canada. From my experience of acting for clients who have had children through surrogacy invariably a relationship is built up between the intending parents and the surrogate, and in some cases the surrogate mother offers to carry another child.

Head 35 - Interpretation

"Domestic Surrogacy" is defined. It is proposed that only surrogacy which takes place in this jurisdiction will be permitted. To satisfy this requirement:-

- The surrogate and the intending parent must be habitually resident in the State
- The embryo transfer must be carried out in the State

The requirement for habitual residence is very restrictive in that it rules out the possibility of a non-resident Irish citizen either acting as a surrogate or qualifying as an intending parent under this part.

I am involved in one matter at the moment where a couple habitually resident in this jurisdiction have a family member who is an Irish citizen by birth, living abroad, who is willing to act as a surrogate and carry a child for them. In all respects this is the type of arrangement envisaged by the Scheme but would fail purely on the habitual residency rule.

Head 36 – Surrogacy Permitted under this Act

The circumstances in which surrogacy may be permitted are set out in this Head. It is proposed that only an altruistic domestic surrogacy arrangement be permitted.

This provision is very restrictive and would seek to exclude many people from being able to parent children through surrogacy. From my own experience I would estimate that in every 100 surrogacy arrangements only one would involve an Irish domestic arrangement. Ireland is very small with a limited population of women willing and able to act as a surrogate. It is possible that with the introduction of legislation there may be an increase in domestic surrogates. It will not however stop people from going abroad for such services. These people and their children should not be discriminated against.

I have acted for Irish citizens who do not live in this jurisdiction, with children born through surrogacy abroad. Once parentage is established in the Irish Courts those children are also Irish, by virtue of their parent's citizenship. Notwithstanding such citizenship those children will not, under these proposals be treated the same as children born through a surrogacy arrangement permitted under the Scheme. This will result in inequality.

Under **Head 36(1)(d)** it is proposed that the surrogacy agreement must be approved in advance of treatment by the Regulatory Authority under **Head 37.**
Consideration should be given to placing time limits on the Authority to deal with such applications.

Head 36 (2)

Proposes to prohibit the provision of

> "..a technical professional or medical service that is to facilitate or give effect to a surrogacy agreement not permitted under **sub-head (1)."**

By way of clarification the explanatory note states that the provision of legal or practical advice on a professional basis to people seeking to undergo a surrogacy agreement abroad, or seeking to enter into a commercial surrogacy arrangement is prohibited.

This provision appears draconian. As a lawyer practising in the area I regularly advise on the law in Ireland in relation to surrogacy and parentage issues arising from surrogacy arrangements undertaken or intended to be undertaken abroad. There are many Irish citizens living outside the island of Ireland who enter into surrogacy arrangements, which are legal within the jurisdiction where the procedure is carried out. Being Irish and having a child born through a surrogacy arrangement means, once parentage is established, that that child may also be Irish. To prohibit a lawyer in this jurisdiction from providing neutral advice to intending parents, or indeed to a child born through a surrogacy arrangement, would be to deprive them of their constitutional rights to obtain information and legal advice. I believe that this proposed sub-section should not be contained in the intended legislation.

Head 36(4) proposes that surrogacy which does not comply with the provisions of Head 36 is not permitted.
Head 86(3*)* contains details of the penalty proposed for contravention of this Head. To suggest a term of imprisonment for a parent who has contravened the provisions of **Head 36(4)** is to taint the conception of the child with criminality. This would not be in the best interests of the child.

Head 37 – Pre-Authorisation of Surrogacy Agreements by the Regulatory Authority

Sub-head (2) proposes that the AHR treatment provider must apply for the consent. It also provides at sub-head (6) that if the consent is not forthcoming that the AHR treatment provider may appeal that decision.

A Surrogacy Agreement is a legal document and sets out the arrangement between the various parties to the Agreement and their understanding of their respective obligations and responsibilities under the Agreement. It is envisaged that the parties to such Agreement be the intending parent and the surrogate. The AHR treatment provider would not normally be a party to the Agreement. If this is the only document which the regulatory authority proposes to consider, then the right of Appeal should rest with the intending parent rather than with the AHR treatment provider.

Head 40 – Prohibition of Commercial Surrogacy

This head prohibits commercial surrogacy.

For reasons expressed elsewhere in this document the possibility of being able to enter into a surrogacy Agreement permitted by the legislation is limited. By prohibiting commercial surrogacy many Irish citizens will be unable to have children through a permitted surrogacy arrangement. This will seriously impact on single males or male same sex couples for whom surrogacy is the only means open to them to parent children.

Head 41 – Surrogacy Agreements and Reasonable Expenses

Subhead (1) provides that:-

> "..a Surrogacy Agreement is not enforceable by or against any person except as prescribed in this Head".

The obligation to pay and reimburse the surrogate's reasonable expenses is enforceable. On the other hand there is no apparent provision for the enforceability of the Agreement as against the intending couple should they refuse to take the child after birth. The only reason a woman becomes a surrogate is for the purposes of giving birth to a child for another or others. She does not agree to carry a child so that she will in law be the mother of the child or have any parental obligations or responsibilities towards such child.

In order to protect the surrogate I would respectfully suggest that the Agreement to take the child on birth would be enforceable as against the intending couple. I refer you to the well

known baby Gammy case. This involved the birth of twins in Thailand through a Surrogacy Agreement. One of the children, Gammy, was born with Downs Syndrome. The Australian intending parents took one baby only, leaving Gammy behind. It is believed that this was due to his disability. To oblige a surrogate mother to keep a child in such circumstances is a completely unintended consequence of entering into the arrangement and in my view places too heavy a burden on her.

Subhead (5) sets out what might be considered to be "reasonable expenses".

I note that there is no reference to child minding costs and the costs associated with providing life insurance and medical insurance for a surrogate mother. I further note there is no reference to eligibility to paid maternity leave. I would respectfully suggest that the legislation should include provision in relation to maternity leave entitlement and the division of same between the surrogate mother and the intending parent, if applicable.

Head 42 – Advertisements for Surrogacy

This Head proposes to prohibit any public expressions of an interest in entering into a surrogacy arrangement either as a surrogate or as an intending parent.

I can understand why such provision might be considered necessary in the context of exploitation of surrogates. In circumstances where the Scheme proposes to permit altruistic domestic surrogacy only I would question the need for such provision. I understand that there are many on line forums where discussions take place and contacts are made.

Head 44 – Information to be provided to and recorded by the Regulatory Authority in relation to a surrogacy agreement

Head 44(1)(a)(b) and (c) repeat that the surrogate will be the legal mother of the child, that her husband will be presumed to be the legal father. The intending parents will not automatically be the legal parents.

As stated elsewhere in this document this proposal completely defeats the purpose of the arrangement between the various parties. In March 2005 the government appointed Commission on Assisted Human Reproduction by a majority recommended that the child born through surrogacy should be presumed to be that of the commissioning couple. If such presumption exists then there will be no need for a foster care arrangement as envisaged in **Head 46.** Parentage is dealt with in various ways in other jurisdictions. Elements could be drawn from the laws in those jurisdictions while at all times keeping the welfare of the child as the paramount consideration.

Head 47 – Application for a Parental Order

The surrogate and her husband, if married, are the parents of that child. This Head proposes that an application for a parental order may be made by the intending parent/parents or by the surrogate.

The proposed six months period within which an application to the court can be commenced leaves the surrogate as legal parent for too long. Even if the application for a Parental Order is made (commenced) before the expiry of the six month period, there could be a further lengthy delay before the application is concluded and the Order made. Currently applications for Parentage and Guardianship in surrogacy matters can take anything from six to twelve months to reach conclusion.

Head 47(8) –

This provides that if more than one child is born to a surrogate at one time that a Parental Order application must be made in respect of all children so born.

One of the pre-requisites for a permitted surrogacy is that the intending parent or one of the intending parents is genetically related to the child. It would be unreasonable to prevent an intending parent from making an application for parentage in respect of his biological child if the surrogate also gave birth to a second child who is not biologically related to the intending parent. I respectfully suggest that this proposal receive careful consideration.

Head 61 – Prohibition of modification of the human genome

I note Head 61(2)(a) proposes to prohibit mitochondrial donation. Consideration might be given to the possibility of the Regulatory Authority having power to make decisions in this regard in certain circumstances.

Fiona Duffy, Partner –
Patrick F. O'Reilly & Co., Solicitors

22nd February 2018.

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SUBMISSION TO THE JOINT OIREACHTAS COMMITTEE ON HEALTH RE: HEADS OF THE ASSISTED HUMAN REPRODUCTION BILL 2017

FEBRUARY 2018

HAYLEY MULLIGAN

Introduction

The General Scheme of the Assisted Human Reproduction Bill 2017 is by any standards an admirably comprehensive legislative regime governing assisted reproductive technologies. When commenced it will regulate the wide and varied practices associated with assisted human reproduction (AHR)[1]. Of particular interest to this submission is the provisions which sets out the mechanism by which surrogacy arrangements will be regulated in Ireland[2]. The General Scheme of the Assisted Human Reproduction Bill[3] has the benefit of the experiences of those tasked before them with making law in this tremendously complex area[4]. Coming some 40 years after the birth of Louise Brown[5], 33 years after the case of Baby Cotton[6] and 17 years after the release of the findings from the Commission on Assisted Human Reproduction[7]. The difficult social, psychological, ethical, legal and medical issues associated with Assisted Human Reproduction (AHR) treatment generally, and surrogacy arrangements specifically, have not been resolved completely by any particular regulatory system. However, the differing approaches adopted by countries offer an

[1] A Bill to provide for; 1) The regulation of assisted human reproduction; 2) Gamete and embryo donation for use in assisted human reproduction treatment and research; 3) Posthumous assisted reproduction involving the gametes or embryos of a deceased person under certain conditions; 4) Pre-implantation genetic diagnosis and sex selection; 5) Surrogacy; 6) Embryo and stem cell research; 7) Independent regulatory authority for assisted human reproduction

[2] See Head 6 of the General Scheme of the Assisted Human Reproduction Bill 2016, available at http://health.gov.ie/wp-content/uploads/2017/10/AHR-general-scheme-with-cover.pdf

[3] Department of Justice and Equality, "Minister Fitzgerald publishes General Scheme of Children and Family Relationships Bill" (Department of Justice and Equality, 2014). Available at: www.justice.ie/en/JELR/Pages/PR14000257

[4] For example, Israel was the first country to legislate for commercial surrogacy arrangements in 1996; UK enacted legislation regulating altruistic surrogacy in Surrogacy Arrangement Act of 1985 (subsequently amended); South Africa legislated for altruistic surrogacy by virtue of Chapter 15 of the Children's Act 2005; Greece approved law 3089/2002 in 2002 pertaining to Medical Assistance in Human Reproduction which regulated altruistic surrogacy arrangements.

[5] On 25th July 1978 Louise Brown was the first person to be born through IVF in Britain; Patrick Steptoe and Robert Edwards, 'Birth After the Preimplantation' (1978) 312 The Lancet.

[6] Re C (a minor) [1985] FLR 846

[7] Report of the Commission on Assisted Human Reproduction (2005), available at http://health.gov.ie/wp-content/uploads/2014/03/Report-of-The-Commission-on-Assisted-Human-Reproduction.pdf

opportunity to understand and assess the impact these legislative choices have on those involved in a surrogacy arrangement, particularly as new challenges continue to emerge within the local and global context[8].

The General Scheme, set out in Part 6, is the mechanism through which parental rights can be transferred from the gestational mother (GM[9]) (and her partner where applicable) to the intended parents (IP) following a surrogacy arrangement. The 'hybrid'[10] model proposed by the General Scheme is surprisingly unique to Ireland. The model is largely based on a fusion between the Israeli model, which allows for pre-implantation sanctioning by a state authority,[11] and the UK model wherein Parental Orders (PO) are granted judicially after the birth of the child. In the following sections I shall set out some of the potential challenges that need to be considered regarding the General Scheme.

The Key Issues to be Addressed

The General Scheme prohibits traditional (also termed partial or genetic) surrogacy under Head 36(1)(b) wherein it states that only 'gestational surrogacy' is permitted. This prerequisite is arguably based on a commonly held (mis)belief that where a genetic link exists between the surrogate and the foetus, the surrogate will experience potentially greater difficulty relinquishing the child upon its birth[12]. The evidence available does not suggest that traditional surrogacy arrangements are any more unstable then non-genetic arrangements[13]. There is no evidence that there is greater bonding

[8] For instance, transnational surrogacy, as a form of reproductive tourism, has become increasingly concerning from a human rights perspective with many considering the economic and social disparity that exists between the intending parents (IP) and gestational mother (GM) to be potentially exploitative[8]. There are also some very real concerns about the treatment of gestational mothers in the global south, and the lack of protections offered to them; see Sheela Saravanan, 'An Ethnomethodological Approach To Examine Exploitation in the Context of Capacity, Trust and Experience of Commercial Surrogacy in India' (2013) 8 Philosophy, Ethics, and Humanities in Medicine; France Winddance Twine, *Outsourcing the Womb* (2nd edn, Routledge 2015), at 54-61; Hague Conference on Private International Law, 'Report of the February 2016 Meeting Of The Experts' Group On Parentage/ Surrogacy' (Hague Conference on Private International Law 2016) <https://assets.hcch.net/docs/f92c95b5-4364-4461-bb04-2382e3c0d50d.pdf> accessed 20 March 2016; Hague Conference on Private International Law, 'Hague Conference On Private International Law, A Preliminary Report On The Issues Arising From International Surrogacy Arrangements.' (Hague Conference on Private International Law 2012)

[9] I use the term 'gestational mother' to refer to both instances of full and partial surrogacy as the somewhat false distinction is often made between 'gestational surrogacy' (otherwise referred to as 'full surrogacy') and 'non-gestational surrogacy' (otherwise referred to as 'partial surrogacy') which infers that the latter does not involve gestation, or at least the *equivalent* gestation as the former. All pregnancies, be they surrogacy arrangements or not, involve gestation therefore I do not choose to distinguish between different types of gestation based on the genetic relatedness of the foetus to the woman.

[10] 'The General Scheme of the Assisted Human Reproduction Bill 2017: A Hybrid Model for the Regulation of Surrogacy in Ireland (4), 83-87' (2017) 4 Irish Journal of Family Law.

[11] Surrogate Motherhood Agreements (Approval of Agreement and Status of New born) Law 5756-1996

[12] The International Federation of Gynaecology and Obstetrics (FIGO) Committee for the Ethical Aspects of Human Reproduction and Women's Health recommended that only 'gestational' or 'full' surrogacy be permitted; however, this was not based on any empirical evidence that there is any greater psychological bonding when there is a genetic link between the surrogate and the child.

[13] Susan Imrie and Vasanti Jadva, 'The Long-Term Experiences of Surrogates: Relationships and Contact with Surrogacy Families in Genetic And Gestational Surrogacy Arrangements' (2014) 29 Reproductive BioMedicine Online ("genetic and gestational surrogates generally reported positive experiences of surrogacy, suggesting that factors other than the presence or absence of a genetic link to the child are more important in determining the success and long-term outcomes of a surrogacy arrangement").

between a surrogate and a genetically related child, than between her and a child she shares no genetic connection with[14]. This is an important consideration as there are considerable health implications for the surrogate if she is required (as a perquisite to any arrangement) to undergo such treatment. Centrally, traditional surrogacy is a far less invasive medical procedure for the surrogate as she would undergo inter-uterine insemination (IUI) rather than *in-vitro* fertilisation (IVF). IVF takes an enormous toll on the health of the surrogate as she has to undergo countless injections, egg retrieval and implantation. Furthermore, the long-term health risks associated with the hormone treatments required by IVF are, as yet, unknown. Traditional surrogacy is also significantly less costly than full surrogacy, especially when intended parents (IP) are relying on donated ovum over that of the GM's. The move towards full surrogacy, over that of traditional surrogacy, advances the genetic essentialist position to the detriment of valuing the social or gestational input. The primacy of genetic essentialism places a greater emphasis on the 'genetic' relationship between the IP and the child, therefore the presence of a genetic link between the GM and the child represents a perceived threat to the position of the intended mother. Whether it is the surrogate's ovum that is used (or that of a donor), the intended mother/parent will still have no genetic connection to the child. Prohibiting traditional surrogacy does not in any way advance the intending parent's (the person who does not contribute gametes) claim to parentage once the other criteria of the arrangement have been fulfilled. The General Scheme, and importantly The Children and Family Relationships Act recognise a variety of family forms based on genetic, social, gestational and intentional parenting. Placing equal value on all of these variations of family and kinship formation reflects a welcome move away from traditional hierarchical structures of family types and bonds.

There may be a fear that if traditional surrogacy is permitted then people may instead opt for more 'informal' arrangements, where they choose not to use a fertility clinic and therefore do not seek approval from the Assisted Human Reproduction Authority (AHR Authority). This is a concern but perhaps no more so than if such arrangements are prohibited outright by the proposed legislation.

[14] Indeed, all research conducted in the UK includes both Full and Partial surrogacy arguments, their findings have produced no difference between the two practices, see Eric Blyth, "I Wanted to be Interesting. I Wanted to be Able to Say 'I've Done Something Interesting with my Life': Interviews With Surrogate Mothers In Britain' (1994) 12 . J. Reprod. Infant Psychol; Ciccarelli, J., 1997. The Surrogate Mother: A Post-birth Follow-up Study (Unpublished doctoral dissertation). California School of Profession Psychology: Los Angeles; Olga van den Akker, 'Genetic and Gestational Surrogate Mothers' Experience of Surrogacy' (2003) 21 Journal of Reproductive and Infant Psychology; Susan Golombok, *Modern Families* (Cambridge University Press 2015); Susan Golombok and others, 'Children Born Through Reproductive Donation: A Longitudinal Study of Psychological Adjustment' (2012) 54 Journal of Child Psychology and Psychiatry; According to COTS (Childlessness Overcome through Surrogacy) '98 per cent of arrangements involving COTS members have reached successful conclusions'. Available at: http://www.surrogacy.org.uk/FAQ4.htm; the Surrogacy UK Working Group on Surrogacy Law Reform conducted research including full and partial surrogacy arrangements, see Surrogacy in the UK: Myth Busting and Reform—Report of the Surrogacy UK Working Group on Surrogacy Law Reform (Surrogacy UK, 2015) Available at: https://www.surrogacyuk.org/Downloads/Surrogacy%20in%20the%20UK%20Report%20FINAL.pdf

Another concern may relate to the impact on the surrogate's existing children who would share a genetic link with the child born through the surrogacy arrangement, as they would of course be half-siblings. Susan Golombok's research in the UK has revealed that children of surrogates already consider children born from a surrogacy arrangement to be part of their kinship[15]. This is true whether genetic connection between them exists or not.

Recommendation: In the absence of empirical evidence suggesting greater bonding between the surrogate and the genetic child in a surrogacy arrangement, and the potential health implications for the surrogate, coupled with the excessive costs involved, it is suggested that the decision on whether or not the surrogates' ovum to be used should rest with the surrogate and the intending parents and should not be prohibited by future legislation.

Further, the transferal of parental rights *ex post facto* the birth should be considered in light of the experiences of other jurisdictions and the available evidence. There is an emerging preference towards transferring parentage from the GM to the IP before birth in a number of jurisdictions.[16] Perhaps even more compelling is the research from the UK wherein the majority of GMs' favour recognition of the IP as the parents of the child at birth[17]. The post-birth approach adopted by the General Scheme is evidently based on the UK Parental Order transfer model. There have been many calls for reform on this particular aspect of surrogacy regulation[18].

The judicially approved transfer model is indeed a salient approach to the transferring of parental rights as it must be remembered that the process is not simply the acquisition of parental rights and responsibilities by the IP, but also the termination of the GM's legal parentage. Relatedly, it has been argued by Dr. Brian Tobin that the AHR Authority[19] should have the competence to approve the legal parentage of the IP once the relevant requirements of Part 6 have been satisfied[20]. In theory it would be possible to transfer parentage to the IP alongside treatment approval by the AHR Authority. However, the question arises, is it appropriate that the AHR Authority have the competence to not simply recognise the IP as the legal parent(s), but by proxy nullify any parental and legal relationship between a woman and the child she is proposing to carry before implantation has even occurred? It is not necessarily the recognition of the

[15] Susan Golombok, *Modern Families* (Cambridge University Press 2015).
[16] Countries where parentage is transferred before birth
[17] Surrogacy UK, 'Surrogacy in the UK: Myth Busting and Reform Report of the Surrogacy UK Working Group on Surrogacy Law Reform' (2015) <https://www.familylaw.co.uk/system/froala_assets/documents/27/Surrogacy_in_the_UK_report.pdf> accessed 22 November 2017.
[18] HL Deb 14 December 2016, vol 777, cols 1317; Surrogacy UK, 'Surrogacy in the UK: Myth Busting and Reform Report of the Surrogacy UK Working Group on Surrogacy Law Reform' (2015)<https://www.familylaw.co.uk/system/froala_assets/documents/27/Surrogacy_in_the_UK_report.pdf> accessed 22 November 2017.
[19] As established by Part 8 General Scheme Assisted Human Reproduction Bill 2017
[20] Brian Tobin, 'The General Scheme of the Assisted Human Reproduction Bill 2017: A Hybrid Model for the Regulation of Surrogacy in Ireland' (2017) 4 Irish Journal of Family Law.

IP that I take issue with, but instead the nullifying effect this has on the GM's rights. Transferring parental rights from the GM to the IP *before* birth leaves the GM in a very peculiar situation - she is gestating a foetus who is in effect a legal stranger to her[21].This is indeed a tremendous responsibility to confer on the AHR Authority whose primary function is oversight, and not adjudication *per se*[22].

Recommendation: I would argue that any transferal of parental rights must be vested in the courts and not considered as part of the administrative process between the AHR facility and the AHR Authority whose role and expertise is confined to the sphere of bioethical decisions and compliance. Although it may seem to be somewhat incongruent that the AHR Authority has the power to sanction a surrogacy arrangement but is expressly prohibited from transferring parental rights because of the finality[23] of the transfer and its effects on the GM, it is thus preferable that this important element of the process is exclusively confined to the jurisdiction of the courts.

Additionally, from a private international law perspective it may also be perceived to be in the best interest of the child that it is a court (as opposed to another body) that oversees the transferal of parentage. The Hague Conference on Private International Law has clearly preferenced judicial assignment of parentage over a determination predicated on the recognition of public document[24], working towards a *lex fori* approach.[25] Thus, if the child was to reside in another country, this could potentially be an important factor for the child and his/her IP.

As has been mentioned above, there is growing evidence that the GM and IP favour a pre-birth parentage transfer approach. There are compelling reasons why this approach may in fact benefit all those involved. Firstly, there is certainty as to parentage for the child. Secondly, there is greater certainty for the GM as she is not reliant on the IP discretion to apply for a PO. In the event that the IP's separate or pre-decease the birth of the child, the child will still be the legal child of the IP's and therefore, entitled to statutory protects including inheritance provision. Thirdly, the IP's

[21] I latter suggest that the transferral should not be seen as full transfer of right from the GM to the IP, instead arguing that the GM retains the locus standi to petition the court for guardianship, custody and/or access.
[22] It is the AHR facility that applies for approval to oversee the surrogacy arrangement, the facility must provide the Authority with sufficient documentation to satisfy the Authority that they have complied with the requirements of the Act. It is then for the Authority to decide whether all the requirements have indeed been met. At no point does the General Scheme envisage the IP or the GM making direct contact with the Authority, all communications are between the AHR facility and the Authority.
[23] As it is currently formulated by the General Scheme.
[24] Hague Conference of Private International Law. REPORT OF THE EXPERTS' GROUP ON THE PARENTAGE / SURROGACY PROJECT (MEETING OF 31 JANUARY - 3 FEBRUARY 2017) Parentage/Surrogacy Project at para 15 "It was also noted that the issuance of a public document is an administrative matter without proceedings comparable to those which precede a judicial decision"
[25] Hague Conference on Private International Law, 'Report of the February 2016 Meeting of the Experts' Group on Parentage/ Surrogacy' (Hague Conference on Private International Law 2016) <https://assets.hcch.net/docs/f92c95b5-4364-4461-bb04-2382e3c0d50d.pdf> accessed 20 March 2016, at 12

will have greater certainty that the GM will not renege on her intention to relinquish the child. Alternatively, there is some evidence to suggest that when parentage is transferred before birth the IP's may attempt to assert greater control over the behaviour of the GM during pregnancy as the IP's appear to ascribe greater value to the genetic relatedness to the child rather than emphasising the role of the gestational mother[26]. There is genuine concern that the role of the GM will be diminished by transferring parentage pre-birth. For that reason, it must be made explicitly clear in any future Act (irrespective of transferal of parental rights to the future child) that whilst *in utero* and during birth, all medical decisions should be made between the GM and her physician. It is the pregnant woman who remains the ultimate arbiter of any, and all, decisions relating to pregnancy and birth. This is already set out in Head 41(2) but it is recommended that this is made explicitly clear in any proposed Bill and perhaps with the availability of damages where the surrogate experiences undue pressure or interference by the IP's.

Despite advocating for a pre-birth parental transfer model which is judicially overseen (as set out below), if the future Bill maintains the post-birth model as set out in the General Scheme, I recommend a specific amendment relating to the transferal of parentage. A question arises as to what would happen in the event that the IP renege on their earlier intention to seek a PO? Any person can withdraw their consent to the agreement before the granting of a PO. Currently there is nothing in the General Scheme that could compel an IP to seek a PO (as their consent is expressly required). Although it may seem somewhat absurd to assign parentage to a person who does not wish to assert such a claim, there is an argument that where one or both of the IP's renege on their earlier intention (post implantation and after fulfilling Head 38) the PO should still be granted, so that persons caring for the child (presumably the surrogate, or possibly the State) can obtain a maintenance order. Head 48 (2)(d) permits the court to waive the consent of the surrogate, but not the consent of the IP's. In the UK the consent of the surrogate mother is "the lynchpin" of PO[27] transfer systems, whereas in the General Scheme it is at the 'discretion' of the IP's to apply for a PO.

Recommendation: Provision should be made allowing for a PO to be made without the consent of one or both of the IPs. This is especially important with regard to the child, as they would have no means of knowing the circumstances of their conception and birth, as there would be no formal record of their intended

[26] Helena Ragone, *The Gift of Life: Surrogate Motherhood, Gamete Donation, And Constructions of Altruism. In Transformative Motherhood: On Giving and Getting in A Consumer Culture.* (New York University Press 1999) ("The children produced through traditional surrogacy arrangements tend to be viewed by all parties through the gift lens, a formulation that explicitly rests upon the shared acknowledgement that what the surrogate gives is literally a part of herself. However, a shift has occurred as gestational surrogacy supersedes traditional [which involves either the implantation of the couple's embryos or donor ova and husband's/partner's semen into a gestational surrogate], specifically, this gift rhetoric is notably underused".)
[27] D and L (Surrogacy) [2012] EWHC 2631(Fam), at 25

parents (either genetic or intentional) if the IP choose not to apply for a PO. As it stands, in the absence of the granting of a PO, the GM (and her husband if applicable) would be the child's legal parents.

It is imperative that surrogacy arrangements are conceptualized as the formation of new and unique relationships which are protected through law and regulation, and not viewed as transactional arrangements. Surrogacy arrangements encompass physical, emotional, social, biological, and psychological connections between the GM and the child, the IP and the child, and also between the GM and the IP. The uniqueness of the role played by GMs in surrogacy arrangements makes them in many respects non-comparable to other persons in the any other form of AHR and therefore they should be recognised as such.

The Proposed Model

I support the pre-authorisation requirements as set out in Heads 35-46. I do however, recommend that Heads 47-49 should be amended so as to allow for a very specific pre-birth PO transfer procedure which, *inter alia* inserts a provision allowing the **GM the right to apply for guardianship, custody and/or access to the child, recognising a continued legal association between the child and the GM upon birth**. Upon successful conception, and before the birth of the child, the GM should be permitted to apply to the court for a PO transferring the rights from her (and her husband where applicable) to the IP. While the child is *in utero* the GM has the explicit and sole authority to apply to the court for such an Order. Upon the birth of the child either the IP or the GM (if she has not already done so) may apply to the court for a Parental Order transfer. This may be done at any stage following the birth and up to 6 months thereafter. It will be up to the IP and/or the GM to decide when they choose to apply for the PO transfer within this period. This maximises the autonomy and decision-making options for both the IP and the GM and guards against perpetuating the (mis)belief that women who are pregnant are lack the capacity to give fully informed consent. The right of the GM to apply for guardianship, custody and/or access will remain with the GM until the child reaches the age of majority. Importantly, this recognises that she too has a vested interest in safeguarding child's best interest. The appropriateness of granting guardianship, custody and/or access will of course be a matter for the court and judged on a case by case basis, having regard to the best interests of the child. Evidence has shown that continued interaction

between children born through surrogacy and the GM has a positive effect on the child's understanding of their birth origins and thus benefits the child's psychological development[28].

This approach offers legal certainty to the child, the GM and the IP. It recognises the symbiotic relationship that exists between the IP, the child and importantly the GM. The model ascribes equitable legal status to each of the persons involved, without enforcing a hierarchy of contribution (be it genetic, gestational or intentional). Therefore, the child could potentially have three legal guardians, but only two of whom would be legal parents at any given time. Importantly, there is no guarantee that GM would be successful in her application, as this would be a matter for the courts. The purpose of granting the GM the *locus standi* to petition the court for guardianship, access and/or custody of the child recognises in law a legal relationship between the GM and the child with whom she has gestated. There are a number of reasons why a GM may seek to assert guardianship, care and/or custody for the child, these may include, but are not limited to; the GM may become aware of unhealthy family dynamics within the IPs family; deceit on the part of the IP; physical or mental health concerns for one or both of the IP; where one or both of the IP commit a crime etc. To take but one example, it may be the case that during the course of the pregnancy the GM becomes aware or worried about the nature of the IP's relationship, the GM may be concerned about the domestically violent or controlling behaviour of one or both of the IPs[29]. In this instance the GM may wish to assert her right to guardianship, care and/or custody. At the other end of the continuum, a GM way wish to apply for an Access Order wherein she requests to see the child once a year, or exchange correspondence with the IP and/or the child to see how the child is. From the research available many GMs involved in altruistic surrogacy arrangements do remain in contact with the IP and the child. Allowing for this to be formalized in law protects the unique relationship that exists between the GM and the child. As has been stated above the degree of contact would of course need to be judged in light of the best interest of the child. The reality is that material circumstances, emotions and situations can and will vary greatly between and within different surrogacy arrangements, it seems completely reasonable that the position of the GM be considered alongside that of the IP. Although parental transfer from the GM to the IP is fully actualized through the Parental Order, there is no conceivable reason why the GM needs to be stripped of *all* rights to the child. On the contrary, harmonious distribution of rights and duties between the GM and the IP protects and safeguards each person's contribution and reflects the reality of involvement to this newly formed relationship.

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[28] V. Jadva, S. Imrie and S. Golombok, 'Surrogate Mothers 10 Years On: A Longitudinal Study of Psychological Well-Being and Relationships with the Parents and Child' (2014) 30 Human Reproduction; Susan Imrie and Vasanti Jadva, 'The Long-Term Experiences of Surrogates: Relationships and Contact with Surrogacy Families in Genetic and Gestational Surrogacy Arrangements' (2014) 29 Reproductive BioMedicine Online.

[29] CW v NT and another [2011] EWHC 33 (A couple, who had entered into a surrogacy agreement with a woman who later sought to keep the child over fears of domestic violence and the unfitness of the IP to parent, had their application for residency rejected. The order was granted in favour of the gestational mother.)

In order to facilitate the application for guardianship, an amendment to s. 6C(2)(b) of the Guardianship of Infants Act 1964 (as amended) would be required to include "(iii) or the women who gestated the child". Similarly, to facilitate an application for custody by the surrogate, an amendment to Section 11E(2)(b) of the 1964 Act (as amended) would be required to include "or the woman who gestated the child". Lastly, regarding access section 11B (as inserted by the Children Act 1997) pursuant to section 55 of the 2015 Act in which a relative of the child, or a person with whom the child resides or has formerly resided should include "or the person who gestated the child".

I believe the proposed model to be wholly consistent with decision handed down by the Supreme Court in MR & Another v An tArd Chláraitheoir[30] , wherein it was held that the *maxim mater semper certa est* did *not* form part of the common law of Ireland, and that the common law of Ireland had *not* addressed the issue of motherhood in surrogacy arrangement.[31] Thus, the notion that motherhood is solely determined by gestation and is thus always certain was not endorsed by the Court. The Supreme Court, in effect, compels the Oireachtas to legislate for different forms of motherhood. In the words of Denham C.J. "there is no definitive definition of "mother" in the Constitution. Nor is there anything in the Constitution which would inhibit the development of appropriate laws on surrogacy"[32]. Yet, rightly observing that "the issues raised are…important, complex and social, which are matters of public policy for the Oireachtas it is thus, quintessentially a matter for the Oireachtas"[33]. In his concurring opinion McKechnie J. was perhaps more emphatic in the need for action on the part of the Oireachtas. Stating clearly in his judgement that if the Oireachtas were to fail to legislate he was willing for the matter to be heard before the Court again. He states:

> "I am satisfied to limit myself by saying that such rights are to be found in Article 40.1 and Article 40.3 of the Constitution. They may well be justified also by reference to other provisions, but I do not consider it necessary to further explore this issue at the present time. If occasion should arise I will, as stated, do so in the future"[34]

In the absence of any law governing surrogacy arrangements the Court ultimately found the GM to be the legal mother MR and DR[35]. However, far from maintaining the *status quo* of legal motherhood, the reasoning of the Court suggests that there are no apparent legal impediments preventing the legislature from recognising in law the advancements which have occurred in science and the changing social norms regarding motherhood.

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[30] [2014] IESC 60
[31] [2014] IESC 60, at 88
[32] MR & Another v An tArd Chláraitheoir [2014] IESC 60, at 114 (Denham C.J)
[33] MR & Another v An tArd Chláraitheoir [2014] IESC 60, at 118 (Denham C.J)
[34] MR & Another v An tArd Chláraitheoir [2014] IESC 60, at 151 (McKechnie J)
[35] MR & Another v An tArd Chláraitheoir [2014] IESC 60, at 118-119 (Denham C.J)

In support of the proposed model as set out above, it is the minority decision of Clarke J. which is perhaps most instructive. When considering the role played by the GM and the genetic mother Clarke J. states:

> "I am, therefore, satisfied that both the genetic mother and the birth mother have some of the characteristics of "mothers" as that term is currently used in our law. The term "mother", historically, referred to both because both were, as a matter of then scientific fact, necessarily the same person. They are no longer now, however, necessarily the same person. But neither has, in my view, by reason of that scientific advancement, necessarily lost their status"[36]

Clarke J. continued, "in those circumstances a law which does not exclude either has the potential to do less harm than a law which necessarily completely excludes one"[37]. The proposed model seeks to do precisely that, it offers legal protection and certainty to the child, the IP and the GM without excluding any one person, thus fully recognising and valuing each and every person within the surrogacy relationship.

To conclude, the forgoing represents my views on what I discern to be some of the most significant omissions within the General Scheme from a number of perspectives, most particularly that of the gestational mother. My Ph.D. research extends beyond the confines of this submission and as such, the Committee are welcome to engage with me further if they deem it to be useful. I would like to take this opportunity to thank the Committee for their time and wish them well in the completion of their important work on this subject.

[36] MR & Another v An tArd Chláraitheoir [2014] IESC 60, at 10.1 (Clarke J)
[37] MR & Another v An tArd Chláraitheoir [2014] IESC 60, at 10.3 (Clarke J)

14: Human Life International Ireland

Submission to the Oireachtas Joint Committee on Health

on the General Scheme of the Assisted Human Reproduction Bill 2017

(See Cover letter attached)

Patrick Mc Crystal, Executive Director,

Human Life International (Ireland)

Why the Joint Committee on Health should reject the General Scheme

of the Assisted Human Reproduction Bill 2017

SUBMISSION

We, at Human Life International (Ireland) register our strongest possible objections to the proposals to fund and further promote IVF legislation in Ireland.

There should be no I.V.F. whatever.

The Catholic Church teaches that IVF is "*gravely immoral*" and an affront to human dignity. All human beings are sacred and inviolable, made in the image and likeness of God, with an eternal soul and that they deserve the *"right to be respected as a person from the moment of conception*." (Catechism of Catholic Church n2378)

The Church teaches children "*have a right to be born of a father and mother known to him and bound to each other by marriage*." (Catechism of Catholic Church n 2376)

IVF is terribly destructive of human life, anywhere from 73%[(1)] up to 96%[(2)] of embryos are destroyed in the process. Each one of us was once a human embryo.

Serious issues arise for anyone promoting, advocating, legislating or participating in any procedure entailing an attack on human life.

From example, Pope John Paul II reminds us of several vital points:

1) "Whoever attacks human life in some way attacks God himself." (Evangelium Vitae n9)
2) God's words from Genesis: "From man, with respect to his fellow man, I will demand an accounting" (Evangelium Vitae n38)

3) “Every individual… has moral responsibility for the acts he personally performs; no-one is exempted from this responsibility and on the basis of it everyone will be judged by God himself.” (Evangelium Vitae n74)

Scientifically, at the moment of fertilization our genetic makeup and sex are determined. A unique individual is created.
The legislation as set out in the General Scheme would permit experimentation on human embryos up to 14 days after fertilization.

To use human embryos as the object or instrument of experimentation constitutes a crime against their dignity as human beings, denying them the right to the same respect that is due to the child already born and to every human person.

By acting in this way the parents and researchers usurp the place of God; and, even though they may be unaware of this they set themselves up as the masters of the destiny of others inasmuch as they arbitrarily decide whom they will allow to live and whom they will allow to die.

It must be noted that IVF does not treat infertility, but by-passes it. It is extremely expensive. IVF typically consists of three treatment cycles of about €5,000 each. In England, IVF is proving so costly that some NHS regions have now stopped funding it.(3)

Spouses who cannot have children because of impaired fertility experience "a suffering that everyone must understand and properly evaluate" *Donum Vitae 8, 1987*.
They must be treated with the fullest respect and compassion in their difficult situation, yet are called, like everyone, to respect the moral law.

There is a completely ethical method of treating infertility.
NaPro (Natural Procreation Technology) is respectful of life, is very successful in achieving full-term pregnancy and is cheaper than IVF which is an expensive treatment. The success rate for NaPro technology is between 40% and 60% after 1 year.(4)

Biomedical science has the potential to alleviate great human suffering. However, when it is applied without careful consideration of the consequences it harms far more than it heals.

Science and technology require an unconditional respect for the fundamental criteria of moral law.(5)

Ministers and elective representatives simply do not have the authority to legislate for the creation of human beings in a petri dish. Human beings are sacred, made in the image and likeness of God and endowed with and eternal soul. There are serious implications for everyone involved.

Patrick McCrystal
Human Life International Ireland

References:

1) https://www.all.org/-after-35-years-ivf-still-a-vast-experiment

2) Approximately 96% of all human embryos conceived in vitro are wasted in the process of IVF [Nicholas Tonti-Filipini, 'Reproductive Technology Outcomes in Australia: Analysing the Data', Bioethics Research Notes March 2003, 15:1,2)]

3) https://www.cambridge-news.co.uk/news/free-ivf-nhs-scrapped-cambridgeshire-13578127

4)http://www.cfp.ca/content/cfp/58/5/e267.full.pdf

5) Fuller synthesis of his subject see *Donum Vitae* "Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation" which was issued on February 22, 1987, by the Congregation for the Doctrine of the Faith. It addresses biomedical issues from the Roman Catholic Church's perspective. See also Catechism of Catholic Church

15: Irish Cancer Society

Irish Cancer Society Response to the Joint Oireachtas Committee on Health's call for submissions on the Assisted Human Reproduction Bill 2017

February 2018

The Irish Cancer Society

Established in 1963, the Irish Cancer Society is the national cancer charity. Our vision is that every person in Ireland will have access to the best possible cancer services; will have the lowest risk of getting cancer, the highest chance of survival, and the best support and information available when affected by cancer.

Our goals are cancer prevention, early detection and fighting cancer with three programme areas to achieve them: advocacy, cancer services and research.

The Irish Cancer Society welcomes the opportunity to respond to the Committee's consultation on the General Scheme of the Assisted Human Reproduction Bill 2017.

Executive Summary

The Irish Cancer Society broadly welcomes the measures contained in the General Scheme of the Assisted Human Reproduction Bill 2017, and the establishment of the Assisted Reproduction Regulatory Authority.

The legislation provides much needed clarity and regulation in the area of fertility treatment in Ireland, which has been lacking for some time.

As the legislation deals with a range of fertility issues, we do not propose to comment on all aspects of the Bill in this submission, but instead will offer our views on areas of particular interest to cancer patients and cancer survivors.

Cancer treatment can affect your fertility, and a patient may need to seek fertility perseveration before they commence treatment to freeze embryos, eggs, or sperm. The requirement to freeze gametes is particularly relevant in the case of childhood cancer patients, and this may be required either pre-treatment or post-treatment.

Gametes cryopreserved may, subsequent to cancer treatment, be used to support attempts to conceive via IUI, IVF or ICSI.

Currently cancer patients can avail of a publicly-funded service to access fertility preservation prior to cancer treatment, which is funded by the National Cancer Control Programme.

Fertility preservation and storage is provided for by the National Oncology Cryopreservation Centre as part of the National Fertility Centre at the Rotunda Hospital[1].

[1] http://rotundaivf.ie/the-journey-through-ivf-treatment/fertility-preservation-for-cancer-patients/

However, cancer patients who need fertility preservation post-treatment must pay for it privately.

The Irish Cancer Society believe the current free at the point of access service should be extended to cancer patients who are required to preserve their fertility post-treatment due to diminished fertility or the early onset of menopause resulting from their treatment. This requirement is particularly important for adult survivors of childhood cancer.

Additionally, cancer patients who wish to seek assisted fertility treatments post-treatment in order to conceive must currently pay for this service, so we are very pleased to hear that the Government, and Minister Simon Harris, have suggested they will examine state funding of fertility treatments from 2019, alongside the publication of this legislation.[2]

Thankfully numbers seeking fertility preservation in Ireland are increasing as more patients are surviving their cancer treatment with an ever improving quality of life post -treatment. Fertility science is rapidly progressing and children are now able to avail of this service at a younger age. However, cancer incidence in the population is increasing and awareness of survivorship needs and issues is growing so more cancer patients are seeking this treatment.

There are are currently 165,000 people living with cancer in Ireland. 40,000 more will be diagnosed with cancer or a related tumour this year.[3]

In 2014 there were 222 childhood cancer cases[4] in Ireland, and we are pleased to see that in Section 22(7) of the Bill, particular consideration has been given to those who would need to seek fertility preservation as children.

The Society welcomes this important piece of legislation which will regulate and control the fertility industry for the first time.

Section 22(8)

Childhood cancer patients and survivors are a small, but important cohort who will impacted by the Bill.

[2] https://www.irishtimes.com/news/politics/government-to-pay-for-couples-to-have-ivf-treatment-1.3242402
[3] https://www.ncri.ie/publications/statistical-reports/cancer-ireland-1994-2015-estimates-2015-2017-annual-report-national
[4] https://www.ncri.ie/data/incidence-statistics

The Irish Cancer Society is concerned by Section 22(8) of the Bill, which could unwittingly cause undue hardship for childhood cancer patients who have sought cryopreservation of their gametes.

Section 22(8):

(8)(a) Except with the approval of the Regulatory Authority under paragraph (b)—

***(i) no gametes may be stored for more than 10 years**, and (ii) no embryos may be stored for more than 5 years.*

b) The Regulatory Authority may grant an extension to the storage periods outlined in paragraph (a) if—

(i) before the storage period has expired, an eligible person makes a written application to the Regulatory Authority requesting such an extension, and

(ii) the Regulatory Authority considers that there are reasonable grounds for granting such an extension in that particular case

Section 22(8) of the Bill says that gametes may not be stored for more than 10 years without permission of the Regulatory Authority. While it is important to have timelines in place, we are conscious that such a timeframe does not cause an unnecessary burden.

Adult survivors of childhood cancer, who underwent fertility preservation as children, may need to store gametes for a longer period of time than this, and could be impacted by this Section of the Bill.

We feel there are workable solutions to this proposal, which may include a time extension for those who have had cryopreservation as a result of cancer or giving powers to the Regulatory Authority to set reasonable grounds for extension. Additionally, the legislation could be amended so that people who had their gametes preserved during childhood (under 18), due to a medical condition, would be exempted from this requirement.

We are pleased to note the Department of Health's openness to engagement on the issue conveyed at Committee hearing[5], and hope consideration of these issues will help bolster the Bill and support childhood cancer patients and survivors.

[5]http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/DebatesWebPack.nsf/committeetakes/HEJ2018011700002?opendocument#C00200

Submission to the Joint Committee on Health on the General Scheme of the Assisted Human Reproduction Bill 2017 on behalf of the Association of Irish Clinical Embryologists

(i) Introduction

The Association of Irish Clinical Embryologists (ICE) was founded in 1998 for three essential reasons: firstly as a means for easier communication between professionals working in the same field, secondly to promote high standards of practice in Clinical Embryology and thirdly, to support the professional interests of embryologists working on the island of Ireland.

Since 1998, the number of clinics has grown, as has the number of embryologists with over 40 members now registered with ICE. Our membership comprises of clinical embryologists of all grades: trainee, clinical, senior and managerial and they are at the front line of the area that this draft bill intendeds to regulate. Ireland has led the way in the implementation of the European Tissue and Cells Directives (the "Directives") and today, the Irish IVF clinics are probably the most heavily regulated worldwide, with the Health Products Regulatory Authority (HPRA) being the competent authority in the Republic of Ireland. Our expertise lies not only in the interpretation and implementation of the existing European Union Tissue and Cell Directive, but also in our biological and analytical skills that play a vital role in the provision of all Assisted Human Reproduction (AHR) services in Ireland.

ICE welcomes the introduction of the new legislation governing the area of AHR and are pleased to submit the following response to the General Scheme of the Assisted Human Reproduction Bill 2017.

(ii) Factual Information

(iii) Recommendations

The following information relates specifically to the draft document and references the text followed by a specific comment or recommendation related to that text.

Head 2 - Interpretation

Assisted human reproduction (AHR) means all treatment or procedures that involve the handling of gametes and embryos for the purposes of establishing a pregnancy.

Comment:

Clarify that this includes the “direct use” of donor sperm that is not currently governed by the EUTCD.

Supernumerary embryo means an embryo that was created and stored for use as part of a person’s own AHR treatment (weather as an individual or as part of a couple), but which remains unused following the completion of that treatment

Comment

It is implied that this includes embryos created using donor gametes as it provides for an individual as well as a couple but it may not explicitly include donor egg created embryos or donor sperm created embryos.

Writing includes voice and video recording and speech recognition technologies

Comment:

Is there a provision for electronic/email consent or photographic representation of consent. E.G patient may be off site/overseas at time of treatment and provision of written consent as described above only posable by email or photographic evidence of document completion.

Head 6 – provision of AHR Treatment

(4) AHR treatment shall only be provided to a woman who is 47 years of age or under, irrespective of whether the woman is using her own gametes, an embryo created using her gametes, or gametes or embryos donated by a third party.

Comment:

The age limit appears to be unduly restrictive. It is clear that this limit has been derived from the females’ ability to parent the child until that child reaches adulthood as well as the comments referred to in subhead (4) of this section. This makes the assumption that when the female is 66 the child will have attained an age of 18 and the parent will no longer be the legal guardian of any resulting child. The clinical basis for determination of the risk to the health of the patient or any resulting child would be a more justifiable method of determination of eligibility for treatment. Should an upper age limit be applied, an age limit of 50 would be more appropriate (ref HFEA guidelines, no upper age limit set. Each licenced ART provider sets its own restrictions)

Head 9 – Consent

3 (a)

(iv) the consent form was signed by the person giving consent

Comment:

Subhead (5) in this section has a provision that allows for a person to direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

This does not clarify if presence can be defined as telephone communication or video link etc. or if the person directed to sign the consent can be an employee of the company providing the consent for signature.

Head 12 – Gamete donation for use in AHR or Research

(1) (b) he or she has attained the age of 18 years

Comment:

This is not consistent with the requirement in Head 6 – provision of treatment (3) AHR treatment shall not be provided to persons who are under the age of 21 years.

This implies that it is acceptable to donate gametes to a third party when one has attained 18 years of age but it is not acceptable to access ARH services (with own or donated gametes) until age of 21 attained.

(**3)(a)ii he or she as attained the age of 18 years**

Comment:

As for (1) (b) this is not consistent with the requirement in Head 6 – provision of treatment (3) AHR treatment shall not be provided to persons who are under the age of 21 years.

This implies that it is acceptable to donate gametes to be used in research when one has attained 18 years of age but it is not acceptable to access ARH services (with own or donated gametes) until age of 21 attained.

Taken together, access by prospective patients to AHR services when one has attained 18 years of age would be recommended.

Head 22 – Storage of gametes and embryos

(8) (a) Except with the approval of the regulatory authority under paragraph (b)-

(i) no gametes may be stored for more than 10 years and

(ii) no embryos may be stored for more than 5 years.

Comment

HFEA guidelines were amended to allow for the storage of gametes and embryos for up to 10 years with patient consent. ICE would recommend a similar approach to storage consent as patients can have embryos stored for more than 5 years and still not consider their family complete and intend using these embryos.

Head 39 – The intending parents

(2) Each intending parent shall be at least 21 years of age..

Comment:

This is not consistent with the requirement of Head 12 Gamete donation for use in AHR or Research (1) b or (3) (a)ii which allow donation at 18 years of age.

(3) (c) an intending parent who is 47 years of age…

Comment:

As this clause in subhead (3) allows for at least 1 intending parent to be under the age of 47 it has broader practical application than the more restrictive terms set out in header 6 (4).

17: Irish Fertility Councellors Association

JCH 377 (a)

The Irish Fertility Counsellors Association (IFCA) was founded in 2008. Its members are counsellors, psychotherapists and psychologists, all accredited or registered with an appropriate body for their discipline. All are fully trained in Specialist Fertility Counselling, by the British Infertility Counselling Association (BICA). We aim to encourage continuous professional development and shared best practice amongst our members to allow for the highest standards in a specialist counselling setting.

Taoiseach Varadkar, in his role as Minister of Health wrote to IFCA in July 2015 assuring us that the upcoming AHR bill/act would enshrine fertility counselling as mandatory. Minister Simon Harris lauds this legislation as a milestone and points out that it is required to protect, promote and ensure the health and safety of parents and children born as a result of AHR and others who may be involved – such as donors or surrogates.

IFCA welcomes the establishment of an AHR Regulatory Authority (AHRRA) for this act and for Sections 33 – 42 of CFR (2015) and related matters; however, it is imperative that the body be truly independent and representative of all sectors, and disciplines working within the area. IFCA holds that, as the body representing specialist fertility counselling in Ireland, complying with current international professional standards in good practice, it should be represented on the Regulatory Authority.

All patients undergoing fertility treatment in Ireland should receive counselling by a member of IFCA, specifically trained and registered/accredited in specialist fertility counselling; and that as stated in HEAD 18 (c) (i) those receiving treatment using donor gametes, embryos or surrogacy are required to have additional implications counselling. We propose that this too should be provided by a suitably trained and registered/accredited member of IFCA.

HEAD 6 (2) acknowledges the vital role of counselling in AHR.

As per HEAD 8 SUBSECTION (4) Counselling ("Specialist Fertility Counselling") must be distinct from the process of Welfare of the Child assessments and the consenting process.

ESHERE –The European Society of Human Reproduction and Embryology states that there is much empirical evidence that if the emotional impact of fertility is neglected and that the problem is reduced to a biological or medical one that psychosocial factors may prevail leading to long term issues. Eshere maintain that there are many definitions of counselling.

"It is an interpersonal process, based on a theoretical framework, which is used to bring about change in a systemic way" according to Prof. Ken Daniels of Christchurch University, NZ. "Counselling with infertile couples is often about support and the clarification of life goals" (Applegarth, L.D., 1999). A place where individuals can be given an "opportunity to explore, discover and clarify ways of living more satisfyingly and resourcefully (British Association of Infertility Counsellors; Journal of Fertility Counselling, 1999). "Professionals involved in counselling should be qualified to specifically provide counselling and psychotherapeutic interventions" (Kemeter, P. (1988) *Studies on Psychomatic Implications of Infertility)*.

HEAD18/20 – refers to the screening and evaluation of gamete and embryo donors, to include counselling of both the donor and the donor's partner should they have one, by a registered/accredited member of IFCA.

HEAD 43 SUBHEAD 1 outlines the requirements for counselling and independent legal advice to be mandatory for each intending parent/party in the surrogacy process, counselling to be provided at each stage of the surrogacy agreement. IFCA acknowledges that we are in a psycho-educational role and that it is incumbent on the specialist fertility counsellor to ensure that the intending parents are referred to an appropriate legal advisor.

HEAD 53 – 56. Access to certain information from the National Surrogacy Register and the National Donor-conceived Person Register - (2) (b) Implications counselling will be mandatory prior to anyone – parent or child recording or requesting information from the Regulatory Authority. We contend that such implications counselling be provided only by those specialist fertility counsellors who are registered/accredited members of IFCA.

We note that it is the intention of the Minister of Health to implement those sections of the CFRA (2015) previously derogated (sections 33 -42). We hold that clarification is needed on matters concerning the following: -

a) the annotation on a birth certificate of a donor-conceived child –
IFCA supports the rights of a donor-conceived child to have information about their genetic origins; however, the possible psychological impact of this information being conveyed in a public office, by an untrained staff member, without adequate supports is very concerning. An annotation, even if it were not specific could lead to a breach of data protection and confidentiality, and would likely raise questions from prospective employers, heads of educational establishments and future spouses.

b) regarding the section on the birth certificate for "father", same-sex couples or solo mothers using donor gametes, will if they enter "donor" be required to obtain a declaration from the clinic attended stating the nature of the treatment they have received and the dates on which they were treated. While this may not be a problem in itself, the issues around this need to be clarified in legislation.

c) same-sex couples will need to be treated as a couple from the initial counselling session through to the conception of the baby, otherwise, it may be complex for the non-genetic parent to obtain full guardianship under the terms of the Act, this too needs specific clarification in the legislation, taking into account the newly evolving family formations within Irish society.

Minister Simon Harris has stated that he will propose models to the government for state funding for fertility treatment. IFCA welcome this initiative and in particular the fact that the broad term of fertility treatment has been used. Less technological treatments than IVF may be sufficient in some circumstances, and were they not funded, these treatments may be bypassed and IVF could become a first line treatment, even when not necessary. IFCA would support funding across the board of all empirically proven treatments to include counselling and therapeutic counselling where required.

18: Irish Fertility Society

Submission on behalf of The Irish Fertility Society to the Oireachtas Joint Committee on Health, regarding the General Scheme of the Assisted Human Reproduction Bill 2017

20th February 2018

The Irish Fertility Society (IFS) represents the great majority of doctors, nurses, scientists and counsellors who work in Assisted Reproduction (AR) in Ireland. Since our inception in 2005 we have promoted high clinical standards and, in the absence of legislation, have developed guidelines for best practice, Ref. 1. We have felt great frustration to date that none of us have had any meaningful input into formulating the legislation under consideration. We would like to thank the Joint Committee on Health for this opportunity to comment on the General Scheme of the Assisted Reproduction Bill (AHRB) and, going forward, are very eager to be involved in optimising this piece of legislation.

We must not forget that the whole point of the exercise is to make things better for patients with fertility problems and not worse. We must also make sure that the interests of the children who result from AR treatment are protected and the interests of society as a whole. We understand the difficulty of the task facing the Joint Committee because of the highly specialised nature of AR and because many of the issues involved are both contentious and arbitrary. Please have the patience not to succumb to legislative fatigue and to stick to the task for as long as it takes; having waited so long for AR legislation we should not rush the process now that the finishing line is in sight. I would like to outline some broad concerns regarding this legislative process, move on to listing specific issues and omissions which concern IFS members and end by suggesting ways in which the Joint Committee can play a beneficial role in modifying the AHR Bill which in its present form is not fit for purpose.

Restrictive AR Legislation and Conscientious Objection

Laws governing AR in Northern and Western Europe have tended to be restrictive, particularly with regard to financial compensation of egg donors and of surrogates. This has given rise to reproductive tourism where patients travel to other jurisdictions to escape restrictions in their own countries. The Joint Committee needs to be aware that this legislation cannot ignore reproductive tourism and also to be aware that an increasing number of European scholars and policy makers are arguing for more lenient national policies towards AR (Ref. 2). This draft legislation, although in the main progressive, is restrictive with regard to egg and sperm donation and to surrogacy and is in danger of looking backwards rather than forwards. Restrictive legislation will give rise to ethical dilemmas for IFS members who may have conscientious objections to unfair restrictions of patients' reproductive autonomy. Conversely, looking into the future, some of our members could have ethical objections to carrying out certain AR interventions. IFS members insist on their rights to such conscientious objection.

Regulatory Bodies, Bureaucratic Duplication and Associated Costs

The Joint Committee needs to be aware that Irish AR units are already licensed and regulated very strictly under the EU Tissues and Cells Directives. The Health Products Regulatory Authority (HPRA) is the competent authority, carrying out inspections every two years at a minimum. Comprehensive quality management systems are in place and every AR treatment carried out must be individually licensed. At this stage, after a decade of regulatory activity, the HPRA has accumulated valuable practical experience with regard to inspecting IVF units. The IFS has stressed in a previous communication to the Department of Health (DOH) the need to avoid any unnecessary duplication of licensing and inspection activity which will involve unnecessary bureaucracy and generate unnecessary costs for the taxpayer. A way must be found to merge the activities currently carried out by the HPRA with those of the proposed new AHRRA, developing a single regulatory body which applies both the EUTCD and the AHRA.
Unnecessary bureaucracy generates additional costs, which may ultimately be passed on to patients; exact total costings for all regulatory activity need to be estimated before any final decisions are made about regulatory bodies and a budget for regulatory activity set.

Statutory Legislation VS Guidelines

The IFS feels strongly that many clinical issues (i.e. the number of embryos which should be transferred at a time, and age limits for accessing treatment), should be the subject of practice guidelines formulated by the AHRRA rather than statutory legislation. The latter mechanism is too inflexible to allow evidence based alteration of practice to take place as new techniques develop and attitudes change in this dynamic area of medical science.

Parts 2 and 3 of the Children and Family Relationships Act (CFRA)

The thorny issue of Parts 2 and 3 of the Children and Family Relationships Act must be resolved at some point. This dysfunctional attempt at piecemeal AR legislation on the part of the Department of Justice is, in retrospect, regrettable. Insufficient consultation took place and the grave concerns voiced by the Institute of Obstetrics and Gynaecology (IOG) were completely ignored. Overshadowed by the referendum concerning same sex marriage, the legislation was rushed through the Dail without sufficient debate. Parts 2 and 3 of the CFRA, as the IFS has repeatedly advised the DOH, are unacceptably coercive with regard to the State forcing information regarding donor origin on 18 year olds, often against the wishes of parents. Even in the UK, where donor anonymity was banned in 2005, the government, after a consultation process, decided not to introduce any legal measure to force parents to tell their children that they were donor conceived, believing this to be a matter best encouraged through good practice rather than compulsion. More recently, the Nuffield Council on Bioethics in the UK has similarly concluded that *"it is not the*

role of State authorities, whether through direct contact with donor-conceived people, as they reach adulthood, or through the use of official documentation such as birth certificates, to intervene to ensure that all donor-conceived people know of the circumstances of their conception". Ref. 3. Parts 2 and 3 of the CFRA threaten the rights of Irish citizens to privacy and reproductive autonomy. They would, if implemented, be open to constitutional challenge and some of our members, on conscientious grounds, will be unable to comply with the measures involved. The DOH has already conceded that patients (more than 1000 per year) can continue to travel to Spain, Czech Republic and the USA for anonymous egg donation so that the National Donor Conceived Persons Register, should it ever materialise, would be hopelessly incomplete.

Points 2 and 3 of the CFRA are also dogmatic rather than pragmatic with regard to financial compensation of egg donors. The IFS feel that Europe is moving on and that it would be foolish for Irish legislation to copy legislation in other jurisdictions which has proved a failure. Points 2 and 3 of the CFRA suggest ignorance of the fact that even the UK (initially a vociferous opponent of any compensation for donors) has relaxed its stance and now allows a payment of €750.00 to egg donors. Egg donation is for many couples a marvellous application of IVF technology which turns failure into success and the fulfilment of parenthood. If altruistic egg donation is to be promoted surely a modest amount of financial compensation should be allowable for donors.

IFS members who are involved in altruistic egg and embryo donation are already finding that some potential donors are not prepared to donate unless the process is anonymous; an absolute ban on donor anonymity (as in Parts 2 and 3 of the CFRA) would, for these patients, prevent an altruistic act taking place. The IFS advise the Joint Committee to recommend that points 2 and 3 of the CFRA be replaced by acceptable and workable legislation as part of the AHRRA.

Specific Issues

There are dozens of objections, suggestions, perceived omissions and matters requiring discussion raised by our members, all of which must be noted and all of which need to be discussed. All are listed and elaborated upon in appendix 1.

Some of the most important of these issues are the following:

1. ***Remit of the AHRA with regard to the types of treatment covered by the Act:*** IFS believes that intrauterine insemination (IUI) treatment should be included

2. ***Age limits:*** Upper limit 45yrs (own eggs) and 50yrs (donor eggs) suggested for women. The absence of an upper age limit for men is discriminatory. Lower limit 18 (should be the subject of AHRRA guidelines and not statutory legislation)

3. ***Mandatory counselling:***

Not acceptable except for donor gamete or embryo treatment, surrogacy or posthumous conception

4. ***Number of embryos transferrable:***
   1, 2 or3. This should be a clinical decision - (should be the subject of AHRRA guidelines and not statutory legislation)

5. ***Age limits for donors:***
   Lower age limit 18yrs, upper age limit 37yrs - - (should be the subject of AHRRA guidelines and not statutory legislation)

6. ***Age limits for surrogates:***
   No more than 40yrs -) - (should be the subject of AHRRA guidelines and not statutory legislation)

7. ***Time limits for cryopreservation of gametes and embryos:***
   Suggest 10 years for both –This needs discussion and resolution - (should be the subject of AHRRA guidelines and not statutory legislation)

8. ***Posthumous conception:***
   3 years too short – This needs discussion and resolution - (should be the subject of AHRRA guidelines and not statutory legislation)

9. ***Egg and sperm donation:***
   Absolute ban on donor anonymity unreasonable. Parts 2and 3 of the CFRA unethical, unworkable and probably unconstitutional. There will be conscientious objections from some IFS members. This needs discussion and resolution.

10. ***Surrogacy:***
    Conditions so restrictive as to amount to an effective ban.
    Conscientious objections from many IFS members. This needs discussion and resolution.

11. ***PGS: omitted from general scheme***
    Needs inclusion as already being carried out

12. ***Composition of AHRRA:***
    Vital to the whole process of effective (and cost effective) regulation. This needs discussion and resolution.

13. ***Additional Functions suggested for AHRRA:***

    a. ***Regulation of ovulation induction and IUI*** which can also generate multiple pregnancies

    b. ***Follow up of pregnancies and children after AR*** with regard to congenital abnormality and adverse outcomes associated with multiple pregnancy

c. ***Measures to prevent financial exploitation of patients*** including through additional unproven tests and treatments

Alterations to the General Scheme and Resolution of issues

The IFS recommends that the Joint Committee on Health devises mechanisms for bringing representatives of the DOH together with representatives of the IFS and the IOG (i.e. those who have put considerable time and effort into formulating the legislative scheme and those who – together with their patients – will spend many years living with the consequences of the legislation). The IFS feels that the legislative process so far has been dysfunctional and that the joint committee needs to ensure that the issues concerned are given the consideration they deserve. This may require modifications of traditional mechanisms.

We look forward to meaningful discussions about the many practical and ethical issues which must be resolved. Our members will be happy to provide any information which may be required by the joint committee. It may be necessary to set up committees to look at specific issues. For issues proving complex and/or difficult to resolve either side should be able to call on experts (from outside the jurisdiction if necessary) to support their arguments. It may also be the case that patient support groups and individual patients whose lives will be impacted by proposed legislation should be able to make submissions to the Joint Health Committee.

Above all, the IFS pleads that this legislative process is not rushed through with undue haste - as was the case for the CFRA, and is not overshadowed by the national debate regarding termination of pregnancy. The time has come for constructive interaction between those who legislate and the AR professionals who have worked for decades at the coalface of AR in Ireland in order to bring about a better future for patients, families and children.

A submission by the IFS to the Department of Health in 2015 is included.
Considering the complexity of the subject matter of the AHRB a briefing document will follow this submission, providing information about the treatments involved and the history of legislation to date.

Appendix 1

Head 2 - Definition of AHR

The IFS feels that IUI treatment should be governed by the AHRA. We therefore suggest the following definition of AHR:
'All treatments or procedures that involve the handling of gametes and / or embryos for the purpose of establishing a pregnancy'

Head 6 – Age Limits for treatment with own gametes

Most IFS members feel that the lower age limit for AR treatment should be 18 bringing it in line with other medical and legal rights but a minority feel that 21 is a wiser lower age limit. Some IFS members feel that the lower age limit should be the same as it is for gamete donors.

The IFS feels that the upper age limit for AR treatment for a woman should be at least 50 when donor eggs are involved considering that women will (rarely) become pregnant naturally up to this age. When women are using their own eggs the issue concerns the probability of success which becomes unacceptably low beyond age 45. The lack of any specific upper age limit for men is remarkable, discriminatory and must be the subject of discussion.

The IFS feel that all of these age limits should be the subject of practice guidelines and not statutory legislation.

Head 6 and Head 7 – Denial of AR Treatment

The responsibility placed on individual AR clinicians of making decisions concerning the denial of AR treatment to certain patients – either on the grounds of the health status of prospective parents or concerns about welfare of the child – are too onerous. In practice, if children are to be protected, such decisions are best made by a collective rather than by an individual. IFS members are adamant that decisions about refusal to provide treatment must be backed up by an ethics committee and that the whole process must be supported by statutory legislation.

Head 8 - Counselling

The IFS does not accept that counselling should be mandatory for all patients undergoing AR. Well-adjusted patients who are comfortable about the AR treatment planned for them and who are not unduly stressed should not be forced to undergo counselling any more than should individuals who are attempting to conceive naturally. Counselling should obviously be available for all patients at all units - as is the situation currently. Counselling should be mandatory only for patients considering treatment involving donor eggs, donor sperm, donor embryos, surrogacy or posthumous conception. Specialist genetic counselling must be provided for patients before they make decisions about Preimplantation Genetic Diagnosis.

Head 10 - Number of Embryos Transferred

The suggestion that no more than 2 embryos can ever be transferred is unacceptable to the IFS. The decision about whether to transfer 1, 2 or 3 embryos is a clinical one and can only made on the day of transfer when embryo quality can be evaluated. The task of AR doctors and scientists is to maximise success rates while keeping adverse outcomes associated with multiple pregnancies to an acceptable minimum. All IFS members aspire to elective single embryo transfer (replacing only one embryo when two or more are available) and all IFS units have policies in place to promote ESET. However, the proposed limit of 2 would be unreasonable for older patients with poor quality embryos, as it would make their low chance of success even lower. We know from experience that these are not the cases that result in multiple pregnancies. This principle remains the same whether treatment is being funded by the State or by the patient herself. The IFS feel that the number of embryos which can be transferred should be the subject of practice guidelines and not of statutory legislation.

The IFS feel that adverse outcomes related to multiple pregnancies must be monitored through the AHRRA and linked to the individual units concerned. A mechanism must be put in place by the AHRRA to address an unacceptably high rate of such adverse outcomes associated with any individual clinic.

Head 12 – Age limits for Gamete Donors

Some IFS members are comfortable with a lower age limit of 18 for gamete donors, while others feel that 21 would be more appropriate. Consideration should be given to having different limits for sperm or egg donation. All non-partner donor sperm is sourced from licensed sperm banks outside of Ireland, where different age limits apply, the majority accepting donors from 18 years. Gamete donation is more onerous for women, and therefore may warrant more maturity to make an informed decision. The IFS feel that an upper age limit of 37 rather than 35 should be used for egg donors; some of our member's work in clinics where a successful known donor egg donation programme is in operation with an upper age limit of 37. It is also the case that good quality supernumerary embryos derived from 37 year old eggs and which might be donated to another patient have a good chance of producing success. This is particularly relevant for egg donation from one patient to another within same sex female couples. Where clinics are dealing with supernumerary embryos. IFS propose the following:

> *"If the supernumerary embryos were created when the prospective donor of the gametes were outside of the age limits (i.e.: female over 35 years at the time of egg retrieval) the age of the donors should be revealed to the potential recipient(s) as part of the informed consent discussion". (As per ASRM Recommendations 2013) Ref. 4.*

The IFS feels that age limits for donors should be governed by AHRRA guidelines and not by statutory legislation

Head 14 – Parentage and non-anonymity in the context of gamete and embryo donation

Some IFS members will have ethical difficulties complying with such non-anonymity because such conditionality will dissuade some potential donors from donating. These members suggest an alternative mechanism where identification of the donors is a possibility – but only if requested by both parties (the donor and the resulting child). Some of our members will have ethical difficulties implementing the Donor Conceived Persons Register either in all cases or in cases involving in-house known egg donors (e.g. sisters) or in cases involving anonymous egg donation which has taken place in other jurisdictions.

Head 16 – Siblings after gamete donation

(3) "*Gametes can be used to create siblings"*. IFS seeks to clarify if this applies to donated sperm that has already been used in Ireland that may not meet the proposed requirements (e.g.: age limits or anonymity)
IFS proposes that if this legislation is implemented it should not apply retrospectively to treatments already commenced prior to the enactment of this legislation, i.e.: if a family is using an existing sperm donor, they can continue to use that donor in order to produce siblings for existing children, without any external time limit. We feel very strongly that this is important to the integrity of the family, and we need to advocate for our patients on this extremely private and personal decision.

Head 22 - Maximum storage period for gametes and embryos

The IFS considers the periods of 10 years for gametes and 5 years for embryos to be too short. Young cancer patients might store eggs or sperm for 20 years before being in a position to attempt pregnancy. For embryos the HFEA in the UK started out with a 5 year limit but subsequently, after consultation, increased the limit to 10 years. At the same time the IFS welcomes the support provided by the proposed legislation for clinics with regard to disposing of gametes or embryos abandoned by patients who have failed to respond to repeated communications. In addition, legislation should permit clinics to dispose of embryos, once the woman has passed the age limit for treatment. This whole issue requires discussion between the DOH and IFS / IOG representatives to arrive at a wise solution which protects the interests of all parties concerned. The IFS feels that limits on storage should be the subject of guidelines from the AHRRA and not statutory legislation.

Head 27 – Recognition of the deceased person as a parent of the child

The IFS consider the 3 year limit between death and the subsequent birth of a child to be too short. One of our clinics has treated a patient who had 2 children by PAR; under the proposed legislation the second of these children would be treated differently to the first, with regard to legal parentage and inheritance rights. This complex matter requires discussion. Please refer to a comprehensive ESHRE review "Death and Conception" Human Reproduction, 2002 Ref. 5.

Head 30 – Pre-implantation genetic diagnosis (PGD) and Pre-implantation genetic screening (PGS)

The IFS insists that provision in the proposed legislation is made for PGS (Preimplantation Genetic Screening – genetic analysis of embryos with regard to aneuploidy) in addition to PGD (genetic analysis of embryos with regard to a specific genetic condition the couple are known to be at high risk of transmitting). This omission needs to be discussed and addressed as PGS is already being carried out by 2 clinics in Ireland.

Genetic screening of adults and awareness of genetic risk (of transmitting genetic disease) is increasing rapidly. IFS members working in PGD programmes are appalled at the lack of an adequate number of clinical geneticists and genetic counsellors in Ireland. This deficit imposes unacceptable delays on couples anxious to begin PGD treatment and must be addressed urgently.

Head 32 – Sex Selection

A minority of our members have no ethical objections to social sexing for family balancing. They feel that the evidence suggests that the Irish population does not favour one gender over the other so that equal numbers of couples would select in favour of girls as opposed to boys. This minority feels that social sexing for family balancing will be legalised at some point in the near future and that, as a consequence, it should be the subject of practice guidelines rather than statutory legislation.

Part 6 – Surrogacy

The IFS feels that the proposed legislation regarding surrogacy is so restrictive as to amount to a practical ban in Ireland. If that is the intention, IFS members demand the right to refer patients to jurisdictions for treatment involving surrogacy even if such arrangements are 'commercial'. To do otherwise would be to fail in our duty to care for women who lack a functional uterus (e.g. because of Asherman's Syndrome) or lack a uterus altogether (e.g. because of emergency hysterectomy after childbirth). The penalties proposed for patients who seek a surrogate and for AR professionals who assist those patients are draconian (fines of up to 100,000.00 euros and custodial sentences of up to 5 years). Does the legislation intend that it would be illegal to ship embryos to another jurisdiction with surrogacy in mind? Many IFS members have already helped patients to avail of surrogacy abroad, or shipped embryos abroad when a patient has emigrated; must such help now cease? We would also like to point out the injustice of allowing legal and medical professionals to profit from their involvement in surrogacy but denying the surrogate (who endures discomfort for months and runs the risk of life threatening pregnancy complications) any financial compensation whatsoever. The IFS would like to draw attention to the opinion of certain European Ethicists that payment of surrogates is not unethical or exploitative if the quantum of payment is fair. Ref. 6. The IFS is also disappointed by the failure of the proposed legislation to recognise the commissioning couple as the legal parents

from the outset as was originally recommended by the CAHR report. Recognising the surrogate birth mother as the legal mother in the first instance is yet another cause of stress and difficulty for couples requiring surrogacy in order to reproduce. It is also inherently dangerous should a child with birth abnormalities result, as the commissioning couple could then abandon the child, leaving it in the care of its 'legal' mother. The IFS feel that an upper age limit of 40 rather than 47 is more appropriate for any surrogate.

Head 37

The requirement to have all consents and arrangements for surrogacy in place before approval by the AHRRA is sought, is arduous. This would involve a lot of time, expense and emotional investment on the part of patients with the possibility that approval might not be forthcoming. Provisional / full approval at an earlier stage, subject to fulfilment of conditions would be fairer to patients.

Head 42

This prohibits the advertisement by any means, to seek a surrogate or offer services as a surrogate, or facilitating such an arrangement. This seems inappropriately restrictive. While we completely agree that no person should be induced or coerced, there should be a facility where information on such arrangements can be accessed by and provided to any interested parties. For example, notices on fertility clinic websites should be permitted, or leaflets summarizing the legislative framework (once enacted).

The IFS feel that surrogacy poses numerous ethical and legal dilemmas which warrant further debate and clarification between the Joint committee, the DOH, the IFS and the IOG.

Part 7 – Embryo and Stem Cell Research

The IFS would like to point out that it is inappropriate to include regulations regarding germline modification and mitochondrial replacement (Head 61) in a part entitles 'research' as these activities are clinical.

Head 67 - Functions of AHRRA - omissions perceived by the IFS

Financial Exploitation

The IFS feels that a function of the AHRRA should be to protect patients against financial exploitation including that associated with additional but unproven tests and treatments.

Regulation of Ovulation Induction and IUI

The IFS feels that a function of the AHRRA should be to regulate fertility treatments such as ovulation induction (i.e. with Clomid) and IUI. These treatments should be regulated because, just as is the case for IVF, they can generate multiple pregnancies.

The IFS feels that an additional function of the AHRRA is necessary, namely a responsibility to follow up children born after AR with regard to birth abnormalities and also to adverse outcomes related to multiple pregnancy. To this end, we recommend that thought be given to delegating this function of the AHRRA's remit to the National Perinatal Epidemiology Centre headed up by Prof. Richard Green. Audit in this way would allow outcomes after AR conception to be compared to outcomes after natural conception.
IFS members have serious concerns in relation to a National Donor Conceived Persons Register (Part 8). Such a register would need to comply with the new Data Protection Act 2018, considering the sensitivity of the information involved. We feel that it is more appropriate to establish other functions of the AHRA and collate all non-identifiable data initially, to establish a register of ALL treatments, without any identifiable information. It is imperative that the AHRRA can maintain the integrity of such information, protect patient data and confidentiality and allow fertility clinics to have confidence in sharing data with a new body.

Head 76 – Membership of the board of the AHRRA

The IFS is concerned about the exact composition of this board. We wonder if (2) should read "*all 11 members shall be appointed by the Minister and **all** shall be people* ……."
We feel that the composition of the board is of vital importance in order for the AHRRA to fulfil its role effectively. We feel that the composition of the board needs to be more specific. We suggest that the Minister might seek nominations for board membership from the IFS.

We propose that the membership of the board includes amongst the 11 members the following personnel:

- At least one Medical Consultant with a minimum of 5 years' experience in Assisted Human Reproduction
- At least one Clinical Scientist with a minimum of 5 years' experience in Assisted Human Reproduction
- At least one consultant gynaecologist not involved in AR
- A nurse / midwife with a minimum of 3 years' experience in Assisted Human Reproduction

The Minister should ensure that at least 50% of the Board Members have experience in the area of AHR, whether in Ireland or abroad, from a regulatory or service provision point of view.
The lack of direct experience of current practices is evident in the legislation already passed (CFRA 2015) and this Draft Scheme. We do acknowledge and welcome the provision for the establishment of Committees (Head 79), covering Appeals / Scientific and Ethics, and others as required.

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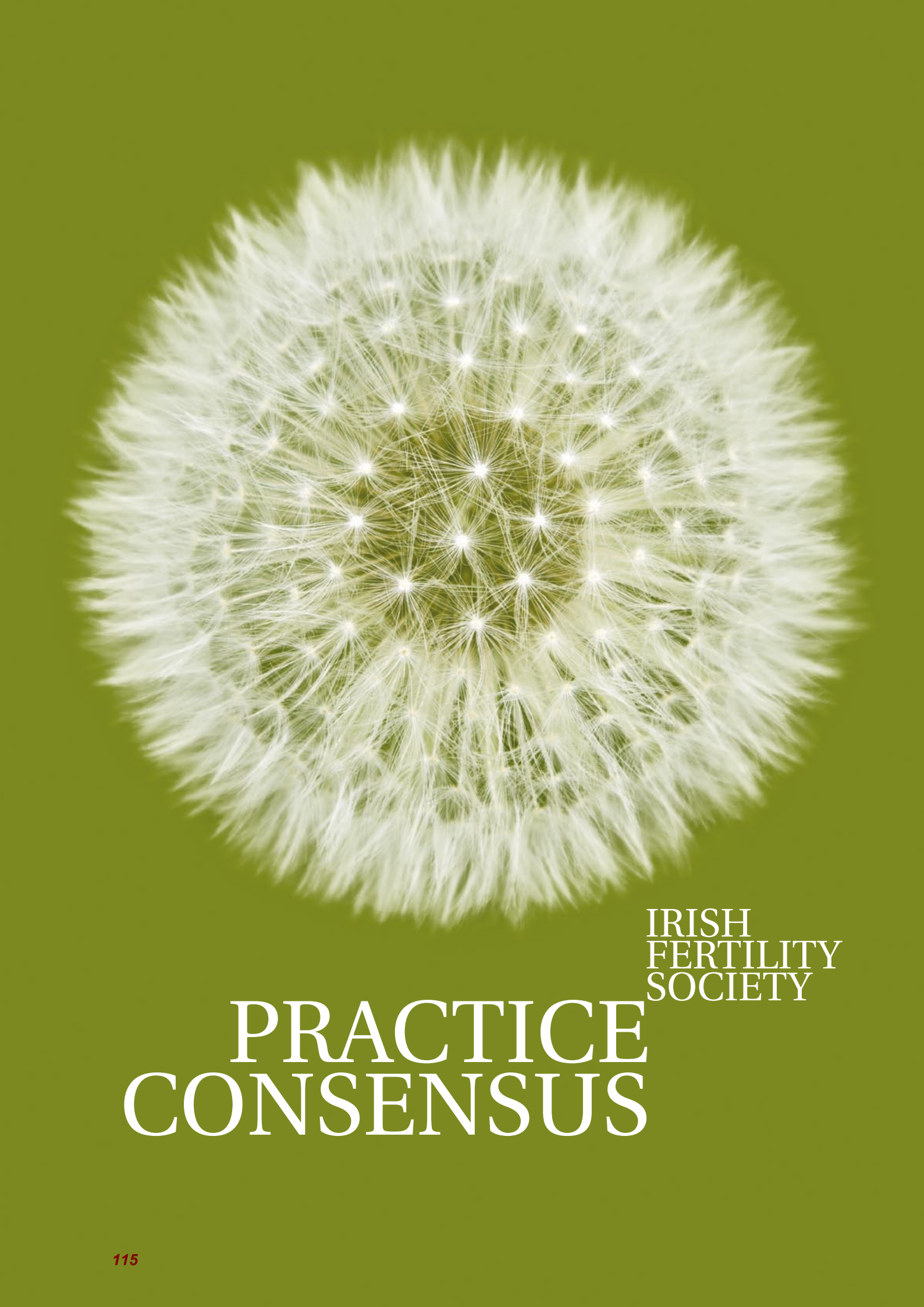

IRISH
FERTILITY
SOCIETY

PRACTICE CONSENSUS

FOREWORD

Denique perfectus!

A long-standing dream has become reality with the publication of the present document.

The Irish Fertility Society (IFS) founded in 2005 is open to all practitioners in Reproductive Medicine in Ireland. Since its inception it was our members desire to produce a document that reflects good practice in the investigations of and treatments for subfertile couples. With no law governing the practice of IVF in Ireland and only the Medical Council "Guide to Professional Conduct and Ethics" available to guide ART practitioners, there was a clear need for a practice consensus to protect the patients and the medical professionals.

The IFS Practice Consensus is the labour of love of all IFS members that for 3 years have collected, debated and finalized a platform of good practice in Reproductive Medicine in Ireland. The consensus contains the opinions of experts in this field and is based on international standards of practice. It covers the investigation of couples at primary, secondary and tertiary level, consent to treatment, all aspects of IVF therapy to include quality and research.

I would like to thank the IFS Executive Committee members who, within their extremely busy clinical commitments, have found generous amounts of time to prepare drafts, meet regularly and finalise this ambitious project. The wide society membership has been consulted at various steps and made a final contribution on the 4th of September 2010. As a professional body we hope this Consensus paper will bring clarity, uniformity and good clinical practice in our field.

This document was conceived with the patient in mind, couples that need medical help to reach the joy of becoming parents.

Edgar V. Mocanu
IFS President
October 2010
Dublin

Contributing ART Units

Clane Fertility Clinic
Abbeyhall, Abbey Lands,
Clane, Co Kildare.

Cork Fertility Centre
Fernhurst House,
College Road,
Cork

Galway Fertility Unit,
Brooklawn House,
Galway West Business Park,
Western Distributor Road,
Rahoon,
Galway

HARI
Rotunda Hospital, Dublin 1

Kilkenny Clinic
Greens Hill,
Kilkenny

Morehampton Clinic
136 Morehampton Road
Donnybrook
Dublin 4

Merrion Fertility Clinic
60 Lower Mount Street,
Dublin 2.

Contributing National Societies

Irish Fertility Counsellors Association (IFCA)

Irish Fertility Society (IFS)

Irish Clinical Embryologists Society (ICE)

Abbreviations

ART	Assisted Reproductive Technologies
ESHRE	European Society for Human Reproduction and Embriology
EUTCD	European Tissues and Cells Directive
HSG	Hysterosalpingogram
ICE	Irish Clinical Embryology
IFS	Irish Fertility Society
IVF	In vitro fertilization
KPI	Key performance indicators
PGD	Pre-implantation genetic diagnosis
IACP	Irish Association for Counselling and Psychotherapy
IHIP	Irish Association of Humanistic and Integrated Psychotherapy
IFCA	Irish Fertility Counsellors Association
BICA	British Infertility Counselling Association

CONTENTS

Foreword 01
Contributing ART Services 02
Contributing National Societies 02
Abbreviations 03
Contents 04

1 INVESTIGATION AND MANAGEMENT OF SUBFERTILITY 05
1.1 General principles 05
1.2 Primary care and referral to secondary care 06
1.3 Secondary level care 06
1.4 Tertiary level care 07

2 INFORMATION, CONSENT AND COUNSELLING 08
2.1 Patient Information 08
2.2 Consent to Treatment 09
2.3 Counselling for patients with fertility problems 10

3 ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENTS 11
3.1 The embryo in vitro 11
3.2 Number of embryos to be transferred 11
3.3 Cryostorage of human reproductive material 12
3.4 Donor treatments 13
3.5 PGD and embryo selection 15
3.6 Forbidden practices 15
3.7 Surrogacy 16

4 QUALITY ASSURANCE 17
4.1 Quality assurance systems in ART 17
4.2 Practitioner qualifications and duties 18
4.3 Training and Continuing Professional Development 21
4.4 Data collection and reporting towards national and ESHRE statistics 22

5 RESEARCH 23

6 REFERENCES 24

1 INVESTIGATION AND MANAGEMENT OF SUBFERTILITY

1.1 General principles

1 In assessing fertility problems and planning treatment, practitioners should consider the needs and rights of all prospective parents and also those of all prospective children.

2 Where there is objective evidence of a significant risk of harm to any child that may be conceived through fertility treatment, there should be a presumption against treatment.

3 All parties should be encouraged to plan their families by their late 20s/early 30s

- Women should be made aware that their fertility begins to decline from the age of 35 and dramatically so from 38 years old.
- Male fertility starts to decline from the early forties.

4 When treatment involves a couple both partners should be seen together. Individuals should also be given an opportunity to discuss issues alone.

5 All parties should be advised to stop smoking as it reduces fertility.

6 Alcohol consumption should be limited to a maximum of 6 units weekly. Binge drinking, in particular, should be avoided.

7 All parties should avoid use of recreational drugs as they reduce fertility.

8 Women should take folic acid supplements pre-conception and for the first 3 months of pregnancy.

9 Those taking medication (including complimentary/herbal treatments) should discuss this with their doctor prior to embarking on pregnancy.

10 Women planning to conceive should be immune to Rubella and have an up to date and normal cervical screening result.

11 All parties should be advised of the influence of weight upon fertility and pregnancy. Careful consideration should be given to the risks associated with fertility treatment and pregnancy in women with a BMI <19 or >30 and BMI should be optimised before treatment.

1.2 Primary care and referral to secondary care

1 Patients who have not conceived after 1 year of regular unprotected sexual intercourse should be offered clinical investigations and referral to fertility services.

2 Taking into consideration the local services, tests to be performed in the primary care setting should comprise:

- Confirmation of ovulation
- Hormonal profile
- Semen analysis

3 Where clinically indicated, other tests such as prolactin, thyroid function tests and an androgen profile could be checked.

4 Where there is a known reason for infertility or a history of predisposing factors or where the woman is aged 38 years or over, or has evidence of reduced ovarian reserve, earlier investigations and referral should be offered.

5 Ovulation induction therapy is not recommended in the primary care setting.

1.3 Secondary level care

1 Good clinical practice dictates that subfertile patients should be seen in an environment separate to pregnant women (outpatient clinics and operating theatres).

2 Ideally, subfertile patients should have a letter of referral to a Consultant with a special interest in Reproductive medicine.

3 Any centre providing semen analysis and other fertility investigations should ensure that staff are appropriately trained, that there is regular internal audit of results and that the unit is registered with an external quality assurance system.

4 Each secondary referral unit should provide the initial investigations detailed above and also tests of tubal patency.

6 Invasive tests such as HSG and laparoscopy should be performed only after assessing other causes of infertility (semen analysis and ovulation).

7 Laparoscopy should be offered to women with previous history or suspected pelvic pathology and HSG considered for others.

6 All those undertaking diagnostic laparoscopy for infertility should have the ability and facilities to treat minimal/mild endometriosis and simple adhesions.

7 All units offering investigation and treatment of fertility problems should have access to appropriate counselling and dietetic services.

8 Women undergoing treatment with clomifene citrate/Tamoxifen should be informed about the risk of multiple pregnancy and be offered follicle tracking during at least the first cycle of treatment.

9 Women who are offered ovulation induction with gonadotrophins should be informed about the risk of multiple pregnancy and ovarian hyperstimulation and follicle tracking must be an integral part of their management.

10 Medical treatment of endometriosis (except as an adjunct to surgery or ART) does not enhance fertility in subfertile women and should not be offered. Endometriosis should be treated by surgery followed by assisted reproduction if subsequent therapy fails.

11 Intrauterine insemination should be considered for patients with mild male factor fertility, unexplained subfertility or minimal to mild endometriosis, though IVF may be more appropriate if the female partner is over 38 years.

1.4 Tertiary level care

1 Each tertiary fertility centre should be equipped to perform assisted reproduction techniques.

2 Each tertiary level specialist centre should have a minimum of one consultant who has undergone certified training in reproductive medicine.

3 All units with practices falling under the EUTCD Directive must be authorized by the Irish Medicines Board and comply with the requirements of the EU directive on tissue establishments.

4 All assisted reproduction units should adopt internationally accepted best practice standards such as those advocated by ESHRE.

5 Each tertiary level specialist centre should have access to specialist endocrinology, urology and genetic services, psychosexual and fertility counselling and imaging.

6 Each tertiary level specialist centre should endeavor to provide training in reproductive medicine.

2 INFORMATION, CONSENT AND COUNSELLING

Patients attending human assisted reproductive programmes are entitled to participate in the decisions about their care.

2.1 Patient Information

Prior to any ART procedure, patients must be given all information which may be of significance to them in a way that is appropriate to, and sufficient for, informed decision-making. Providers should discuss information in an appropriate way. The information should be given verbally and in a written form, in plain language. Where there is a communication barrier patients should be advised to have an interpreter present.

Full information should include accurate and objective data about the following:

1 the general and clinic specific policies and guidelines regarding treatment

2 the likelihood of achieving a pregnancy without ART

3 the patient selection policy

4 the viral screening requirements

5 the treatments available

6 the expected waiting time for treatment

7 the risks involved in the procedures to include the risk of failure to reach transfer, surgical risks and OHSS

8 the likelihood and significance of potential short or long-term physical and psychosocial implications for the participants or the child to be.

9 the potential risks of having children with developmental and birth defects

10 success rates relevant to the individual patients based on clinic data

11 the number of embryos to be transferred and reasons

12 risk associated with multiple births and the potential for ectopic pregnancy and miscarriage

13 costs involved in the treatment

14 options on gamete and embryo storage, duties of patients and clinics

15 the counselling and patient support services offered by the treatment provider

*See also **Section 3** regarding treatments involving gamete and embryo donation and surrogacy.*

2.2 Consent to Treatment

Each Unit/Clinic should:

1 Ensure consent forms are in place for every procedure/treatment provided by the Unit/Clinic.

2 Ensure informed consent has been obtained in writing before ART treatment is carried out.

3 Ensure that the information given is clear, in accordance with the guidelines in the previous section (patient information), understandable and comprehensive.

4 Ensure that the information given in consent forms is regularly audited, reviewed and updated in accordance with medical, legal, ethical and other guidelines and developments.

5 Ensure that the person obtaining an individual's consent is appropriately trained, experienced and competent and has a full understanding of the treatment and its implications.

6 Ensure adequate time for the patient to consider and understand the information provided making sure that obtaining consent is not an isolated event, but rather an ongoing process.

7 Ensure each consent takes into consideration:

i. Nature of treatment
ii. Complexity of treatment
iii. Risks of treatment
iv. Side effects of treatment
v. Patient's individual needs and priorities
vi. That the information is clearly understood by all parties

8 A patient's decision to refuse or decline treatment must be respected and documented *(See also Irish Medical Council Guidelines/EUTCD regarding consent).*

9 Where a Doctor, Scientist, Nurse or others have doubt or concerns regarding a patient's capacity to give consent or refuse treatment they should follow Medical Council Guidelines on Professional Conduct and Ethics, Section D, Paragraph 34, 2009.

2.3 Counselling for patients with fertility problems

Each Centre/Unit should provide access to an appropriate counselling service. Patients should be actively encouraged to utilize it.

Counselling offers the opportunity in a safe, confidential and neutral place to explore the following:

1 The emotional and psychosocial impact of infertility to date, prior to seeking treatment.

2 The place of fertility treatment process within the unique context of the patient(s) lives.

3 Any concerns, fears, relating to treatment options /choices for the patient(s)

4 Existing and future lifestyle issues and patient support systems.

5 The non-judgmental, supportive and informative role of the counselor and counselling process.

6 The role of the counsellor as a liaison / advocate professional where seen as appropriate by the counsellor and the patient.

3 ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENTS

3.1 The embryo in vitro

1 Embryos should be created only with the intention of achieving a pregnancy.

2 The embryo formed through ART/IVF should not attract legal protection until placed in the human body, at which stage it should attract the same level of protection as the embryo formed in-vivo.

3 Each unit must ensure that protocols are in place to deal with the processing, freezing, storage and distribution of the in-vitro embryo in line with the EUTCD.

3.2 Number of embryos to be transferred

1 Multifoetal gestation (twin and higher order pregnancies) leads to an increased risk of maternal and foetal/neonatal complications for both the offspring and the mother.

2 The number of embryos to be transferred should be agreed by the clinical team and the patient(s). Informed consent documents should be completed and the information recorded in the clinical record.

3 Individual clinics are encouraged to generate and audit their own data regarding patient and embryo characteristics and the number of embryos to be transferred.

4 In accordance with best practice, every effort should be made to minimize the incidence of multiple pregnancies without significantly compromising outcome.

The following general guidelines are recommended:

I. Following discussion of success rates and risk of multiple pregnancy all couples should be offered the opportunity to opt for single embryo transfer.

II. In patients under the age of 38, no more than 2 good quality embryos should be transferred, however the final decision as to the number of embryos transferred rests with the clinical team.

III. The maximum number of embryos transferred at one time should not exceed 3, irrespective of female age.

IV. In donor egg cycles, the age of the donor rather than the recipient should be used to determine the appropriate number of embryos to transfer.

3.3 Cryostorage of human reproductive material

Patients should be made aware prior to freezing that it is their responsibility to maintain annual contact with the Unit where they have stored gametes or embryos.

In the event of loss of contact, the Unit must make reasonable efforts to re-establish contact. Failing this, the Unit can apply the terms of the original consent.

1. Gametes: Sperm and oocytes

1 Appropriate protocols should be in place in each unit to govern the freezing, storage, use and disposal of frozen gametes.

2 Informed consent should be obtained prior to freezing. This should include clear statements regarding how and for whom the gametes may be used. It should also detail the length of time for which the gametes will be maintained in the cryopreserved state and the need for donors to keep in regular contact with the unit regarding their plans for their cryopreserved gametes.

3 Each unit should have a clear policy regarding use of cryopreserved gametes in cases where gametes are abandoned, couples disagree, separate or where one or both partner(s) die or become incapacitated. These details should be included in consent forms.

2. Embryos

4 Embryo freezing programmes optimize the safety and success of one ART treatment cycle.

5 Freezing of embryos is essential in certain clinical scenarios (e.g. high risk of ovarian hyperstimulation, uterine anomaly, difficult transfer).

6 Freezing of embryos is a requirement in the development of effective single embryo transfer policies and the reduction in multiple pregnancy rates.

7 Appropriate protocols should be in place in each unit to govern the transfer (to the uterus), freezing, storage and disposal of frozen embryos.

8 Informed written consent must be obtained from the patient(s) involved prior to cryopreservation. This should include clear statements regarding how,

when and for whom the embryos may be used. It should also detail the length of time (in line with international best practice) for which the embryos will be maintained in the cryopreserved state and the need for patient(s) to keep in regular contact with the unit regarding their contact details and their plans for their cryopreserved embryos.

9 Each unit should have a clear policy regarding the use of cryopreserved embryos in cases where embryos are abandoned, where the commissioning couple cannot agree on a course of action, where couples separate or where one or both partner(s) dies or becomes incapacitated. These details should be included in the consent forms.

10 Each unit should have in place appropriate protocols to govern the options available for cryopreserved embryos. These options should include voluntary donation of cryopreserved embryos to recipients, voluntary donation for ethically approved medical research or allowing them to perish at couples' request after an appropriate time for reflection. Counselling is highly recommended prior to the final decision.

3.4 Donor treatments

ART involving donor sperm, oocytes or embryos offers some patients their only chance of achieving a pregnancy.

1. Legal Parentage

Care providers and potential donors and recipients should be aware that the issue of the legal parentage in Ireland of children born through donor programmes is complicated by the absence of legislation and the lack of any clear judicial precedents.

The following statements are not currently supported by legislation but reflect the views of the IFS:

1 In the case of a child born through ovum donation and in the case of a child born following embryo donation, the gestational mother (i.e. the woman who gives birth to the child, (surrogacy and gestational carriage excepted) should be recognised as the legal mother of the child. The consenting treatment partner, if any, should be recognized as the second legal parent.

2 In cases involving sperm donation, there should be a requirement that the consenting treatment partner, if any, of the sperm recipient also consents to be recognised as the child's parent and that this commitment should form the basis of legal parentage. The sperm donor (unless agreed by the treating couple) should not be recognized as the legal father of the child.

3 Couples who choose sperm donation services should be made aware that, under current Irish law, the legal rights of men who are not married to the woman who gives birth to the child are uncertain.

2. Counselling/Anonymity

1 Suitably qualified professionals must provide appropriate counselling in advance to all recipients (and donors where applicable) of donated gametes and embryos. Such implications counselling must be a pre-condition for informed consent by patients.

2 The issue of anonymity or non-anonymity should be discussed with all potential recipients and donors where applicable. Current literature suggests that donor conceived children benefit from openness by their parent(s) and disclosure of their genetic origins.

3 Any child born through the use of donated gametes or embryos should, on maturity, be able to identify the donor(s) involved in his/her conception only if the donor(s) at the time of donation agreed to the disclosure of their identity. This should be part of a legal framework that clearly absolves the donor from financial or other legal responsibility for the child.

4 Donors should not be able to access the identity of children born through use of their gametes or embryos unless the child initiates the identification process.

3. Selection of donors

1 A detailed medical and family history must be taken from all donors and GP information obtained and screening performed as per EUTCD. If there is any concern that a donor may transmit a serious medical disorder to a child, they must not be considered as donors of gametes or embryos.

2 Donors should be over 21 years of age; female donors should ideally be less than 38 years and of proven fertility. Male donors should ideally be at least 21 years of age, and less than 40.

3 The number of families in Ireland resulting from any one donor should be restricted. Clinics must participate in the ICE donor data collection.

4. Payment

1 Donors should be paid reasonable expenses for their altruistic act.

3.5 PGD and embryo selection

1 Genetic counselling is a pre-requisite for PGD treatment.

2 PGD should be permitted to reduce the risk of serious genetic disorders. PGD should also be allowed for tissue typing only for serious diseases that cannot otherwise be treated.

3 Pre-conception sex selection should be permitted only for the reliable prevention of serious sex linked genetic disorders.

3.6 Forbidden practices

The IFS prohibits the following practices:

1 Creating a human embryo other than for the purpose of achieving a pregnancy in a woman

2 Creating a human embryo for experimental purposes only

3 Human cloning (a genetic copy of a living or dead human)

4 The exportation or importation of a human clone

5 Placing a human embryo clone in a human body or the body of an animal

6 Creating a human embryo that contains genetic material provided by more than 2 persons

7 Creating a human embryo other than by fertilisation

8 Developing an embryo older than 14 days outside the human body

9 The generation of interspecies (chimeric, hybrid) embryos

3.7 Surrogacy

1. Gestational Carrier / Surrogacy

- A Gestational Carrier is not genetically related to the child she is carrying
- A Surrogate donates her egg in addition to carrying the child.

1 The IFS supports the practice of gestational carriage and surrogacy.

2 Ideally surrogates should have completed their family before offering their services.

3 Counselling must be mandatory for couples considering gestational carriage or surrogacy.

4 Gestational carriers and surrogates should be paid reasonable expenses for their altruistic act.

2. Legal Parentage

1 Potential Gestational Carrier commissioning patients must be made aware of the lack of relevant Irish legislation. They must also be aware that UK legislation relating to Gestational Carriage favours the carrier with regard to the parental rights and that commissioning patients must essentially adopt any child born.

2 Consequently, potential commissioning patients must be advised to take legal counsel before proceeding with any arrangements. The parental rights of the commissioning patients should be stipulated in the contract.

3. Screening for Communicable Diseases

1 The commissioning patient(s) must be screened in line with the EU Tissues and Cells Directive. The carrier and partner (if any) must also be screened.

4 QUALITY ASSURANCE

4.1 Quality assurance systems in ART

A quality management system at an assisted conception unit should be designed to ensure that services delivered comply with good clinical practice. It should also comply with all current national and EU legislation governing the safety and quality of tissues and cells.

1. Personnel (Responsible person)

As part of a Quality Management System, an assisted conception unit should have a ‘Responsible Person’ in line with EUTCD.

2. Quality Manual

An assisted conception unit should compile a quality manual detailing all standard operating procedures and policies relating to clinical practice. This manual should also form the basis of internal training for new members of staff.

3. Document Control

All documents in use within an assisted conception unit should be controlled to ensure only the current version is in use. Relevant medical documents should be stored for a period of 30 years in accordance with current national and EU legislation. Other documents should be stored for a minimum of 10 years.

4. Traceability

Assisted conception units should ensure that all tissues and cells procured, processed, stored or distributed within their services can be traced from the donor to the recipient and vice versa. This rule should also apply to relevant data relating to products and materials coming into contact with these tissues and cells. All stored tissues and cells should be labelled using a unique coding system.

5. Training

All staff employed by an assisted conception unit in Ireland should be suitably qualified and trained to carry out their role, in accordance with national and EU legislation requirements.

6. Compliance

A system of compliance is an essential element of any Quality Management System.

7. Audit

An audit system should be implemented to:

i. determine the effectiveness and efficiency of an assisted conception unit's quality system

ii. confirm that all scheduled activities comply with unit policies and procedures and adhere to current legislation

iii. ensure external suppliers are providing a service in accordance with national and European legislative guidelines.

8. Supplier Agreements

Third party contracts should be put into place with suppliers of critical goods and services to an assisted conception unit.

4.2 Practitioner qualifications and duties

1. The Person Responsible:

1 should be appropriately trained and qualified and hold a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences.

2 must have practical training and experience in an established fertility unit for a minimum of 2 years

3 must have sufficient understanding of the scientific, medical, legal, social, ethical and other aspects of the unit's work to be able to supervise its activities properly

4 must have the appropriate qualifications and responsibilities as provided in Article 17 of the EUTCD

5 must have appropriate managerial and team building skills

2. The Delegate Person Responsible

1 must be appropriately trained and qualified and hold a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences.

2 must have practical training and experience in an established fertility unit for 2 years

3 should be capable of taking over the duties and responsibilities of the responsible person in their absence (provided in Article 17 of the EUTCD)

3. Medical staff

All medical staff must:

1 be currently registered with the Irish Medical Council

2 comply with the Medical Council's Guide to Professional Conduct and Ethics for Medical Practitioners

3 comply with the requirements of the Medical Council with regard to Continuous Professional Development (Medical Practitioners Act 2007)

4 maintain appropriate Medical Indemnity cover

5 comply with the requirements of EU Tissue and Cells Directives 2004/23/EC, 2006/17/EC and 2006/86/EC.

6 comply with their unit's policy to avail of continuing professional education, training and personal development.

7 Should ideally be a member of the IFS

4. Medical doctors with overall clinical responsibility for treatment services

Medical doctors with clinical responsibility for treatment services must:

1 hold an MRCOG, MRCPI or an equivalent post-graduate qualification

2 have had sufficient experience (min 3 years) in an established and recognized fertility unit to be qualified to take full charge of the unit's treatment services

3 ideally be a certified Subspecialists in Reproductive Medicine

4 comply with their unit's policy to avail of continuing professional education, training and personal development.

5 comply with the requirements of EU Tissue and Cells Directives 2004/23/EC, 2006/17/EC and 2006/86/EC

6 ideally be a member of the IFS

5. Nursing

All Nursing staff must:

1 be registered with An Bord Altranais

2 have the appropriate Registration/Diploma/Degree (An Bord Altranais 2002)

3 comply with their unit's policy to avail of continuing professional education, training and personal development.

4 comply with the requirements of EU Tissue and Cells Directives 2004/23/EC, 2006/17/EC and 2006/86/EC

5 ideally be a member of the IFS

6. Embryology

All embryology staff must:

1 hold a third level Diploma/Degree appropriate to working in a laboratory that handles tissues and cells

2 ideally be a registered member of the Irish Clinical Embryologists (ICE) and IFS

3 comply with their unit's policy to avail of continuing professional education, training and personal development.

4 comply with the requirements of EU Tissue and Cells Directives 2004/23/EC, 2006/17/EC and 2006/86/EC

7. Laboratory managers

All laboratory managers *(in addition to the requirements for embryology staff)*:

1 must hold a minimum of an M.Sc. or PhD in an area related to assisted reproduction, or an equivalent level of experience.

2 must have a minimum of five years experience in such a laboratory to supervise and be responsible for a recognized fertility clinic laboratory.

3 must have appropriate management, training, organizational and communication skills.

4 must be involved in a recognized and monitored continual professional development program.

5 must have an understanding of, and ensure compliance with the EU Tissue and Cells Directives and the Statutory Instruments.

6 must ensure that the organization is in compliance with all appropriate professional accreditation standards, regulations and laws.

7 should ideally be registered as a Senior Clinical Embryologist by ESHRE.

8. Counsellors

All counselling staff should:

1 hold a third level Diploma/Degree in the field

2 be a registered and accredited member of a professional body (IACP, IHIP, IFCA, BICA)

3 recognise and work within the limitations of their training and experience

4 monitor and maintain fitness to practice

5 comply with the requirements of EU Tissue and Cells Directives 2004/23/EC, 2006/17/EC and 2006/86/EC

6 comply with their unit's policy to avail of continuing professional education, training and personal development.

7 adhere to professional codes of practice including those in relation to ethics, fitness to practice and complaints.

8 ideally be a member of the IFS.

4.3 Training and Continuing Professional Development

Each clinic must ensure that all staff (medics, nurses, embryologists, counsellors, administrators) have the following training and continuing professional development programmes in place:

1 Initial basic training

2 Updated training to ensure skills maintenance in each one's specific area

3 Participation in peer review processes e.g. regular patient review meeting with review of charts, inter-departmental review of cases and regular quality management meetings.

4 Participation in clinical audit with a systematic review and evaluation of current practices and with reference to research based standards to improve patient care. e.g.

- Analysing patient outcomes
- KPI reporting
- Patient satisfaction surveys

4.4 Data collection and reporting towards national and ESHRE statistics

1 While anonymous data from Ireland has been reported for many years now, IFS supports the establishment of a national register of ART data and perinatal outcomes.

2 All anonymous data should continue to be reported annually, internally (Ireland) and collectively to the European body, ESHRE.

RESEARCH

1 All research studies should receive approval from a relevant research ethics committee and conform to the Declaration of Helsinki and Irish Medical Council guidelines.

2 Human embryo research, including embryonic stem cell research, for specific purposes only, should be permitted on surplus embryos that have been donated specifically for research.

3 Patients donating embryos for research must receive pre-donation information and implications counselling and they must give informed consent for the use of donated embryos for research.

4 No inducement, financial or otherwise, should be offered/accepted for the donation of embryos for research.

5 Once donated embryos are used for research their subsequent use for reproductive purposes must be prohibited.

6 The generation of embryos through IVF specifically for research purposes should be prohibited.

6

REFERENCES

European Commission (2006a) Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

European Commission (2006b) Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

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INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

Submission on the General Scheme of the Assisted Human Reproduction Bill 2017

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22 February 2018

Introduction

This document gives the opinions of members of the Institute of Obstetricians and Gynaecologists (IOG) on aspects of the recently published Heads of the Assisted Human Reproduction Bill 2017. The IOG represents Obstetric and Gynaecological opinion in Ireland. It acts as an advisory body and strives to promote excellence in the areas of patient care and professional standards.

As a professional group, we congratulate the Minister and his department for producing this draft scheme and we absolutely welcome it. There has long been a need for legislation in this area to protect our patients, their prospective children and those of us working in the field.

This document was prepared by an IOG working group of Reproductive Medicine Specialists currently practising in Ireland but also with a vast experience in the field, in Ireland and internationally.

Our submission contains 14 major recommendations. These are initially discussed and also form the basis of our Executive Summary. Detailed comments on individual Heads and Subheads are then listed chronologically as they occur in the draft Bill.

Members of the working group are available to discuss this submission with relevant persons/bodies and would welcome such discussion.

Section I: Major recommendations

1. Assisted human reproduction (AHR) is one of the most rapidly evolving specialties in medicine. It is important that legislation is not overly prescriptive and inflexible. There is a need to allow for adaptation to new scientific and medical advances. The legislation should therefore contain broad principles with specific detail contained in a Code of Practice determined by a regulatory authority with statutory powers.

2. It is important that aspects of AHR treatments and procedures are not confused with those of early pregnancy. It is imperative to differentiate between the internationally accepted definition of an embryo which exists following fertilisation up to 8 weeks gestation[1] and the ***preimplantation*** or *in-vitro* embryo which is what is relevant to this Bill. It has been determined by the Irish High Court and Supreme Court that Article 40.3.3.of the constitution does not apply to preimplantation or *in-vitro* embryos[2,3].

3. The age limits for treatments are in some ways contradictory and over specific.
    - It is suggested that a person can donate gametes (eggs or sperm) at the age of 18 but cannot receive treatment until the age of 21. We recommend that these ages should be reversed i.e. a person should be able to receive treatment at 18 years of age but should not donate eggs or sperm to another/research until 21 years of age. See further comments under Heads 6 and 12.
    - With regard to an upper age limit for the treatment of men or women, a specific age should not be specified in legislation. Rather, treatment should be provided in line with current and internationally accepted best practice. This should be

determined and enforced by the regulatory authority. See further comments under Heads 6 and 12.

4. We agree that counselling services are extremely important in AHR and that professional counselling should be encouraged. However, we feel very strongly that professional counselling should only be mandatory in cases of donor assisted conception, posthumous assisted reproduction or surrogacy *or* where healthcare staff have particular concerns about a patient's emotional state or coping ability. This view is in line with international norms and opinion[4,5]. To make counselling mandatory for all intending parents is patronising, discriminatory and unnecessarily expensive. See further comments under Head 8.

5. Consent to AHR treatment is complex and has been the subject of Irish court cases[2,3]. The provision of appropriate consent forms and oversight of consent procedures should be a function of the regulatory authority. See further comments under Head 9.

6. The number of embryos to transfer is controversial and must be tailored to the needs of patient(s). The decision to transfer 1, 2 or 3 embryos should be made by the clinical team involved. The Act should specify that multiple pregnancy rates be kept within strict limits, in line with international best practice and this should be determined and enforced by the regulatory authority. The transfer of three embryos should be discouraged but should be allowed in selected poor prognosis couples. See further comments under Head 10.

7. We support the principle that gamete and embryo donation should be altruistic. It is imperative that there is no exploitation or coercion of vulnerable persons or groups. However, at present, any gamete or embryo donation or surrogacy which occurs in Ireland involves only family members or very close friends. The vast majority of people requiring such services need to travel abroad or import e.g. sperm from overseas. This will continue if Irish legislation is overly restrictive.

   If the aim of this legislation is that such services be provided in Ireland, (and this is something we would fully support), consideration needs to be given to ethical means of encouraging donation and surrogacy on an altruistic basis. We would therefore favour a modest compensatory payment system, similar to that for gamete and embryo donation in the UK. Provision also needs to be made for egg sharing. See further comments under Heads 19 and 41.

8. The time limits for the storage of gametes and embryos are too short. We also have concerns re the rights of 16-18 year olds and issues relating to consent in this age group. See further comments under Head 22.

9. We welcome the proposals regarding posthumous reproduction. This is a matter of concern for many of our patients. However, it seems discriminatory, on the basis of equality and non-discrimination, that a surviving male partner cannot use his deceased female partner's oocytes or their joint embryos, if she previously consented to this. See further comments under Head 24.

10. A major omission in this document is the omission of PGS (Pre-implantation Genetic Screening). This must be included. Motochondrial donation should not be prohibited. See further comments under Head 30.

11. The provisions for surrogacy are restrictive. It is our considered opinion that the demand for surrogacy, will not be met by domestic surrogacy.
    - Irish patients will continue to travel overseas and will bring their children home to Ireland. The legal situation of these children and their intended parents must be secured.
    - It would be unethical for a doctor to refuse medical care to a patient who is having treatment overseas, even if that treatment involved surrogacy abroad. It would be a breach of the patient/doctor relationship and is likely to be challenged in court as was the case with Article 40.3.3.of the constitution. See also under Head 36.
    - We suggest extra measures to protect the health and legal status of the surrogate – see under Heads 38, 41, 43, 44.
    - In keeping with our belief that a modest compensatory payment system is desirable to encourage egg donation we feel similarly regarding surrogacy.

12. With regard to the legal parenthood of children born after surrogacy, we support the recommendation of the Commission on Assisted Human Reproduction, 2005[6] that it should be the intending parent(s) rather than the birth mother who should be the legal parent(s) from the outset. This is particularly relevant to the current draft Bill which precludes the use of the surrogate's own eggs and insists that at least one of the intending parent(s) provides the gametes used. (The current draft scheme proposes that the surrogate (and her husband, if she has one) is the legal parent until such time as a parental order has been granted to the intending parent(s) – this must be a minimum of 6 weeks after the birth). We accept that our view will be legally challenging but it is our considered opinion that it is the most humane and equitable manner in which to address this difficult situation. It would be particularly important in the case of disputes between the intending parents and the surrogate and in the case of children born with a disability (who might otherwise find themselves abandoned by the intended parents and left in the care of the surrogate mother). See further comments under heads 44 and 46.

13. We are abhorred by to the proposal that a donor-conceived person who applies for a birth certificate at or after the age of 18 be informed regarding his/her mode of conception (by donor or surrogacy). As previously noted by the Institute of Obstetricians and Gynaecologists in relation to the Children and Family Relationships Act of 2015, we are of the strong opinion that the imparting of such unsolicited and highly sensitive information to individuals regarding their mode of conception, which their parents may not have told them, is irresponsible and dangerous from a mental health perspective, particularly in the case of psychologically vulnerable individuals. This degree of relay of unsolicited information is not the international norm, even in countries where open disclosure of conception-related information is advocated. We suspect that this could be legally challenged on the basis of right to privacy. At the very least, if this intrusive measure is to be introduced, a suitable system for the imparting

of this information by suitably trained personnel should be clearly established and funded. See also under Head 51.

14. We make suggestions as to the appropriate composition of the Board of the regulatory authority. See further comments under Head 76.

Section II: Detailed comments on individual Heads and Subheads

Head 2 – Interpretation (p10)

"assisted human reproduction (AHR)" means all treatment or procedures that involve the handling of gametes and embryos for the purposes of establishing a pregnancy;"

Comment: We presume that Intrauterine insemination (of sperm) is included. It should be.

"embryo" means a human embryo formed by the fertilisation of a human egg by a human sperm;

Comment: We refer to the World Health Organisation (WHO) definition[1] which defines an embryo as the product of the division of the zygote to the end of the embryonic stage, eight weeks after fertilization. (Zygote: a diploid cell resulting from the fertilization of an oocyte by a spermatozoon, which subsequently divides to form an embryo). As stated in major recommendation 2, it is imperative to differentiate between this internationally accepted definition of an embryo (up to 8 weeks gestation) and the preimplantation or *in-vitro* embryo. We suggest using the term preimplantation embryo for the purposes of this Bill.

"gamete" means,
(a) a human sperm, which is formed in the body of and provided by a man, or
(b) a human egg, which is formed in the body of and provided by a woman.

Comment: We suggest the definition of gametes be simply either a human sperm or a human egg. It is unnecessary to say 'in the body of or provided by a man/woman', and this could cause confusion in the case of transgender individuals.

"pre-implantation genetic diagnosis (PGD)" means a procedure for genetically testing embryos for specific genetic or chromosomal mutations prior to transfer involving the biopsy of embryos to remove one or more cells, and selection of embryos for transfer on the basis of the results from the analysis;

Comment: We suggest using the WHO definition[1] ie analysis of polar bodies, blastomeres or trophectoderm from oocytes, zygotes or embryos for the detection of specific genetic, structural and/or chromosomal alterations.

"surrogate" means a woman who carries a pregnancy in pursuance of a surrogacy agreement and who is the legal mother of any child born under a surrogacy agreement;

Comment: We disagree with this definition. It is based on the legal standing of the surrogate, rather than explaining what she is. We suggest instead the internationally accepted definition

as used by the European Society for Reproduction and Embryology[7] i.e. a 'surrogate' is a woman who becomes pregnant, carries and delivers a child on behalf of another couple (intended or commissioning parents).

Additional comment: PGS should be included – see later in Part 5.
Definition of Preimplantation Genetic Screening (PGS): analysis of polar bodies, blastomeres or trophectoderm from oocytes, zygotes or embryos for the detection of aneuploidy, mutation and/or DNA rearrangement[1].

Head 5: General Principles (p15)

Subhead 1: *In all decisions regarding the provision of assisted human reproduction (hereafter referred to as AHR) treatment, due regard shall be given to the health and wellbeing of children born as a result of such treatments and to women who receive such treatments.*

Comment: Men should be included here because they are affected by treatment and undergo procedures such as surgical sperm retrieval.

Additional comment: There should be a statement similar to Head 17, Subhead 1 regarding access to AHR treatment irrespective of gender, marital status or sexual orientation.

Head 6: Provision of AHR treatment (p16)

Subhead 3: *AHR treatment shall not be provided to persons who are under the age of 21 years.*

Comment: AHR treatment should be provided to persons 18 years of age and over. To discriminate against 18 to 21 year olds would be ethically questionable and would disadvantage certain ethnic groups in our society.

We accept the explanation that the WHO states that, to make a diagnosis of infertility a couple should have been trying to conceive for at least one year. However, there are certain individuals where it is not necessary to wait one year to realise that they cannot conceive spontaneously (absent or no/blocked fallopian tubes, post cancer treatment or men with severe oligospermia). The age of consent for sexual activity is 16 so an 18 year old could well have been trying to conceive for 2 years and this is the norm in some ethnic minorities.

Subhead 4: *AHR treatment shall only be provided to a woman who is 47 years of age or under, irrespective of whether the woman is using her own gametes, an embryo created using her gametes, or gametes or embryos donated by a third party*

Comment: See our comment in major recommendation 3 concerning age limits ie these should not be specified in the legislation but should, rather, be the remit of the regulatory authority. Limits should be based on internationally accepted best practice and should take into account likely chances of success. This is more in line with international norms. Medical opinion on upper age limits is likely to evolve as medicine evolves and specific limits should therefore not be specified in the legislation.

Subhead 5: *A man may be provided with AHR treatment, if the AHR treatment provider is satisfied, on reasonable grounds, that the man presents a reasonable expectation to be able to parent the child until that child reaches adulthood.*

Comment: See our comment in major recommendation 3 concerning age limits ie these should not be specified in the legislation but should, rather, be the remit of the regulatory authority. In both sexes, ability to parent is a consideration, regardless of age.

Head 8: Counselling (p20)

Sub Head 1: *All intending parents wishing to undergo AHR treatment shall be provided with counselling from a counsellor who delivers services on behalf of the AHR treatment provider.*

Comment: We absolutely agree that all intending parents be *offered* counselling and indeed encouraged to avail of such services. However, this should not be mandatory except in the cases of donor assisted conception, posthumous conception or surrogacy or where healthcare staff have particular concerns about a patient's emotional state or coping ability. To make counselling mandatory for all intending parents is patronising, discriminatory and unnecessarily expensive. Persons with infertility are no different to any other persons who are trying to parent except that they require medical help in order to conceive. While fertility treatment may be stressful, many other medical treatments (e.g. for cancer) are more stressful and counselling is not mandatory in these situations. Mandatory counselling for all would add an unnecessary expense in a health service with limited resources. These costs will ultimately be borne by patients.

International research suggests that counselling should be *offered* but significant numbers of patients do not require counselling. This is also our experience. This is in keeping with guidance from international bodies such as the HFEA (Human Fertilisation and Embryology Authority, UK) and ESHRE (European Society for Human Reproduction and Embryology) . Guidelines published by ESHRE in 2015[4] and titled 'routine psychosocial care in infertility and medically assisted reproduction—a guide for fertility staff' make 120 recommendations for good practice – mandatory counselling is not recommended.

The following excerpt supports this approach

'One important issue is that the majority of patients with fertility problems suffer from their inability to become pregnant, but cope effectively with this emotional burden as indicated by their satisfactory emotional adjustment (Verhaak et al, 2005a, b). Patients who are already able to adjust well to the stressor of infertility are not likely to benefit much from additional psychosocial support. Moreover, it should be questioned if scarce availability of psychosocial professionals should be offered to patients who are already well adjusted. It seems more reasonable to focus psychosocial treatment possibilities on those who need it most. This is in line with recommendations in several psychological intervention studies in infertility (Connolly et al., 1993; De Klerk et al., 2008). The challenge is not to improve emotional adjustment in all patients with fertility problems, but to identify beforehand those with (the risk of) serious adjustment problems, and to provide them psychosocial treatment, tailored to their individual vulnerabilities'.[5]

Head 9 – Consent (p22)

Subheads 1 and 2(e):

(1) Consent for AHR treatment shall be obtained, in the prescribed form, by the AHR treatment provider before treatment commences and shall cover all stages of treatment.

(2) A person's consent under subhead (1) shall—

(e) be sought again if the nature of treatment changes after initial consent has been given or if more than two years have elapsed since consent was provided

Comment: It is essential that consent is obtained prior to the commencement of treatment but also during each stage of the treatment for example prior to each oocyte collection and essentially prior to each embryo transfer. This was exemplified in a case which went to the Irish High Court and Supreme Court[2,3]. Consent should be re-signed if one year has elapsed since the original consent (not 2 years as in the draft).

Subhead 3 (c): *(c) Separately from and subsequent to the provision of information referred to in paragraph (b), the person giving his or her consent shall have received the counselling referred to in Head 8.*

Comment: As stated, we disagree with the mandatory nature of the counselling proposed.

Subhead 6(a): *The AHR treatment provider shall retain the original of each consent or revocation or alteration of consent given to the provider under this Act, and*

Comment: Given the growing use of electronic records we suggest that the original signed consent or alteration of consent may be scanned and stored electronically with shredding of the paper consent.

Head 10 – Embryo Transfer (p26)

Subheads 1 and 2:

(1) *(a) A woman undergoing AHR treatment, who has a favourable prognosis, shall be offered single embryo transfer in each cycle.*
(b) The transfer of two embryos should only be considered if no high quality embryos are available.

(2) An AHR treatment provider shall not transfer more than two embryos in any one treatment cycle.

Comment: The number of embryos to transfer is controversial and must be tailored to the needs of each patient/s. An arbitrary restriction discriminates against some patients. Many factors need to be considered including female age, embryo stage and quality, no of prior pregnancies, no of prior treatment cycles, general health and obstetric risk factors. These are clinical and medical factors, decisions about which should be made by suitably qualified personnel. It is unrealistic to specify one embryo as the standard though this would be the aspiration as success rates improve. The transfer of 3 embryos should be limited but there may be occasional poor prognosis cases where it is allowed, with informed consent, following appropriate and documented medical advice/discussion.

The Act should specify that multiple pregnancy rates in each clinic be kept below rates determined by international best practice. The acceptable multiple pregnancy rate should be specified by the regulatory authority and this should be enforced. When the state provides funding, it will have a greater right to impose restrictions.

Head 12: Gamete Donation for use in AHR or research (p29)

Subhead 1 (b): *A person, may donate his or her gametes to be used in providing AHR treatment to one or more other people if he or she has attained the age of 18 years,*

Comment: As previously noted, it is contradictory that someone may donate gametes at the age of 18 but they are not allowed to have AHR at the age of 18. We feel the age of consent for AHR treatment of any type should be 18 and not 21. We would favour an older minimum age of 21 for gamete donation.

Subhead 1 (c): *A person, may donate his or her gametes to be used in providing AHR treatment to one or more other people if, in the case of an egg donor, she is not more than 35 years of age, or*

Comment: As regards egg donation, the limit of 35 years is appropriate for non-related donations but there are cases where a sister or a friend may want to donate to a patient and in such cases it would be reasonable, following appropriate and documented medical discussion and informed consent that a higher age limit be applied.

Head 19: Non-commercial gamete and embryo donation for AHR procedures or research (p55)

Comment: Please see our major recommendation No 7. As donation is an altruistic act we would favour a modest compensatory payment similar to that in the UK (£35 for sperm donation and £750 for egg donation). These limits should not be specified in the Act but should be determined by the regulatory authority from time to time. Provision needs to be made for egg sharing and also for expenses involved in donating supernumerary gametes and embryos. Counselling should be provided prior to any egg sharing arrangement.

Head 22: Storage of Gametes and Embryos (p59)

General comment: it should be clarified/specified that this includes the storage of ovarian or testicular tissue with a view to subsequent reproduction using eggs or sperm from that tissue.

Subhead 7 (a) and (b): *(7) Notwithstanding subhead (2), a person's gametes may be stored without his or her consent where—*
(a) he or she is under the age of 18 years and his or her parent(s) or legal guardian(s) has provided consent for the collection and storage of the gametes, and
(b)a registered medical practitioner has certified in writing that the person is to undergo medical treatment and that in the opinion of the registered medical practitioner - (i) the treatment is likely to cause a significant impairment to the person's fertility, and (ii) the storage of the gametes is in the person's best interests.

Comment: The situation with regard to 16 -18 year olds should be clarified – can parents override a 16 year old's consent/lack of consent? Cases are likely also to arise where a 16 year old might want to store gametes or ovarian or testicular tissue and his/her parents might refuse consent.

Subhead 8 (a, b):

(a) Except with the approval of the Regulatory Authority under paragraph (b)—

(i) no gametes may be stored for more than 10 years, and

(ii) no embryos may be stored for more than 5 years.

(b) The Regulatory Authority may grant an extension to the storage periods outlined in paragraph (a)

Comment: These time limits for storage are too short. It is unrealistic to expect a person/s to complete their family within 5 years. In the case of children and young adults undergoing fertility preservation, many will need to store gametes for longer than 10 years. It would be cumbersome for clinics and individuals to have to apply to the regulatory authority for an extension of these times. It is also important, however, to avoid situations where individuals or couples abandon their gametes or embryos. An alternative would be a requirement that consent be resigned each 5 years to allow continued storage and this could be done at the AHR clinic without resource to the regulatory authority. Storage of embryos or gametes should cease when the individuals for whom they were derived request this, when they are not deemed suitable for AHR treatment or if they do not maintain contact with the clinic in order to provide 5-yearly repeated consent.

Head 24: Posthumous assisted reproduction (PAR) procedures involving gametes or embryos (p66).

Subhead 1(b): *Subject to the provisions of Part 2 of this Act, an AHR treatment provider may only undertake posthumous assisted reproduction (PAR) in situations where:*

(b) The gametes or embryo specified in paragraph (a) shall only be made available for use by the deceased person's surviving partner, where she will carry the pregnancy.

Comment: It seems discriminatory, on the basis of equality and non-discrimination, that a surviving male partner cannot use his deceased female partner's oocytes or embryos formed from both their gametes. International practice shows that it is very rare for men to do this but, nonetheless, the option should be available. There may be instances where the male surviving partner has a new partner who might need donor eggs and the couple might decide to use those of the deceased person. In other circumstances surrogacy would be required and this should be allowed. Given that lesbian partners of the deceased woman are allowed use her oocytes or embryos, it seems discriminatory not to allow male partners.

Head 29: Interpretation (Part 5) (p78)

Comment: Regarding the definition of "life-limiting disease". Some life-limiting diseases present in adulthood. Use of the word 'child' is confusing and we suggest it be replaced with the word 'offspring'.

Head 30: PGD (p79)

Comment: We refer to our comments under Head 2, regarding the definition of PGD.

PGS: As already noted under recommendation 10, a major omission in this document is the omission **of PGS (Pre-implantations Genetic Screening)**. This is defined as "analysis of polar bodies, blastomeres or trophectoderm from oocytes, zygotes or embryos for the detection of aneuploidy, mutation and/or DNA rearrangement"[1].

In current ART practice, PGS is probably more frequently accessed than PGD and is particularly indicated for people who have recurrent implantation failure, recurrent miscarriage or advanced female age. In the United States, PGS is almost routine in ART treatment and it is rapidly becoming so in certain clinics in Europe. Many Irish patients are accessing this and it is done very frequently in several Irish clinics. To omit this would not allow Irish clinics keep pace with developments in ART. It would also leave patients with no alternative but to travel abroad or to consider aneuploidy screening in pregnancy with subsequent termination of affected pregnancies.

Head 34: Consent, provision of information and counselling (p86)

Subhead 3 (b) and (c):
(b) Prior to giving his or her consent under paragraph (a) the person in question shall have been provided with information about the disease in question and the procedure to be carried out from a geneticist, including information about the potential risks and implications involved, and

(c)(i) Separately from and subsequent to the provision of information referred to in paragraph (b), the person giving his or her consent shall have received counselling from a genetic counsellor.

Comment: AHR providers should certainly ensure that patients considering PGD or PGS are sufficiently informed and counselled. However, we state categorically that the provision of genetic services in this country is totally inadequate. Access to the services of geneticists and genetic counsellors is extremely difficult. We suggest that counselling by either a geneticist or genetic counsellor, in conjunction with the AHR unit's medical and counselling staff, would be sufficient in many cases. Again, this type of detail should be the remit of the regulatory authority.

Head 36: Surrogacy permitted under this Act (p91)

General comment regarding surrogacy: As stated in recommendation 12, with regard to the legal parenthood of children born after surrogacy, we support the recommendation of the Commission on Assisted Human Reproduction, 2005[6] that it should be the intending parent(s) rather than the birth mother who should be the legal parent(s) from the outset. This is also the view of the Ethics Committee of the American Society for Reproductive Medicine[7].

This is particularly relevant to the current draft Bill which precludes the use of the surrogate's own eggs and insists that at least one of the intending parent(s) provides the gametes used. (The current draft scheme proposes that the surrogate (and her husband, if she has one) is the legal parent until such time as a parental order has been granted to the intending parent(s) – this must be a minimum of 6 weeks after the birth). We accept that our view will be legally challenging but it is our considered opinion that it is the most humane and equitable manner in which to address this difficult situation. It would be particularly important in the case of disputes between the intending parents and the surrogate and in the case of children born

with a disability (who might otherwise find themselves abandoned by the intended parents and left in the care of the surrogate mother). See further comments under heads 44 and 46.

Subhead 1(a): *Surrogacy may be permitted under the following circumstances—*
(a) it is domestic surrogacy,

Comment: The need for surrogacy in Ireland will not be met by domestic surrogacy i.e. surrogates resident in Ireland. Irish patients will continue to travel overseas and will bring their children back. The legal situation of these children and their intended parents must be secured.

Subhead 2: *Subject to subhead (3), it is prohibited for any person to intentionally provide a technical, professional or medical service that is to facilitate or give effect to a surrogacy agreement not permitted under subhead (1).*

Comment: It would be unethical for a doctor to refuse medical care to a patient(s) who is having treatment overseas, even if that treatment involved surrogacy abroad. It would be a breach of the patient/doctor relationship for a doctor not to be able to advise patients on treatments available abroad.

It is possible that some couples will have embryos frozen in Ireland and may wish to transfer these to another jurisdiction for surrogacy. The authors have already been involved with some such cases. If person(s) are able to use their embryos for treatment, they should not be precluded from taking them abroad for such treatment. Under international law (EU Directives) all clinics are required to assist in order to import or export gametes or embryos.

The prohibitions in this act would also apply to lawyers and other healthcare professionals such as embryologists, nurses and counsellors. This is not in the best interest of patients.

Head 38: The surrogate (p96)

Subhead 1(d): *A woman may act as a surrogate as part of a surrogacy agreement under Head 36 only if she is 47 years of age or under at the time of the embryo transfer as part of the surrogacy agreement,*

Comment: The upper age for surrogacy should be 40 years. As the surrogate will not have the benefit of keeping the child, her health and wellbeing need protection and the risks of pregnancy increase significantly after 40.

Head 39: The intending parents (p98)

Subhead 3(b): *Every surrogacy agreement shall involve an embryo which was or will be created using a gamete from an intending parent*

Comment: We note that this precludes surrogacy treatment for single men with infertility due to azospermia or other severe sperm abnormalities, single women with premature ovarian failure and single men and women with serious inheritable disease. It also precludes surrogacy in couples (heterosexual or same sex) where both partners have a fertility or genetic issue.

This concurs with Head 17, Subhead 3(a) which precludes embryo donation for the purposes of surrogacy.

Subhead 3(d): In this subhead, we interpret subsections (i) and (ii) as meaning that one or two intending parents must meet only one of the four options listed as (I) to (IV).

Additional comment: We suggest that the surrogate should, as part of the agreement to the authorisation for surrogacy, provide a written undertaking (similar to that in Head 39, subhead 4) that she will not be the legal parent of the child.

Head 42: Advertisements for surrogacy (p105)

Comment: There should be some provision for clinics or maternity hospitals to inform the public that they are willing to consider surrogacy arrangements or that this is a service they facilitate. Otherwise it would be extremely difficult for any patients in Ireland to access surrogates.

Head 43: Requirement for counselling and independent legal advice (p106)

Comment: The surrogate's spouse, civil partner or cohabitant should also be seen by a counsellor and he/she should also receive legal advice.

Comment: We wonder whether the surrogate's spouse needs to agree to and sign the agreement. We request clarification on what would happen if the spouse, civil partner or cohabitant is unhappy with the arrangement?

Head 44: Information to be provided to and recorded by the Regulatory Authority in relation to a surrogacy agreement (p107)

Subhead 1(a, b, c): *Prior to giving his or her consent to the surrogacy agreement, the surrogate and each intending parent involved shall be informed—*

> *(a) that the surrogate will be the legal mother of any child born as a result of the surrogacy agreement,*
>
> *(b) that the surrogate's husband, if she has one, will be presumed to be the legal father of any child born as a result of the surrogacy agreement unless the contrary is proven on the balance of probabilities as set out in section 46 of the Act of 1987, and a declaration under section 35 of the Act of 1987 that he is not that child's father is granted,*
>
> *(c) that an intending parent will not automatically be the legal parent of any child born under the surrogacy agreement,*

Comment: See our major recommendation 12. It needs to be clarified what will happen if the intending parents decide not to pursue a Court order, particularly in a case where the child is

born with a disability. Would the surrogate (and her husband if she has one) in such a case be left to care for the child?

Head 51: Interaction of the National Surrogacy Register and the register of births (p128)

Subhead 3: *Where a person who has attained the age of 18 years applies for a copy of his or her birth certificate, an tArd-Chláraitheoir shall, when issuing a copy of the requested, also inform the person that further information relating to him or her is available from the National Surrogacy Register.*

Comment: As previously noted by the Institute of Obstetricians and Gynaecologists in relation to the Children and Family Relationships Act of 2015, the imparting of unsolicited and highly sensitive information to individuals at or after the age of 18 regarding their mode of conception, which their parents may not have told them, is irresponsible and dangerous from a mental health perspective, particularly in the case of psychologically vulnerable individuals. This degree of relay of unsolicited information is not the international norm, even in countries where open disclosure of conception-related information is advocated. We suspect that this could be legally challenged on the basis of right to privacy. At the very least, if this intrusive measure is to be introduced, a suitable system for the imparting of this information by suitably trained personnel should be clearly established and funded.

Head 61: Prohibition of modification of the human genome

Subheads 2 (a) and 3: *Mitochondrial donation and mitochondrial replacement involving human gametes or embryos is prohibited.*
(b) In this section mitochondrial donation and mitochondrial replacement refers to the removal of any nuclear DNA from an egg or embryo, which has abnormal mitochondria and the insertion of this nuclear DNA into another enucleated egg or embryo, which has healthy mitochondria.
(3) It is prohibited to place a human gamete or embryo, referred to in Subhead (2), which has undergone mitochondrial donation or mitochondrial replacement into the body of a woman in an attempt to achieve a pregnancy.

Comment: It is our considered opinion that mtitochondrial donation and replacement should be allowed, under strict regulation, in approved centres and in line with documented international best practice guidelines.

Head 67: Functions of the AHRRA (p156)

Comment: Given the complexity of the legal issues involved, the AHRRA should produce national consent forms to be used by all AHR providers. This would ensure the appropriateness and uniformity of consents.

No: 20 . John Duffy

Head 76: Membership of the Board of the AHRRA (p174)

Comment: The Board of the AHRRA should include at a minimum the following professions:

- A Medical Practitioner with experience in the field of AHR
- Another Medical Practitioner
- A Biological Scientist with experience in the field of AHR
- Another Biological Scientist
- A Nurse with experience in the field of AHR
- A Counsellor with experience in the field of AHR
- A Lawyer with experience in the field of AHR
- An Ethicist
- A Layperson/ Patient advocate

Executive Summary

We welcome this legislation. It will be of immense benefit to our patients, their children and to service providers. However there are important issues, which require attention. These are presented in this document.

Key recommendations relate to:

- The need to allow for adaptation to new scientific and medical advances
- The proposed age limits for treatment
- The provision of appropriate counselling services
- Informed Consent
- The number of embryos to transfer
- The need for ethical means of encouraging gamete and embryo donation and surrogacy in Ireland
- Time limits and consent for storage
- The right of a male partner to be able to avail of posthumous assisted reproduction
- The inclusion of PGS (Pre-implantation Genetic Screening) and Mitochondrial donation
- The provisions for surrogacy, in particular their restrictive nature, the legal parenthood of children born after surrogacy and the duty of care that health professionals have to assist those pursuing surrogacy abroad
- Interaction of the National Surrogacy (and Donor Conception) Register and the register of births
- The proposed AHRRA

We welcome further discussion of these complex and important issues.

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2. *Roche v Roche* (2006) IEHC 359

3. *Roche v Roche* (2009) IESC 82

4. ESHRE guideline: routine psychosocial care in infertility and medically assisted reproduction—a guide for fertility staff†
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Submission to the joint committee on Health for the AHR bill 2017

reference Surrogacy Part 6 , page 90 forward

Comment 1 (based on facilating surrogacy support group / personal experience)

Without the ability to provide a close relative etc. IVF Surrogacy is simply not going to be an option for the vast majority of couples concerned in Ireland as was In our own personal case. The Bill offers provision for Surrogacy in Ireland in certain cases but should not inadvertently or otherwise prohibit or complicate surrogacy arrangements for Irish Citizens travelling abroad. Note The UK has domestic Altruistic legislation and also have a legal mechanism for surrogacy abroad. Ireland currently has government published guidelines for Irish citizens undertaking surrogacy abroad. link

Comment 2 (based on facilating surrogacy support group / personal experience)

Irish intended parents are generally very well informed and thoroughly research Surrogacy substantially in advance to ensure the welfare of the surrogate before and after the child is born they also show great consideration for the Childs interests in knowing their beginnings at age appropriate times. Either through story telling , night prayers photo albums and support group "talk and tell workshops" undertaken in Ireland by NISIG and the Donor Conception Network. Irish surrogacy families love their children so much !! With many having been through a very difficult medical history including Cancer , Multiple IVF failures and multiple miscarriages.

Comment 3 (based on facilating surrogacy support group / personal experience)

A voluntary register for experienced Irish family law professionals detailing their experience in this specialist area would help eliminate inconsistent family law process practices undertaken i.e. inconsistent mechanisms used in establishing legal linkages to the child born through surrogacy. Many couples have expressed great frustrations of solicitors unfamiliar with this area attempting to deal with their issues and not fully aware of the complexities involved, Causing multiple family law court applications.

Comment 4. based on facilating surrogacy support group / personal experience)

In relation to the bill stating that professional law family advice for commercial Surrogacy /Surrogacy abroad will be banned *(Subhead 2 -page 92)* I believe strongly that couples will continue to undertake the process abroad without protection from Irish family law advice. This could cause major diplomatic issues particularly for the DFA and of course the child and couple. Ireland does not have the infrastructure for surrogacy other than close relatives undertaking altruistic surrogacy on behalf of intended parents. To attempt to ban legal advise is an irresponsible action under this legislation.

Comment 5. (based on facilating surrogacy support group / personal experience)

It is imperative that a detailed timeline is issued in relation to commencement of the bill to ensure couples are not unduly stressed by this very demanding process . **This is of the upmost importance.** protection notably. AHR legislation in terms of Surrogacy for Irish citizens is needed.

Comment_6. (based on facilating surrogacy support group / personal experience)

The initial advice for anyone considering Surrogacy arrangements must be to ensure they consult with an experienced family law solicitor at the earliest stage before undertaking the process. This requires clear and unambiguous statement in the pending AHR legislation.

While the male partner currently enjoys full parental rights to the child born through surrogacy. The female intended parent (or non biological partner in case of same sex couple) do not currently have the parental transfer rights. The proposed procedure in the Bill is cumbersome and likely to be very slow and costly . Therefore I would recommend timelines to be prescribed for this and to streamline the process further.

Dr Brian Tobin at UCG , Prof Deidre Madden ,Nula Jackson SC and the following listing of legal professionals have undertaken **the vast majority of Surrogacy cases** in recent years (2014 to 2018) may advise further.

Listing of most experienced Legal professionals in Ireland consulting in area of Surrogacy. (2014 to 2018)
Tracy Horan 01 6461002 tracy@dhs.ie Annette Hickey solicitor@carmodymoran.ie Fiona Duffy fiona.duffy@pforeilly.ie Marion Campbell info@mcsolicitors.ie Caroline Lindsay Poulsen (Barrister) clpoulsen@lawlibrary.ie

Table 1

In relation to International experience the Canadian model for Transfer of parentage is widely considered to be best practice. While Greece has a Court application prior to surrogacy , Greece has not been as successful in Surrogacy arrangements for Irish citizens as the Canadian based clinics. mainly due to translation and infrastructural issues. The Families through surrogacy organisation (Familiesthrusurrogacy.com) can advise further in this regard. .

Comment 7: (based on facilating surrogacy support group / personal experience)

ETDs are issued in the case of Non EU countries and the USA and Canada. I,e ETDS are issued for Ukraine ,Asia, and Georgia. Therefore the numbers released by the DFA are a dramatically incorrect figure in relation to the actual number of families formed though Surrogacy in Ireland. While no one knows the exact number, **I would estimate over 250 families including those whom have undertaken surrogacy within the state with relatives. (sisters of female intended parents etc)** (Duffy J , Nov 2017), estimates are based on experience as the surrogacy group metting facilator with NISIG (National Infertility Support and information group)

Comment 8: (based on facilating surrogacy support group / personal experience)

Equivalent of Adoptive leave to be detailed / referenced further in the bill with Parental and paternal leave rights to be legislated The unavailability of adoptive leave (Equavilant) is a matter of great anxiety amongst Surrogacy families in Ireland.

Comment 9: (based on facilating surrogacy support group / personal experience)

All Intended parents considering starting the process should undertake fertility counselling with many currently given the support needed through NISIG. This is a demanding process.

Recent opinion pieces in Press regarding concerns of AHR Bill for reference.
The journal.ie 27 October 2017 Irish daily mirror 11th November 2017

Table 2

Summary of conclusions and recommendations:

- Without the ability to provide a close relative etc. IVF Surrogacy is simply not going to be an option for the vast majority of couples concerned within Ireland.
- In relation to not being able to access professional law family advice for commercial Surrogacy ,**couples will undertake the process abroad** without protection from Irish family law advice. This will lead to a high risk scenario for anyone involved. To attempt to withdraw legal advice from Irish citizens attending foreign countries is highly undesirable for all. I recommend the wording is changed to state "No legal practioners will provide advice for commercial surrogacy arrangements undertaken within the state"
- A voluntary register for experienced Irish Professional family law practioners in relation to Surrogacy would help ensure consistency in surrogacy family law cases. I would expect a warm welcome from the Circuit courts for this proposal.
- A legal sub group to be formed with some / all of the named persons invited as listed in table 1 of this submission with the addition of Dr Brian Tobin and Deidre Madden as experienced specialists in this complex area of health and family law. This will help ensure the family law aspects are covered prior to legislation being enacted.
- Paid Leave , parental, paternal and adoptive leave equivalent to be provided to both intended parents within the Bill. With Adoptive leave (equivalent) to be made available with immediate effect to those undertaking this very demanding process this is long overdue.
- Counselling to be strongly encouraged as part of the process for all concerned. This is a very demanding process.
- The Government should recognise children born through surrogacy in the state and outside the state to irish parents who reside in Ireland. by where a process is in place to ensure they can retrospectively gain same rights as for children under the pending 2017 AHR bill. (i.e. ensure legal mechanisms are in place) again a legal sub group could advise on the detail needed.
- The Bill must state clearly if there is going to be any change in the provision of emergency travel documents made available for surrogacy arrangements abroad.

I would be willing to appear in a public session at a Committee meeting.

Go raibh maith agat.

John Duffy

No 21: LGBT Ireland

Submission on the General Scheme of the Assisted Human Reproduction Bill 2017

1. About LGBT Ireland

LGBT Ireland is a national charitable organisation which provides quality support services to Lesbian, Gay, Bisexual, and Transgender (LGBT) people across the country. Informed by the issues and experiences raised through our frontline services, we also provide training and advocacy support, to enhance the visibility, inclusion and rights of the LGBT people living in Ireland. In 2017, we responded to 1,957 contacts to our helpline, web chat and email services and over 63,000 people visited our website www.lgbt.ie, for support and information.

2. LGBT People's Needs in relation to AHR Services in Ireland

People contact us on a range of issues relating to sexuality and gender identity, including same sex couples and LGBT individuals, looking for information about parenting pathways and family rights and recognition in Ireland. The information most commonly sought in these areas include:

- The AHR options available to same-sex couples in Ireland and which clinics are open to treating same-sex couples.

- The current legal situation regarding recognising both partners in a same sex couple as the legal parents of their child/children born through AHR, including whether both parents can be registered on the child/children's birth certificate.

- The legal situation regarding whether a non-birth parent can apply for legal documents on behalf of their child/children (e.g.) a passport.

To inform our submission further, we also called for LGBT people to contact us specifically about their needs in relation AHR services. From this consultation, additional issues identified include:

- The importance of AHR services being accessible to people with a transgender identity. A growing number of younger transgender[1] people are making decisions concerning their fertility before starting hormone therapy or undergoing surgery to remove/alter their reproductive organs. This may include the preservation of sperm, or the freezing of eggs or embryos. Currently they do so without clarity in relation to the AHR pathways, including surrogacy, which will be available to them, should they wish to have a child in the future.

Many of the issues identified through our own services were also raised in a national study undertaken with LGBT parents and those planning parenthood, in 2011. The LGBT Parents in Ireland

[1] The term transgender refers to a person whose gender identity and/or gender expression differs from the sex assigned to them at birth. This term can include diverse gender identities.

Report[2] detailed the experiences of 153 LGBT parents and 170 LGBT people planning to become parents.

In relation to study participants who were already parents, 20% had their child/children through AHR with a clinic, while 44% of those planning parenthood, intended to use AHR in a clinic. The study found that the LGBT people who had accessed AHR services abroad, reported much higher levels of satisfaction than those accessing the services in Ireland. A key finding of this research was **the need for clear policies and information to be developed on the AHR options for LGBT people living in Ireland, including surrogacy, particularly in relation to equality and non-discrimination in service provision.**

3. Legislation on AHR

3.1 Implementation of existing provisions from the Children and Family Relationships Act 2015

Parts 2 and 3 of the Children and Family Relationships Act 2015 provide for legal parentage for intending parents in cases where a child is born following donor-assisted human reproduction (DAHR). These provisions are part of the 2015 Act as signed into law; however, they have yet to be commenced. This has generated a high degree of legal uncertainty for people who are raising children born following donor-assisted human reproduction. In particular, it creates an uncertain environment for children born following DAHR who are being raised by couples, where only the mother is the legal parent.

Non-commencement of these provisions is particularly problematic for female same-sex couples, where the presumption of paternity does not apply. **Parts 2 and 3 of the 2015 Act should be commenced as soon as possible to provide stability and certainty for children born following DAHR.**

3.2 Discrimination and Equality-proofing

LGBT Ireland welcomes the proposed scheme as it has the potential to bring the law and regulation in the area of AHR up to date with the realities of 21st century life and recognises that increasing numbers of same-sex and single people are having children. In particular Head 17, prohibiting discrimination on grounds of gender, marital status, and sexual orientation is very welcome as a general principle.

Ideally, however, it should also clearly state that **discrimination based on gender identity is also not permitted**. In addition, the reference to **marital status should refer instead to 'civil status',** which (as used in the Employment Equality Act 1998 and Equal Status Act 2000) includes the condition of

[2] Jane Pillinger & Paula Fagan 2011: *Report from a study into the experiences of Lesbian, Gay, Bisexual and Transgender People in Ireland who are parents or who are planning parenthood.* LGBT Diversity, Cork.

being married, widowed, separated, divorced, single, in a civil partnership or being a former civil partner.

The Scheme should be **carefully examined to ensure that it adequately addresses and accounts for the particular situation of same-sex couples**. For instance, under Head 8 counsellors providing counselling to intending parents wishing to undergo AHR treatment should have, in particular, specific training in the counselling of same-sex couples and people who are LGBT. LGBT Ireland notes that the Irish Human Rights and Equality Commission has a statutory obligation[3] to examine and report its views on any implications for human rights and equality.

3.3 International dimensions

The Scheme directs itself primarily to arrangements that parties make and procedures carried out in the State. For instance, Head 36 refers to and permits surrogacy specifically in a domestic context, where both the surrogate and intending parent are habitually resident in the State and the embryo transfer takes place in the State. It seems, therefore, that a parental order made under Head 47 may only be made in respect of a domestic surrogacy. No provision is made for international surrogacy or to clarify the legal implications of surrogacy carried out abroad. The Scheme seems to prohibit surrogacy arrangements made by Irish-based couples outside the State or the involvement of surrogate mothers who are habitually resident abroad. It prohibits people from providing a technical, professional or medical service that facilitates a non-domestic surrogacy arrangement.

This will greatly limit the options for intending parents and close down avenues currently available to such parents. The Scheme also fails to address the situation of couples who have already entered into foreign surrogacy arrangements, who currently face a challenging legal situation on their return to Ireland.

3.4 Donor preferences

Notably, Head 12(7) allows a donor to specify the circumstances in which the clinic may use his or her gametes. For instance:

“In providing his or her consent to the donation of his or her embryos, under Subheads (2) or (3), a donor— (i) shall, in the context of subhead (2), specify the AHR treatment procedures that his or her embryos may be used in…”

LGBT Ireland recommends that specific language is included in this provision such as, “in accordance with the law”, to ensure that a donor cannot specify that they do not wish their gametes to go to a lesbian or gay couple. Under the Equal Status Act 2000, it would be unlawful for a clinic or other service provider to discriminate in the provision of their services. Additionally, given the strong protections afforded to same-sex couples under the Irish Constitution and the European Convention on Human Rights (ECHR), steps should be taken in law to ensure that discrimination in the provision

[3] Irish Human Rights and Equality Act 2014, section 10 (2)(c).

of AHR services cannot take place on grounds of sexual orientation (or other protected categories such as the nine grounds under the Equal Status Acts).

3.5 Posthumous parenting

The provisions of Head 24 appear to presuppose that at least one of the couple will be female. Head 24(1)(b) states "The gametes or embryo specified in paragraph (a) shall only be made available for use by the deceased person's surviving partner, where she will carry the pregnancy." It is unclear what would happen where a male partner in a same-sex relationship wishes to preserve his sperm for use after his death in a surrogacy arrangement involving the man's partner and a surrogate.

3.6 Sex selection

The provisions of Head 32 (prohibiting sex selection except in cases where there are firm medical reasons for so doing) are welcome, and are in line with the principle of gender equality underpinning the Scheme.

4. Summary of Recommendations

- LGBT Ireland recommends that existing provisions in the Children and Family Relationships Act 2015, be commenced as soon as possible, to provide stability and certainty for children born following DAHR.

- Head 17 of the Scheme should clearly state that discrimination based on gender identity is also not permitted. In addition, the reference to marital status should refer instead to 'civil status'.

- LGBT Ireland recommends that the Scheme address the situation of couples who have already entered into foreign surrogacy arrangements and who currently face a challenging legal situation on their return to Ireland.

- LGBT Ireland recommends that international surrogacy should be permitted where the relevant state has rules analogous to those contained in the Scheme."

- LGBT Ireland seeks clarity in the scheme as to the circumstances that a donor can specify in the use of his or her gametes via the inclusion of specific language to denote that human rights and equality protections afforded by law cannot be superseded by individual donors' directions.

- Clarity is also recommended in relation to whether male partners in a same sex relationship are cover under Head 24 Posthumous Parenting.

NATIONAL INFERTILITY SUPPORT AND INFORMATION GROUP

Submission on General Scheme of Assisted Human Reproduction Bill 2017

February 2018

Introduction

The National Infertility Support and Information Group (NISIG) was established in 1996, and is the only charity in Ireland focusing on infertility.

NISIG's vision is for those facing reproductive challenges to be supported, along with the families created through that support, in a society that is fully accepting of them. Its mission is to provide practical supports to, and advocate on behalf of, those who experience reproductive challenges, and their families.

NISIG services are growing and adapting year on year, and currently include:

- A support number which is available 24 hours a day, every day, for those in need.
- Active sub groups to address the concerns and needs of donor conception and surrogacy parents and potential parents.
- Support group meetings throughout Ireland. These are currently held in Dublin, Cork, Limerick and Portlaoise.
- A quarterly newsletter which is distributed to members, fertility clinics and health and legal professionals.
- Peer to peer support.
- A dedicated website.
- Engagement with key opinion leaders and key clinicians to elicit active support for NISIG's work, as well as the broader issues of lack of regulation and funding.
- Engagement with the media, both print, radio and online, to highlight the issues for those coping with infertility, as well as informing them of the work and services of NISIG.

In 2017, NISIG held 20 support meetings throughout the country, attended by over 300 people. The telephone helpline is used almost daily by those affected by infertility, as well as family members.

Members of NISIG are called upon for input to other organisations. Former Chairperson, Helen Browne, was a member of the Committee on Assisted Human Reproduction which was established in 2000, and reported in 2005. NISIG is also a member of Fertility Europe.

Since NISIG's inception over 20 years ago, ongoing progress made in reproductive technologies have led to an increasing and evolving workload. The HSE's Chief Medical Officer stated at the recent hearing before the Oireachtas Committee on Health [January 2018] that almost 9,000 treatment cycles were provided in 2017. It is impossible to know how many are going overseas for treatment. NISIG knows anecdotally that many of our members, particularly the ones going the donor route, do so. NISIG is in daily contact with individuals and couples who plan to utilise or are undergoing, donor conception or surrogacy, and lack of clarity of the legal situation has been a huge issue for such individuals.

NISIG is a strong advocate of public funding for fertility treatment – as is the norm for other medical treatments - and our hope is that this legislation will be a step towards achieving this.

NISIG has long called for the introduction of a regulatory body, based on the UK HFEA model, as imperative in underpinning progress on the AHR sector in Ireland. As such, we warmly welcome the proposal in Part 8 to set up an Assisted Human Reproduction Regulatory Authority. We also note, in Head 76, that "*The Minister may request relevant stakeholders to nominate appropriate candidates for consideration for appointment to the Board",* and that these stakeholders includes groups such as NISIG. Again, we warmly welcome the inclusion of the 'patient' voice at this level.

Surrogacy offers opportunities for women with complex medical conditions to have children, and we are privileged in NISIG to share the joy that much loved and long awaited children bring to these women and their partners. Likewise, we are aware of many same sex couples who have been able to form their families with the help of surrogates.

As such, NISIG welcomes the fact that legislation will finally address the lack of regulation around surrogacy. However, we do have some serious reservations around some aspects of the bill which we will address further.

Head 6 – Provision of AHR Treatment

NISIG notes that Head 6 (4) states that: *AHR treatment shall only be provided to a woman who is 47 years of age or under, irrespective of whether the woman is using her own gametes, an embryo created using her gametes, or gametes or embryos donated by a third party.*

NISIG believes that this is unnecessarily restrictive. While we do understand that best medical practice is the benchmark, treatment should be agreed between the woman and her medical advisors, particularly where donor eggs are concerned. Many of our members feel they are 'running out of time', causing considerable further stress. As noted earlier, technology is advancing year on year, with the possibility that these age limits may be inappropriate in just a short space of time. Indeed, NISIG notes that: *A man may be provided with AHR treatment, if the AHR*

treatment provider is satisfied, on reasonable grounds, that the man presents a reasonable expectation to be able to parent the child until that child reaches adulthood.

NISIG therefore feels that there should be room for flexibility to be exercised by experienced clinicians.

Head 8 – Counselling

NISIG welcomes the recognition of the value of counselling for those undergoing fertility treatment, subject to proper regulation of counsellors and psychotherapists. NISIG wonders, however, if this should also be incorporated at other stages of the treatment cycle. This might typically be at points where treatments have failed, and failed repeatedly. This would necessarily involve instituting a standard of practice in clinics to reduce the number of patients that do engage in repeated failed treatments.

As an ideal, counselling here might best be separated from the treatment provider.

Head 10 – Embryo Transfer

NISIG acknowledges that current best practice is that single embryo transfer be offered in each treatment cycle. However, notwithstanding this, many of our members have indicated to us that successful outcomes have only been possible with two or three embryo transfers. While this is to be discouraged, we do ask that some leeway be given to clinicians on a case by case basis.

Head 12 – Gamete Donation for use in AHR or research

Some clinics, particularly in the UK, allow women undergoing treatment cycles to 'share' their eggs with other women undergoing treatment as a way of keeping their costs down. Subhead (2)(a)(ii) states that a person can donate his or her gametes when their own treatment has been completed. NISIG would like clarification if this specifically rules out 'egg sharing', and if this has been considered by the committee.

Head 15 – Revocation or alteration of consent to donation

Subhead (6)(a) states that *'in situations where two people have provided consent to the donation of embryos for use in providing AHR treatment to others or research and one of those donors subsequently alters his/her consent, then the licence holder must have regard to the consent of the other donor involved before implementing the alteration of consent.'* NISIG feels it is unclear whether if one donor involved in the creation of an embryo withdraws their consent, then the embryo cannot be used. Some of our members use embryo donation to form their families, and may complete their families at a later stage using further embryos from the same donors. This needs clarification.

Head 16 – Limits on the use of donated gametes and embryos

Subhead (5)(a) states that *'it is prohibited for an AHR treatment provider to use, as part of an AHR treatment procedure, gametes, including embryos created using those gametes, or embryos provided by a given donor, following the death of that donor'.* As with Head 15, members are concerned that they cannot complete their families using gametes from the same donor, if the donor dies. NISIG would ask why it would not be possible to have their wishes recorded as to the posthumous use of their gametes?

Head 22 – Storage of gametes and embryos

Head 22(8)(a) states that: *Except with the approval of the Regulatory Authority under paragraph (b)— (i) no gametes may be stored for more than 10 years, and (ii) no embryos may be stored for more than 5 years.* NISIG absolutely acknowledges the need to have guidelines on storage of gametes and embryos. However, NISIG feels that this can be unnecessarily restrictive, especially in the context of, for example, fertility preservation for cancer treatments. We acknowledge that the relevant agencies will have their own submissions on this issue, and we would like to support them in that context.

However, NISIG members have also expressed reservations about these restrictions. In reality, 5 years for storage of embryos may not allow people time to plan their families and treatment options. This is a real concern, and again adds to the stress of undergoing treatment.

Head 24 – PAR procedures involving gametes or embryos

(1) Subject to the provisions of Part 2 of this Act, an AHR treatment provider may only undertake posthumous assisted reproduction (PAR) in situations where: (a) The deceased person provided his or her consent for his or her gametes, or an embryo created using his or her gametes, to be used for PAR after his or her death, (b) The gametes or embryo specified in paragraph (a) shall only be made available for use by the deceased person's surviving partner, where she will carry the pregnancy.

NISIG would like clarification as to whether this would preclude, in the second instance, a male partner using his dead partner's gametes (or embryo) via surrogacy.

Part 6 – Surrogacy

NISIG welcomes long overdue legislation to regulate surrogacy. We acknowledge that surrogacy is a complex issue, encompassing health, family law and logistical difficulties.

Many of NISIG's members have already undertaken surrogacy arrangements, or are in the process of researching their options or starting the process.

This is not a journey which is undertaken lightly. Surrogacy is an extremely costly option, in both financial and personal terms. For couples, this is often the last step on an arduous merry-go-round of treatment, followed by crushing disappointment, followed by treatment again.

As with all like-minded commentators, NISIG absolutely affirms that the needs of the child are paramount in any discussion of surrogacy. This is reiterated by our surrogacy members, who consistently campaign for the needs of their children, and put them at the centre of their ongoing engagement with NISIG. NISIG has responded by expanding services to include family events for donor and surrogacy families, and a new programme of *Family Conversations,* informal workshops for the families of donor and surrogacy children.

Surrogacy, therefore, is an issue at the core of NISIG's work. And knowing how complex the whole area is, and how long awaited legislation has been, we feel that it is imperative that legislation has to get it right first time. And our members do have some serious doubts over some of the bill. The complexity of the issue has led to surrogacy being left out of previous legislation [ref Children and Family Relationships Act 2015]. Serious consideration must be given to this section of the proposed Bill, to ensure that it serves all those that it intends to.

NISIG believes the following need particular scrutiny:

Head 36 – Surrogacy permitted under this Act

This Head provides that: (1) Surrogacy may be permitted under the following circumstances —

(a) it is domestic surrogacy,

(b) it is gestational surrogacy,

(c) it is non-commercial in accordance with Head 40,

(d) the surrogacy agreement has been approved in advance of treatment by the Regulatory Authority under Head 37,

(e) the surrogate meets the requirements set out in Head 38,

(f) each intending parent, or the intending parents together, where there are two intending parents, meet the requirements set out under Head 39,

(g) each intending parent and the surrogate provides his or her consent under Head 45 prior to seeking authorisation of the agreement under Head 37,

(h) the treatment is provided in accordance with Part 2 of this Act;

(i) any donor gametes used as part of a surrogacy agreement shall be subject to the provisions of Part 3;

(j) the personal details of each intending parent, the surrogate, a donor, where applicable and any child born under the surrogacy agreement shall be recorded in accordance with Head 44 and Head 50.

Head 36(1)(a) goes to the crux of the matter – surrogacy *must* be a domestic arrangement. The reality is that this places surrogacy outside the realm of the possible for our members. All NISIG members who have availed of surrogacy have necessarily done so abroad. Those who are currently on the journey know that they will have to go abroad. Without the ability to provide a close relative or other family member, surrogacy is not going to be an option for the vast majority of the couples concerned. As with egg and sperm donors, there is not a pool of altruistic people in Ireland ready to come forward, and this is only likely to happen over a long period of time – if ever – with attitudinal and educational change.

NISIG is more alarmed to read on: *(2) Subject to subhead (3), it is prohibited for any person to intentionally provide a technical, professional or medical service that is to facilitate or give effect to a surrogacy agreement not permitted under subhead (1).*

Notwithstanding this, couples *will* continue to go abroad. Are they to do this without accessing any legal advice? Many of the people who approach NISIG are understandably daunted by the whole situation and our stand out piece of advice is to *always* seek legal advice. We cannot stress this enough.

NISIG urges the committee to not just revisit this subhead, but to remove it completely.

This subhead seems to draw a veil over the whole issue of overseas surrogacy. NISIG members who went overseas to form their families through surrogacy arrangements have told us that they fear their children will be stigmatised by this Bill. A member specifically asked:

“Can the government give NISIG and the surrogacy community which it represents assurances that these particular children, including our child, won’t feel inferior or of less value than any other child of this state?”

If the child is to be placed at the core of the legislation, then consideration needs to be given to the child born through international surrogacy. We would ask the committee to consider extending appropriate provisions for the retrospective transfer of legal parentage to those children who have already been brought into the state, most of whom are Irish citizens. Any procedures to ensure the same should be clear and straightforward.

NISIG notes that Head 50 of the Bill directs the Regulatory Authority to assign and maintain a National Surrogacy Register. NISIG members who already have children would like to know if their children are to be included in this register, and if so, on what basis. It is a question that donor parents in general need to have answered.

NISIG is aware that not all the provisions of the Children and Family Relationships Act have yet been enacted. We would hope that, if this bill is passed, a detailed timeline will be issued relating to the commencement of the each section, particularly as they relate to surrogacy, to ensure that couples are not unduly stressed by this very demanding process.

NISIG would also like to highlight what we see as an omission in the Bill, and that is the extension of maternity and paternity leave provisions to parents through surrogacy in a similar way to those currently extended to adoptive parents through the Adoptive Leave Act 2005. If this is not done, it will present a missed opportunity to recognise the medical necessity of alternative routes to parenthood.

We would like to conclude this section with a testimonial sent to us when the bill was published. We offer this so that the committee can see the real barriers people with fertility issues are facing and will continue to face, in light of the provisions of the bill:

We are a newly married couple aged 31. I have Cystic Fibrosis and was fortunate enough to receive a double lung transplant in 2006. This has enabled me to live a full and normal life thus far.

However as a result of my medications that I must take due to the transplant, anti-rejection medication etc., it is impossible for me to carry a child. This is because the medications would have to be stopped in order for the foetus not to be harmed and this in turn could endanger my own life.

I am in good health, maintain a full time job as a primary teacher and to all extents have no major health issues.

My husband and I want nothing more than to have a child and have a family together. While the new surrogacy legislation is positive, as it may enable new mothers the right to paid maternity leave etc, it is extremely limiting and if brought forward would make it impossible for us to have a child through surrogacy.

Due to the Cystic Fibrosis, which is a genetic disease, I have no sisters (or brothers) which means I have no one who would altruistically act as a surrogate for me here in Ireland.

While we agree that a control over commercial surrogacy is needed in order to avoid the exploitation of women, the complete ban of international surrogacy seems to be a very worrying development and this will prevent many couples, like ourselves who are medically unable to bear their own children, to have a family that is genetically their own.

I urge the powers that be to continue to discuss this issue and look realistically at the Irish people who will be availing of this. We are doing this out of necessity. Please do not make this journey any more difficult than it already has been.

Summary and conclusion

- NISIG welcomes the proposed introduction of a regulatory body, and is broadly supportive of the inclusion of patient voices on this body
- NISIG feels that the upper age limit of 47 for women undergoing IVF treatment is unnecessarily restrictive, particularly as reproductive technologies continue to evolve
- NISIG welcomes the recognition of the value of counselling in the case of AHR, and wonders if this might be extended
- While single embryo transfer is best clinical practice in most cases, NISIG would like clinicians to have leeway to provide the best service they see for their patients
- NISIG would like clarification on whether 'egg sharing' is to be permitted in Irish clinics
- References to revocation of consent by donors and death of donors need to be clarified
- NISIG believes that the limit on storing embryos for just 5 years might be unnecessarily restrictive for some who are trying to complete their families
- NISIG would ask for clarity on if a male surviving partner can use embryos via a surrogate
- Restricting surrogacy to domestic arrangements effectively rules surrogacy out as an option for many couples struggling with infertility
- The prohibition on providing technical, professional and medical services, save for domestic surrogacy arrangements will cause unnecessary further distress to many hundreds of couples in the state
- NISIG would ask the committee to revisit offering the same rights to parents whose children have been born through international surrogacy as those proposed under this bill
- NISIG would ask that consideration be given to issuing timelines around the enactment of the particular provisions around surrogacy

- NISIG would like to see the extension of maternity and paternity leave provisions to parents through surrogacy.

In conclusion, NISIG broadly welcomes this legislation as long overdue, comprehensive and forward thinking. We sincerely hope that it lays the ground work for public funding for fertility treatment for the one in six people in Ireland who will be touched by infertility.

Where we do have serious reservations – even alarm – is over some of the proposals regarding surrogacy, and we do hope that the committee uses this opportunity to engage with representative groups, such as NISIG, who are touched by this issue daily.

Indeed, AHR is not an abstract construct. It touches many thousands of Irish citizens each year, many of whom do not wish to speak publically on such a private issue.

NISIG thanks the committee for the opportunity to comment on the proposed legislation, and welcomes further consultation.

23: National Women's Council of Ireland

NWCI'S RESPONSE TO THE GENERAL SCHEME OF THE ASSISTED HUMAN REPRODUCTION BILL 2017

February 2018

National Women's Council of Ireland

(01) 6790100

www.nwci.ie

NWCI'S RESPONSE TO THE GENERAL SCHEME OF THE ASSISTED HUMAN REPRODUCTION BILL 2017

February 2018

Executive summary

The National Women's Council of Ireland (NWCI) welcomes the publication of the General Scheme of the Assisted Human Reproduction (AHR) Bill. NWCI supports legal regulation of AHR services to safeguard the interests of women, couples, children and healthcare professionals. The development of a regulatory framework will further support the state to fulfil its commitment to provide publicly-funded access to AHR.

Summary of recommendations

NWCI's comments on the General Scheme reflect our focus on the promotion and protection of women's health within the treatment of infertility and the provision of AHR services. Our comments centre on the need for:

- Inclusion of patient and women's representation on the board of the Assisted Human Reproduction Regulatory Authority and in the carrying out of its functions.
- Development of public education, information and research functions for the Authority to: inform the public about infertility prevention; provide impartial information on AHR treatments and providers to patients; and develop data on AHR use and patient experience.
- Provision of counselling for patients throughout the treatment process.

NWCI does not make recommendations on the Heads addressing surrogacy, as the organisation does not have an official position on surrogacy. However, we raise issues for consideration in relation to surrogate mothers.

NWCI recognises that the regulation of AHR is only one of the elements required to reduce the distress caused by infertility. A range of actions must be taken to ensure we support people to start their families, reduce the numbers of people experiencing infertility and provide equitable access to AHR treatments for those who require it. Thus, looking at issues beyond the scope of the General Scheme, NWCI's submission also highlights the need for:

- Supportive policies and benefits for people seeking to start a family (e.g., affordable childcare, paid parental and paternity leave, affordable housing).
- Provision of quality infertility care across health service through the roll-out of a Model of Care for Infertility.
- Public funding of AHR to ensure equitable access.

Introduction

NWCI welcomes the development of legislation on AHR, which when implemented can have a significant positive impact on women's reproductive healthcare, on women and couples seeking to conceive and on the provision of AHR in Ireland. Our response to the General Scheme centres on the promotion and protection of women's health within the treatment of infertility and the provision of AHR services.

NWCI recognises the provision of AHR is just one element required to reduce the suffering caused by infertility in Ireland. Action must be taken on a range of areas to ensure we support people to start their families, reduce the numbers of people experiencing infertility and provide AHR treatments for those who require it:

- Government must introduce social and economic policies which support people to have families at a time of their choosing and to combine family and work commitments.
- We must increase information about infertility, its causes and prevention.
- We must undertake research on causes and cures of infertility which could significantly reduce the need for AHR treatment.
- We must reduce stigma about infertility so that people seek support quickly.
- We must ensure that AHR providers and treatments are regulated to provide the best quality of care.
- We must ensure that all those who require AHR can access public treatment.

Submission structure

- Part 1 provides an overview of NWCI's work on reproductive health and our role in promoting women's perspectives and the perspectives of our membership in legislative developments. It outlines why a gender perspective, which responds to women's health needs, is important in the context of the development of AHR legislation and provides an overview of current AHR provision in Ireland.
- Part 2 details our comments on specific Heads of the General Scheme. *NWCI does not propose to comment on all aspects of the General Scheme, our comments are confined to areas where we believe the Bill can be revised or strengthened for the benefit of women's health.*
- Part 3 discusses the importance of the legislation to the development of publicly-funded AHR treatments on an equitable basis.

NWCI's submission was developed following consultation with NWCI's membership, engagement with academics and health researchers working on AHR and with individuals with experience of infertility and AHR treatment.

PART 1: Women's Health and AHR

NWCI is acutely aware of the distress experienced by women who experience infertility. For many women their decision to seek AHR treatment will have been preceded by a series of negative events, such as multiple miscarriages, pelvic pain, endometriosis and/or gynaecological surgery.

The AHR Bill represents a significant first step in addressing the difficulties faced by women and couples seeking AHR services in Ireland. These difficulties include: lack of independent information about AHR providers and treatment; limited public understanding of infertility and how infertility may prevented; and lack of public access to treatment.

The AHR Bill will provide a necessary framework to regulate services and standardise practice across providers. Once regulation is in place it will then be possible to address the lack of equity in access to AHR in Ireland, which remains primarily a private service, unaffordable to many.

NWCI's work on reproductive health

NWCI is Ireland's leading women's membership organisation, representing 180 member groups and a growing number of individual members. We work to ensure women's equal access, participation, and recognition in Irish society. One way in which women's equality is realised is through women's control of their reproductive and maternal health. This is why reproductive health has been a core area of NWCI's work for many years. We are closely involved in improving women's access to contraception, increasing maternity entitlements, advocating for affordable, quality childcare and for the ongoing development of women-centred maternity care. NWCI has a unique role in communicating the health concerns of women in Ireland through ongoing consultation with our membership base and other organisations. Our work on women's health over the last 40 years has highlighted women's experiences of healthcare services and has drawn attention to the various barriers different groups of women may experience accessing health services.

NWCI advocates for reproductive healthcare services which are based on best medical practice and which reflect the lived experiences of women. We engage with the issue of infertility from a broad perspective, reflecting the diversity of experiences women face and the different decisions women make about reproduction and family formation. Thus, in addition to seeking regulation and public provision of AHR, NWCI recognises the need for much more significant focus on the prevention of infertility and on family-friendly supports and policies for people seeking to start a family.

Our comments on the General Scheme are grounded in NWCI's *Every Woman*[1] model for reproductive healthcare for women and girls.

Every Woman model of reproductive healthcare

In 2017, NWCI launched our *Every Woman* model for quality, universal, lifelong reproductive healthcare for women and girls.

The model recognises that women have a life-long need for reproductive healthcare services across six priority areas, which should be available through the health system:

1. Relationship and sexual health education;
2. Affordable and accessible contraception;
3. Sexual and reproductive health services;
4. Comprehensive pregnancy care, **including fertility treatment**;
5. Reproductive cancer care; and
6. Menopause services

Reflecting the fact that some women and couples may need assistance to conceive and have children, NWCI advocates for access to fertility treatment as a key component of reproductive healthcare for women.

Every Woman further describes key principles which should underpin the provision of all reproductive healthcare services, including AHR:

- Services should be private, with confidentiality between the doctor and patient protected.
- Services should be accessible through public funding.
- Services should be comprehensive.
- Services should be of high quality, complying with best medical practice and standards.
- Services should be adequately funded to ensure timely access.

In examining the General Scheme, NWCI has considered how the legislation can support access to AHR in way which upholds the *Every Woman's* principles for reproductive healthcare.

Women's health and AHR

In this section we provide an overview of why a women's health perspective should inform the AHR Bill. An in-depth discussion of AHR and women's health in an Irish context are provided in two 2009 reports produced by the Women's Health Council (the statutory body, since dissolved, with responsibility for women's health): *Infertility and Treatment a*

[1] NWCI (2017) 'Every Woman – affordable, accessible healthcare options for women and girls in Ireland'. http://everywoman.nwci.ie/

review of pyscho-social issues[2] and *Infertility Treatments for Women - A Review of the Bio-medical Evidence*[3].

The female body is the primary site of most AHR treatments[4,5] and this necessitates careful consideration of AHR provision from a women's health perspective. This is not to imply that AHR and infertility treatment is a 'woman's issue'. Infertility results from both male and female causes and infertility results in significant distress both for women and men.

Infertility is a complex issue which intersects with biological and medical concerns and with social issues related to family formation and women and men's gender roles. Historical and cultural beliefs have tended to inextricably link women's identity with procreation and caring. This can have very negative impact on women who are having difficulty having a child and also ignores the suffering infertility causes to men and men's role in raising families.

While the devastating effects of infertility are felt by both women and men, the evidence points to a much more negative effect on women's lives.[6,7] There are many reasons why women have a more negative experience of infertility, which are linked to women's biological and social role as mothers.[8] In most cases, women will undergo the majority of AHR procedures, regardless of whose infertility (female or male) is impaired. As women undergo the bulk of invasive procedures, they are responsible for daily monitoring of their menstrual cycles and experience disruption in their work/life schedules to accommodate rigid treatment regimes.[9] Treatment cycles can also negatively affect women's career progression and financial security.[10,11]

More attention should be paid to assessing male infertility, which is much less invasive than the assessment for women. Investigation of males could lead to significantly better outcomes given that in a third of cases infertility is caused by male reproductive issues.[12] Early, basic testing for men could identify infertility issues at an early stage and resolve them at the lowest level of complexity.

In addition to the physical impacts, infertility can lead to a range of psycho-social impacts, from emotional effects, feelings of loss of control, effects on self-esteem and identity, impacts on relationships and grieving of the loss of a future parent-child relationship.[13] These psycho-social impacts can also be affected by gender, with women

[2] Available at: http://health.gov.ie/wp-content/uploads/2014/03/infertPsychosocial.pdf
[3] Available at: http://health.gov.ie/wp-content/uploads/2014/03/infertBiomedEvid_Full.pdf
[4] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council
[5] Institute of Public Health in Ireland (2017) 'Submission to a new National Women's Strategy 2017-2020'.
[6] Greil, A. L. (1997). "Infertility and Psychological Distress: a critical review of the literature." Social Science and Medicine 45 (11): 1679-1704.
[7] Peterson, B. D., L. Gold and T. Feingold (2007). "The experience and influence of infertility: considerations for couple counsellors." *The Family Journal* 15 (3): 251-257.
[8] Klock, S. (2008) 'Psychological Issues Related to Infertility'. http://www.glowm.com/?p=glowm.cml/section_view&articleid=412
[9] For experiences in the Irish context, see: Mahon, E. and Cotter, N. (2014) 'Assisted reproductive technology – IVF treatment in Ireland: A study of couples with successful outcomes'. *Human Fertility*, 17(3), 165-169. DOI: 10.3109/14647273.2014.948498
[10] Redshaw, M., C. Hockley and L. L. Davidson (2007). 'A qualitative study of the experience of treatment for infertility among women who successfully became pregnant.' *Human Reproduction* 22 (1): 295-304.
[11] Deech, R and Smajdor, A (2007) *From IVF to Immortality: Controversy in the Era of Reproductive Technology* Oxford University Press.
[12] Eunice Kennedy Shriver National Institute of Child Health and Human Development. 'How common is male infertility, and what are its causes?' https://www.nichd.nih.gov/health/topics/menshealth/conditioninfo/infertility
[13] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council

finding counselling services useful in supporting a sense of belonging and validating their reactions.[14]

To help reduce the negative impact of infertility on individuals, it is essential that society recognises women's contribution to society outside of procreation and caring, as well as the contribution which men can and do make to raising families.

Policies and appropriate supports for people seeking to start a family

The issue of infertility directly relates to how Irish society supports women and couples who wish to form families.

Maternal age is considered one of the key determinants of conception, and much public attention has been dedicated to the increasing age of first-time mothers. Women are often criticised for 'waiting too long' to start their families. This narrative of maternal delay does not recognise the constraints which women and their partners make decisions about family formation. Research[15],[16] clearly indicates the impact of societal factors on family formation, including the high cost of housing, economic and employment uncertainty and the absence of supportive family policies.

Fear of discrimination in the workplace and the unequal distribution of care work can impact on women's pregnancy decisions. Many women (and couples) will want to have some financial security before starting their family. This indicates that much greater emphasis should be placed on how people wishing to start a family can be supported through economic and social policies which increase people's ability to combine work and family responsibilities.[17],[18] NWCI has consistently advocated for social and economic policies which support women's choices for family formation and child-bearing, including access to affordable, secure housing and flexible working arrangements.[19]

- *NWCI recommends implementation of policies and benefits to support people seeking to start a family, including access to affordable childcare and improvements in paid parental and paternity leave.*

[14] Schmidt, L. *et al.* (2003). "Patients' attitudes to medical and psychosocial aspects of care in fertility clinics: findings from the Copenhagen Multi-centre Psychological Fertility (COMPI) Research Programme." *Human Reproduction* 18 (3): 628-637.
[15] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council
[16] Morgenworth, E. (2018) *Prospects for Irish Regions and Counties – scenarios and implications.* ESRI Research Series No. 70
[17] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council
[18] Women's Health Council (2005). Submission to the European Commission's Green Paper: "Confronting demographic changes: a new solidarity between generations" (COM 2005). Dublin: The Women's Health Council.
http://www.whc.ie/publications/EU_Submission_Demographic_Changes.pdf
[19] For example, see NWCI (2017) 'Value for Money and Money for Values – Pre-Budget Submission' http://www.nwci.ie/index.php/learn/publication/value_for_money_and_money_for_values_making_the_national_budget_work_for_wo; NWCI (2009) ' Who cares? Challenging the myths about gender and care in Ireland'. http://www.nwci.ie/download/pdf/who_cares_october_2009.pdf; NWCI (2005) 'An Accessible Childcare Model'. https://www.nwci.ie/images/uploads/nwci-childcare_report.pdf

Prevention of infertility

More must also be done to prevent people experiencing infertility, thereby reducing the need for AHR treatment.

A substantial proportion of infertility may be preventable. For example, untreated sexually transmitted infections are a preventable risk factor for infertility in both women and men. Established and possible causes of infertility include genetic abnormalities, aging, certain acute and chronic diseases, lifestyle risk factors such as smoking and body weight and exposure to environmental, occupational, and infectious agents.[20]

Prevention of infertility should be integrated into reproductive health promotion for both women and men, including:

- Comprehensive approaches to STI screening, treatment, prevention
- Clear public health messages on how to prevent infertility
- Chronic disease prevention to reduce the incidence and severity of conditions such as diabetes and polycystic ovary syndrome
- Health promotion campaigns to address lifestyle factors that may affect infertility

➢ *NWCI recommends an increased emphasis on the prevention of infertility and on efforts to increase public awareness of infertility, its causes and treatments.*

AHR in Ireland

There are two major overarching concerns in relation to the AHR provision in Ireland - there has been no legal regulation of AHR providers & services and AHR treatment is only available privately.

Infertility is recognised by the World Health Organisation as a disease[21], yet access to infertility treatment is not available in the Irish public health system. This is despite the reality that infertility is a common public health issue with one in six couples in Ireland experiencing problems conceiving a child.[22] Reflecting patient demand, AHR has been available in Ireland since 1987 and the number of people privately accessing AHR treatments and services has increased over time.

Surveys indicate that the Irish public supports better access to and regulation of AHR. In 2002, a survey by the Commission on Assisted Human Reproduction (CAHR)[23] found that 68% of people agreed with the availability of AHR services. A 2013 survey of Irish public

[20] Centers for Disease Control and Prevention (2014) *National Public Health Action Plan for the Detection, Prevention, and Management of Infertility*. https://www.cdc.gov/reproductivehealth/infertility/pdf/drh_nap_final_508.pdf
[21] http://www.who.int/reproductivehealth/topics/infertility/definitions/en/
[22] Report of the Commission on Assisted Human Reproduction (2005) http://health.gov.ie/wp-content/uploads/2014/03/Report-of-The-Commission-on-Assisted-Human-Reproduction.pdf
[23] Report of the Commission on Assisted Human Reproduction (2005)

opinion[24], led by researchers in the Royal College of Surgeons in Ireland, also showed public approval for AHR. Most participants (77%) agreed that any fertility services offered internationally should also be available in Ireland and 63% agreed the Government should introduce AHR legislation.

Legal Regulation of AHR Provision

The need for legal regulation of AHR has been a concern for many years[25], with statutory regulation proposed by the Department of Health's CAHR in 2005.[26] The only progress in developing a legal framework – in advance of the publication of the General Scheme – was the Children and Family Relationships Act 2015 which includes un-commenced provisions on donor-assisted AHR.[27]

In the absence of regulation, people are availing of services in a legal vacuum[28] and clinics are operating without adequate regulation.[29] AHR services have been largely reliant on physician self-regulation through their professional bodies.[30] There are no nationally-approved guidelines for counsellors working in AHR, or for other health professionals in areas such as liaison and follow-up care for both successful and unsuccessful treatment.[31] In the absence of statutory regulation, professionals or clinics may interpret best practice in different ways, leading to inconsistency in treatment and patient experience.

Regulation is essential to standardise practices across clinics. Regulation can be used to ensure a range of positive outcomes for patients, including that clinics:

- Undertake clinically-indicated treatment
- Provide the least invasive treatment first
- Manage and clearly identify risks to patients
- Provide information on success rates in a format which is accessible to patients

[24] DJ Walsh, ES Sills, Gary S Collins, CA Hawrylyshyn, P Sokol, APH Walsh (2013) 'Irish public opinion on assisted human reproduction services: Contemporary assessments from a national sample'. *Clinical and Experimental Reproductive Medicine* 2013;40(4):169-173https://epubs.rcsi.ie/cgi/viewcontent.cgi?article=1029&context=obsgynart

[25] Allison, J. (2016) 'Enduring politics: the culture of obstacles in legislating for assisted reproduction technologies in Ireland'. Reproductive Biomedicine and Society Online, 3, 134-141.

[26] Report of the Commission on Assisted Human Reproduction (2005) http://health.gov.ie/wp-content/uploads/2014/03/Report-of-The-Commission-on-Assisted-Human-Reproduction.pdf

[27] UL (2017) Information booklet on Donor Assisted Human Reproduction (DAHR) and the Law in Ireland https://www.ul.ie/engage/sites/default/files/2017,%20No%2013%20Information%20booklet%20on%20Donor%20Assisted%20Human%20Reproduction%20DAHR%20and%20the%20Law%20in%20Ireland.pdf

[28] Department of Health (2017) General Scheme of the Asissted Human Reproduction Bill. Accessed at http://health.gov.ie/blog/publications/general-scheme-of-the-assisted-human-reproduction-bill-2017/

[29] Walsh, D. *et al.*(2013) 'Irish public opinion on assisted human reproduction services: Contemporary assessments from a national sample'. Clin Exp Reprod Med, 40(4):169-173

[30] Allison, J. (2016) 'Enduring politics: the culture of obstacles in legislating for assisted reproduction technologies in Ireland'. *Reproductive Biomedicine and Society Online*, 3, 134-141.

[31] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues.* Dublin: The Women's Health Council.

Access to AHR

The second major concern in relation to AHR is the lack of public access to treatment, making AHR inaccessible to many in Ireland. This is because AHR services are overwhelmingly provided by private clinics and paid for by patients themselves (some clinics may offer services to public patients on a discretionary basis and there is some public provision for cancer patients[32]). The only financial support provided by the state comes through subsidisation of the purchase of drugs and tax relief on health expenditure. Yet, even this limited support is inaccessible to many who cannot afford to meet the up-front costs of treatment. NWCI welcomes the Government's intention to provide public funding for fertility treatments[33] so that AHR can be provided as universal service within the publicly-funded health system. The AHR Bill will provide the long-required regulation to underpin state services.

PART 2: Comments on the General Scheme

NWCI recognises the many positive elements in the General Scheme, particularly in relation to the establishment of a Regulatory Authority to license and monitor AHR treatments and service providers. In this section we make comments on specific Heads of the Bill which we believe require clarification or amendment to best support women's health.

Representation of patient and women's interests

Head 76 Membership of the Board

As has been outlined above, infertility is a public health issue which impacts a significant number of women, men and families in Ireland. It is crucial that the lived experiences of those undergoing fertility treatments are integrated into the process of regulation and the structures of the Assisted Human Reproduction Regulatory Authority (the Authority).

Head 76 (2) states that all the members of the Board of the Authority shall be appointed by the Minister and must be people who have experience or expertise in matters connected with the functions of the Authority, or in corporate governance and management generally.

Head 76 (5) states that the Minister 'may' request relevant stakeholders to nominate appropriate candidates for consideration for appointment to the Board. The explanatory

[32] Currently, cancer patients can access publicly-funded fertility preservation *prior to cancer treatment* (funded by the National Cancer Control Programme). However, cancer patients who need fertility preservation post treatment must pay privately.
[33] Dept. Health Press Release, 3rd October 2017 'Government approves the drafting of the Assisted Human Reproduction Bill'. http://health.gov.ie/blog/press-release/government-approves-the-drafting-of-the-assisted-human-reproduction-bill/

note elaborates on this by highlighting a number of examples, such as the Institute of Obstetricians and Gynaecologists, the Royal College of Physicians in Ireland, the Nursing and Midwifery Board of Ireland, the National Infertility Support Group, Legal representation and Scientific, Research and Ethicist representation.

NWCI would draw the attention of the Committee to Schedule 1 of the UK's Human Fertilisation and Embryology Act 1990[34], which outlines the requirements to be a member of the Human Fertilisation and Embryology Authority. Of particular note this Authority must comprise of a mixture of the following:

> (a) any person who is, or has been, a registered medical practitioner;
>
> (b) any person who is, or has been, concerned with keeping or using gametes or embryos outside the body; and
>
> (c) any person who is, or has been, directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so.

In making nominations for appointments to the Authority, the Minister should have regard to the need for diversity of expertise and experience and to the need to appoint persons who have the expertise to carry out the functions of the Authority or to ensure that those functions are carried out. The UK approach ensures that the members of the UK Authority are as representative as possible.

- *NWCI recommends that AHR patients (individuals with experience of AHR treatment) should be represented on the Authority's Board.*
  NWCI recommends a clear commitment in legislation to this effect, so that the word 'may' be replaced with 'shall'. We further recommend that consideration be given to the formulation of the composition of the UK Authority.

Given that women's interests are central to the regulation of AHR treatments, it is essential that women's voices form part of the Authority. Such an undertaking forms part of the UK Human Fertilisation and Embryology Act 1990, which states in section 5, schedule 1(4)(2) in making appointments regard shall be had to 'the desirability of ensuring that the proceedings of the Authority, and the discharge of its functions, are informed by the views of both men and women'. A more prescriptive provision for the composition of the Irish Human Rights and Equality Commission forms part of the Irish Human Rights and Equality Act 2014.[35]

- *Given that women's interests are central to the regulation of AHR treatments, NWCI recommends the Board of the Authority shall comprise of at least 40% of the underrepresented sex.*

The patient/user perspective should also be integrated into the workings of the Authority. Ongoing engagement with patients using AHR can ensure that the monitoring and licensing of services meets the identified needs of patients, as well as those of clinicians and

[34] The Human Fertilisation and Embryology Act of the United Kingdom was passed in 1990, leading to the formation of the Human Fertilisation and Embryology Authority (HFEA), the first statutory body to regulate and control assisted conception anywhere in the world.
[35] Section 12(2) of the Irish Human Rights and Equality Act 2014 states: Of the members of the Commission, not less than 6 of them shall be men and not less than 6 of them shall be women, and in a case where there are 14 or more members, not less than 7 of them shall be men and not less than 7 of them shall be women.

service providers. It is evident that good practice in AHR clinics encompasses more than medical care. A more holistic approach to patient care is believed to improve health outcomes, increase patient and team satisfaction, reduce negative psychosocial reactions and help patients better come to terms with their experience.[36] Patients can provide insight into how services are provided and suggest how services can better meet patient need – how their care options are described, how the planning process for treatment is shared between the clinical staff and the patients and how alternative options, such as adoption, are discussed. The health service has developed a range of mechanisms to engage patients in regulation and service development. The Authority should seek to engage patients in reference panels and through the undertaking of research on patient experience.

- *A core function of the Authority should be to engage with people who have personal experiences of AHR and to conduct research to ensure patient experiences inform the development of regulation and AHR services.*

Raising public awareness about causes and prevention of infertility

Head 71 Duty of the AHRRA to provide information

Considering the widespread nature of infertility more attention should be given to its prevention and to raising public awareness of its causes and cures.

While infertility is a relatively common problem, people often feel isolated in their experience. Better public awareness of infertility and information on where to seek support would ensure individuals feel better supported. Awareness would also reduce the stigma which often surrounds infertility, supporting individuals to seek early investigation by health services. People experiencing infertility should also be directed towards the supports available to them, including counselling and support groups.

All information should be provided in a form that is accessible to people who have additional needs, such as people with disabilities and people who do not speak or read English.[37]

- *Provision of public education about infertility should be a core function of the Authority. The Authority should be responsible developing and disseminating information on the main known causes of fertility problems, preventative measures and supports available (support groups).*

[36] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council
[37] NICE (2017) Fertility Overview. Accessed at https://pathways.nice.org.uk/pathways/fertility

Informed choice and the provision of independent information

Head 9 Consent; Head 67 Functions of the AHRRA; Head 71 Duty of the AHRRA to provide information

Informed choice is integral to the process of AHR treatment and can only be made with accurate, accessible information.

AHR treatment options are complex and patients need to understand their options properly to be able to make informed choices. While there is a large amount of medical and academic research on AHR treatment it is difficult for patients at a vulnerable time in their lives to be able to access reliable, clear information.[38] Access to independent information would further benefit health professionals caring for those seeking infertility advice and treatment.

Currently, there is a lack of comprehensive independent information on AHR treatments available in Ireland. In particular, there is no independent information on Irish clinic success and failure rates.[39] As outlined by the Women's Health Council[40], success rates in relation to the various treatments may be confusing for the lay population as they are reported in clinical language and there is no standard format that allows for comparison between clinics.

According to Head 9(3)(b), '[p]rior to giving his or her consent …. the person in question shall have been provided with relevant information about the proposed AHR treatment or treatments, as the case may be'. Relevant information is left undefined.

Head 71 of the Bill outlines the duty of the Authority to provide information. Head 67 (6) states, 'to the extent [AHRRA] considers appropriate, advice and information on activities governed by this Act'. The explanatory note that accompanies this provision recognises that this information is best provided by an independent organisation.

NWCI considers that provision of accurate and up-to-date information on AHR practices should be an integral function of the Authority. The Bill should designate specific responsibility to the Authority for provision of all independent information on AHR treatments and related matters. The UK's Human Fertilisation and Embryology Authority (www.hfea.gov.uk) is the Government's independent regulator overseeing AHR treatment (licensing, inspections and standard setting). The UK Authority also provides impartial information on all aspects of the AHR process and treatments via its website.

- *Given that informed choice has been raised as integral to the process of AHR treatment, the Authority should be responsible for providing free, clear and impartial information to all affected by fertility treatment.*
- *Given the significance attached to the provision of 'relevant information', it should be defined to include at a minimum the physical risks and psychological repercussions involved in proceeding with AHR treatment.*
- *Given that access to accurate and up-to-date information on success rates is essential to making an informed choice, the Authority should ensure reported*

[38] Women's Health Council (2009) *Infertility Treatments for Women - A Review of the Bio-medical Evidence.* http://health.gov.ie/wp-content/uploads/2014/03/infertBiomedEvid_Full.pdf

[39] Institute of Public Health in Ireland (2017) 'Submission to a new National Women's Strategy 2017-2020'.

[40] The Women's Health Council (2009) *Infertility and its Treatments A Review of Pyscho-social Issues,* para. 3.3.1.

success rates in relation to the various treatments are accessible for a lay population and are provided in a standardised format enabling comparison between clinics.

Research function of the Authority

Head 67 Functions of the AHRRA

This is a crucial period for the development of AHR services in Ireland. In the coming years AHR services will be subject to regulation and will be provided as a universal service. Yet, we know very little about the current operation of AHR services and the level of demand, or the experiences of patients receiving AHR treatments.[41] The most recent data from the European Society of Human Reproduction and Embryology (ESHRE) reported that in 2011, Ireland had 3,040 AHR treatment cycles resulting in 680 infants (0.9% of national births).[42] While this provides some indication of the number of AHR cycles (not all clinics in Ireland provide data to ESHRE), we do not know the overall numbers seeking treatment.

A programme of ongoing research is needed to document AHR demand and use in Ireland and patient experience of AHR services. The Authority should collect regular health intelligence on AHR in Ireland, with data analysed by gender, age, socio-economic and ethnic categories. Disaggregation will provide information on AHR use and outcomes for different groups of women, such as women with disabilities or LGBTQ women, who may experience multiple discriminations in access to treatment. It is important that significant attention is given to research which documents the experiences of people who have previously, or are currently using AHR services.

- *Given the paucity of domestic data in this area, the Authority should be explicitly mandated to study and report on the broad social, ethical, health, legal and economic implications of AHR on a periodic basis.*

Access to quality counselling

Head 8 Counselling

Head 8 provides for the provision of 'pre-treatment counselling' for AHR patients.

Infertility and the process of undergoing AHR treatment can cause significant distress and psycho-social impacts. Patients abroad and in Ireland have continually expressed a need for more emotional advice and support throughout the process. In its 2005 report, the CAHR recommended that counselling be available from appropriately qualified counsellors

[41] Evelyn Mahon and Noelle Cotter , Assisted reproductive technology- IVF treatment in Ireland: A study of couples with successful outcomes , Human Fertility , Vol 17, (3), 2014, p165 - 169

[42] M.S. Kupka, T. D'Hooghe, A.P. Ferraretti, J. de Mouzon, K. Erb, J.A. Castilla, C. Calhaz-Jorge, Ch. De Geyter, and V. Goossens(2011) Assisted reproductive technology in Europe, 2011: results generated from European registers by ESHRE† The European IVF-Monitoring Consortium (EIM)‡ for the European Society of Human Reproduction and Embryology (ESHRE) Human Reproduction, Vol.31, No.2 pp. 233–248, 2016

before, during and after treatment as an integral part of the service offered by AHR clinics.[43]

Counselling and psychological support is important throughout the whole treatment process, particularly at stressful times, such as implantation, waiting for a pregnancy test, or dealing with an unsuccessful outcome. When treatment is coming to an end, counselling support can support patients to consider other options such as adoption, or to accept that that they will not have a child.

- *Counselling should be provided before, during and after treatment to those considering AHR treatment so that they are properly supported and are adequately informed of the risks involved, the potential benefits that may be obtained and the possibility of success in their particular situation.*[44]

According to Head 8, all intending parents wishing to undergo AHR treatment shall be provided with counselling from a counsellor who delivers services on behalf of the AHR treatment provider. It is important that counsellors are trained to provide AHR counselling and are in a position to provide impartial support to their patients. Work is ongoing in the Department of Health in relation to implementing provisions for the designation and regulation of counsellors under the Health and Social Care Professionals Act 2005. Any subsequent regulatory developments in this area must be taken into consideration as the Bill progresses.

- *Counselling should be provided by suitably qualified professionals who should adequately convey the complex medical and scientific ramifications of different treatment approaches in verbal and written form.*[45]

Age restrictions

Covered in a number of Heads

A number of age restrictions to treatment are outlined in the General Scheme. For example, Head 6(3) states AHR treatment shall not be provided to persons under the age of 21 years and Head 6(4) that AHR treatment shall only be provided to women who are 47 years and under. Comparable age restrictions are not provided for men. This appears to be discriminatory and requires explanation.

While setting a female age limit for treatment is part of many countries' criteria for publicly-funded AHR treatment, there is significant variation in these age limits. In countries with no age limits, discretion to determine access rests with the clinic or doctor, who may rely upon other clinical indications, such as the patient's ovarian reserve and hormonal levels.[46]

[43] Commission on Assisted Human Reproduction, Report, (2005), xv, recommendation 12.
[44] Exact extract from the Commission on Assisted Human Reproduction, Report, (2005), xv, recommendation 12.
[45] Extract from the Commission on Assisted Human Reproduction, Report, (2005), xv, recommendation 12.
[46] Keane, M. *et al.* (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.

- *Consideration should be given to the removal of specified age restrictions for AHR treatments in favour of a provision by which clinicians can determine a patient's eligibility for treatment based on agreed clinical criteria set down by the Authority.*

Functions of the Regulatory Authority

Head 67 Functions of the AHRRA

Given that AHR has not been regulated in Ireland to-date, it is vital that the new Authority has the designated functions and power to speedily create a robust regulatory system.

NWCI would draw the Committee's attention to the detailed legislation (Health Act 2007) governing the Health Information and Quality Authority (HIQA). This Act sets out HIQA's regulatory powers in considerable detail. For example, the sections governing inspections and investigations and concerning designated centres articulate matters such as a right of entry. Schedule 3B of the UK's Human Fertilisation and Embryology Act 1990 also makes provisions in relation to inspection, entry, search and seizure.

- *The powers of the Authority, including inspections and investigations, should be articulated in detail.*

Complaints procedure

No current Head

It is important for patients to understand what, if any power, the Authority has to intervene in complaints against licensed centres.

The Authority should have a specific statutory duty to investigate patient complaints. Complaints made by patients about the treatment or service that they have received at a centre licensed by the Authority may impact on the Authority's duty to provide advice and information to patients. Depending on the matters raised, complaints may also give rise to a duty to investigate serious adverse events.

- *The Authority should have the power to investigate complaints and concerns raised by patients and to censor clinics or practitioners where necessary.*

Review Clause

No current Head

AHR technologies have rapidly advanced in the last decade. It is essential that this Bill not only responds to present AHR provision but can regulate developments over time.

While a structured process of post-enactment review of legislation was incorporated into parliamentary procedure in November 2013 and re-affirmed in 2016, it is not yet

conducted on a regular basis. Certain Acts stipulate that their operation must be reviewed after a period of time, a task for which the Minister is generally responsible. For example, under the *Gender Recognition Act 2015* (s.7), a review of the operation of the Act is to begin two years after its commencement and a report made to the Houses of the Oireachtas no later than 12 months after the review begins.

- *Given the continued advancement of AHR, NWCI urges the incorporation of a review clause into this Bill to ensure that the new legislation carries out its intended propose, to address any gaps in the application of the law and to ensure its ongoing relevance into the future.*

Storage time limits for childhood cancer patients

Head 22 Storage of gametes and embryos

Cancer treatment can affect fertility and a patient may need to seek fertility preservation before treatment begins. Section 22(8) states that gametes may not be stored for more than 10 years without permission of the Authority. This may have implications for adult survivors of childhood cancer who underwent fertility preservation as children and need to store gametes beyond this time limit.

- *There are a number of ways in which this issue could be addressed via amendment to the current text: including a time extension for those who have had cryopreservation as a result of cancer; giving powers to the Authority to set reasonable grounds for extension; or by stating that people who had their gametes preserved during childhood due to a medical condition would be exempted from this requirement.*

Comments on regulation of surrogacy as outlined in the General Scheme

NWCI is not in a position to make a recommendation on the surrogacy elements of the General Scheme, as the organisation does not have an official position on surrogacy. However, in considering the text of the General Scheme we would raise issues for consideration in relation to surrogate mothers.

The surrogate mother

The technological advances presented by AHR naturally give rise to ethical and legal concerns. This is particularly the case for surrogacy which intersects with issues relating both to women's reproductive health and to the need to protect women from exploitation.

There is considerable concern about the practice of surrogacy given the potential for the coercion and exploitation of surrogate mothers in Ireland and in other countries. Broadly,

there are three main concerns related to surrogacy – the commodification of women and children; exploitation of women, including of the birth mother and/or of intending parents; and child protection. Individual women's, human rights and health organisations have taken different positions on surrogacy – calling for its prohibition, for strong regulation of practices, or supporting surrogacy in a range of forms.

NWCI believes that any consideration of altruistic surrogacy should place a particular focus on the potential experience and position of the surrogate mother, who would typically be the most vulnerable party in any arrangement. Any potential surrogate mother would bear any negative emotional, physical or lifestyle risks of the pregnancy. Further, a surrogate mother would face significant additional risks, such as the intending parents reneging on the surrogacy arrangement and she is left as parent of the child, or alternatively she may wish to keep the baby and the prior surrogacy agreement is held against her.

In the case that the Irish Government decides to regulate altruistic surrogacy in Ireland, significant attention must be given to legal, economic and health safeguards to protect surrogate mothers from exploitation.

PART 3: Development of Equitable Access to AHR

NWCI's *Every Woman* model advocates for women in Ireland to have access to all elements of reproductive and sexual healthcare services. NWCI welcomes the Government's intention to provide public funding for fertility treatments so that AHR can be provided as universal service within the publicly-funded health system. The WHO (2016) *Action plan for sexual and reproductive health*[47] recommends states include diagnosis and treatment of infertility as a standard component of basic health care packages. The all-party Sláintecare model for reform of the health system recommended that 'maternity care, including IVF'[48] would be part of healthcare entitlements in a universal healthcare system.

Universal access to AHR requires mechanisms of public oversight and transparency, including data on the use, practices, and outcomes of AHR treatments. Thus the introduction of the AHR Bill is essential to underpin the development of public provision of AHR. It is important that in tandem with the development of the AHR Bill, steps are taken to prepare for universal access to treatment, including development of care pathways for patients and clinical criteria for access.

Currently, women in higher socioeconomic groups are proportionally more likely to use AHR services in Ireland.[49] Public funding is essential to achieve equitable access for all women requiring treatment. Private-only AHR provision is likely to have created

[47] WHO (2016) *Action plan for sexual and reproductive health: towards achieving the 2030 Agenda for Sustainable Development in Europe – leaving no one behind.* Copenhagen: WHO.
http://www.euro.who.int/__data/assets/pdf_file/0018/314532/66wd13e_SRHActionPlan_160524.pdf

[48] P.59, Houses of the Oireachtas Committee on the Future of Healthcare (May 2017) *Sláintecare Report.*
https://www.oireachtas.ie/parliament/media/committees/futureofhealthcare/Oireachtas-Committee-on-the-Future-of-Healthcare-Slaintecare-Report-300517.pdf

[49] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.

suppressed demand by those who require AHR treatment but cannot afford it. Evidence also suggests that in countries such as Ireland which do not have public access to AHR, people wait longer to receive treatments as they save to meet the costs.[50]

Public funding can also bring additional benefits. It can ensure quicker access to AHR for eligible patients, which is significant given the impact of age on fertility. In other countries public funding for AHR has been used to establish safer embryo transfer practices, reducing incidence of complicated pregnancies.[51]

Current costs

Currently, AHR costs are prohibitive for many. Some individuals will stretch their finances to the limit to pursue treatment and many others are not able to access treatments at all.[52] For example, a single in vitro fertilization (IVF) cycle in a private Irish fertility clinic ranges from €4,100 to €5,900, while intracytoplasmic sperm injection costs between €5,200 and €6,400.[53] Patients will also incur additional costs such as initial consultations, testing, investigations and counselling fees.

Patients who access fertility treatments may claim 20% tax relief on the costs involved under the tax relief for medical expenses scheme. To avail of tax credit the patient must have the resources to pay for the service to then claim the tax relief in the future, making this process inequitable for many who cannot afford initial costs. The Medical Card, High Tech Drug Scheme and Drug Repayment Scheme provide some relief from drug costs. Some private health insurers[54] offer some coverage for assisted reproductive services, but this is only available for those who can pay privately for insurance.

Public funding of AHR

Following enactment of the AHR legislation, the Government has said it will provide public funding for AHR.[55] As identified by the Health Research Board's review of funding[56], internationally AHR is primarily funded via three mechanisms – full funding, partial, or no funding from public health system. The Health Research Board review[57] indicated that the

[50] Keane, M. *et al.* (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[51] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[52] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council.
[53] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[54] Laya covers up to a maximum of €1,000 per female recipient and Voluntary Health Insurance covers infertility treatment at an approved centre up to €2,500 per lifetime for members of the VHI PMI 0411 plan, which is only one of its many plans. See, Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[55] Dept. Health Press Release, 3rd October 2017 'Government approves the drafting of the Assisted Human Reproduction Bill'. http://health.gov.ie/blog/press-release/government-approves-the-drafting-of-the-assisted-human-reproduction-bill/
[56] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[57] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.

overall economic cost to society of AHR treatment is relatively modest – even for countries offering generous public funding, AHR represents 0.25% of the national health budget.

Internationally, publicly-funded AHR is subject to eligibility criteria and the number of publicly-funded cycles also varies by jurisdiction.[58],[59] The criteria adopted in Ireland should be based on safety, clinical evidence, equity and the likelihood of successful outcome.

- *NWCI recommends the development of a mechanism for public funding of AHR to ensure equitable access, while ensuring providers provide safe and cost-effective services.*

Care pathways for universal access

The creation of public access to AHR necessitates the urgent development of a Model of Care for Infertility. This model of care will coordinate care across all of the healthcare providers a woman will interact with during her treatment, including primary care, gynaecology, hospital services and AHR providers. As outlined in the UK's National Institute for Health and Care Excellence quality standard for fertility[60], a person-centred, integrated approach is vital to deliver high quality care.

- *The Model of Care for Infertility in Ireland should address all areas of infertility care, including: provision of information; initial advice; investigation; medical and surgical management of male/female and unexplained fertility; access to IVF and other procedures; counselling; and access to fertility preservation for patients with cancer.*
- *In providing for a system of universal access to AHR treatments, the state should also consider the psycho-social supports which will be required by individuals before, during and after such treatments. This should include mechanisms to plan with patients for when treatment will end, and the provision of supports, particularly for those who have an unsuccessful outcome.*

[58] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[59] NICE UK Press Release, 31st October 2014, 'The importance of 3 full cycles of IVF'. https://www.nice.org.uk/news/blog/the-importance-of-3-full-cycles-of-ivf
[60] NICE (2014) *Fertility Problems – quality standard.* nice.org.uk/guidance/qs73

Conclusion

NWCI welcomes the opportunity to respond to this consultation on the General Scheme of the AHR Bill. NWCI, as the national women's membership organisation, is committed to the regulation of AHR treatments to protect women's health.

While the legislative basis represented by the General Scheme is an essential step, much more will be required to ensure infertility care in Ireland achieves best practice for women and couples in Ireland, including:

- Policies and benefits to support family formation
- Increased emphasis on prevention of infertility and pre-conceptual health
- Public awareness of fertility problems and treatments
- Equitable access to AHR

As the AHR Bill progresses, NWCI will continue to bring forward evidence-based proposals, the perspectives of our members and the lived experience of women on all elements of AHR. In this way we will work with the Department of Health, the HSE and the future Assisted Human Reproduction Regulatory Authority to ensure the provision of AHR supports women's health and advances equality for women in Ireland.

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24: Professor Deirdre Madden

Submission to the Joint Committee on Health on the General Scheme of the Assisted Human Reproduction Bill 2017

21 February 2018

Professor Deirdre Madden, School of Law, University College Cork

1. General Introduction

i. Regulation of Assisted Human Reproduction (AHR) is necessary to ensure that AHR treatments are provided safely and in line with international best practice. Calls for legislation in this area have been made by the Commission on Assisted Reproduction (CAHR), the courts, legal and medical practitioners, academic commentators and patient representative organisations for many years. Therefore, I strongly welcome the publication of the General Scheme of the Assisted Human Reproduction ('AHR') Bill 2017 which is needed to bring clarity, certainty and regulatory oversight to this area in order to protect the rights and interests of prospective parents, clinicians and any children born through AHR.

ii. I welcome the fact that the Bill has been informed by the recommendations of the CAHR, in particular in relation to the establishment of a regulatory authority to license clinics and to ensure that they are independently inspected against national standards and a Code of Practice which is put in place following consultation with a range of professional experts, current and prospective parents, and with input from the public.

iii. The Bill broadly achieves the aims of clarity and certainty in relation to IVF and treatments with donor gametes and embryos subject to some suggestions below in respect of some specific draft provisions. However, in my opinion the provisions in relation to surrogacy are flawed and will result in continued travel for surrogacy to other jurisdictions by couples who will be unable to avail of the very limited mechanism offered by this Bill. The lack of clarity in respect of the legal position of children born in such circumstances is contrary to the best interests and rights of such children and must be rectified.

iv. I look forward to the commencement of Parts 2 and 3 of the Children and Family Relationships Act and details of proposals for State funding of AHR treatments in the near future.

2. Head 2 – Interpretation

i. The definition of the word 'child' in this context as a person under the age of 18 years is problematic as it applies to both children born through AHR *and* young persons under 18 years who may themselves seek to avail of AHR treatment or storage of gametes. Different legal considerations apply to these different groups. In Ireland it is commonly understood in medical practice that a person may give their own consent to medical or surgical treatment once they have reached the age of 16 years. This is based on s.23 of the Non-Fatal Offences Against the Person Act 1997 and will be discussed further below.

ii. 'Surrogate' – this definition should be confined to 'a woman who carries a pregnancy in pursuance of a surrogacy agreement' and should not refer to the legal status of the woman who gives birth.

3. Head 5 – General Principles

i. There is no reference to the health and well-being of men who receive AHR treatments. Although men's exposure to physical risk in AHR is more limited than is the case for women, they may also experience anxiety and stress during the process and therefore may need psychological and emotional support during the AHR process and ought to have their well-being taken into consideration.

4. Head 6 – Provision of AHR treatment

i. Para (2) states that a woman may be provided with AHR treatment if (a) she is unlikely to become pregnant or carry a pregnancy or give birth in the absence of such treatment; **or** (b) pregnancy or child birth would not pose a disproportionate risk to the health of the woman or the child… The word 'or' seems incorrect here as it would mean that a woman seeking AHR treatment could satisfy the statutory criteria by meeting (a) *or* (b) i.e. she could claim to be eligible for AHR treatment if pregnancy would not pose a disproportionate risk to her health irrespective of whether she had any difficulty conceiving or carrying a pregnancy as provided under (a). If it is intended that a woman seeking treatment should have difficulties conceiving or carrying a pregnancy and that a risk assessment must be done to ensure as far as possible that pregnancy would not pose disproportionate risk to her, I suggest that this paragraph be changed to (a) **and** (b).

ii. The criteria in para (2) does not include women who *are* able to become pregnant and carry a pregnancy but who are carriers of genetic disease which they wish to avoid passing on to their children by seeking AHR treatment such as egg donation (permitted under Part 3) or through pre-implantation genetic diagnosis (permitted under Part 5). The criteria should be amended to include women in this category.

iii. The minimum age limit of 21 years is based on a clinical diagnosis of infertility. This does not appear to be reasonable as some young people may be aware from an early age that their clinical condition, such as cancer during adolescence, will require them to seek AHR treatment and therefore it is unnecessarily restrictive to preclude them from seeking treatment until the age of 21 years.

iv. The arbitrary upper age limit of 47 years for women is not clearly justified in the explanatory note. The note states that the AHR treatment provider needs to make a clinical risk assessment, which clinicians are trained to do on a daily basis in keeping with international best practice, so it would appear to me to be more reasonable to give discretion to the provider in this regard rather than set an absolute age limit enforceable by the sanction of a criminal offence. Guidelines on the exercise of this discretion could be provided by the regulatory authority.

v. The absence of an upper age limit for men while perhaps defensible clinically, is difficult to justify in light of the upper age limit for women. A man up to age 70 could reasonably satisfy the requirement that he could be expected to parent a child until adulthood. While there may obviously be different clinical risks for women in terms of carrying a pregnancy, this should be a matter for the clinical discretion of the AHR provider following consideration of the both parents' health and expectations of being able to parent a child until adulthood.

5. Head 7 – Welfare of the Child

i. It is not clear what 'account has been taken of the welfare of any child…' means. Although guidance will be issued by the regulatory authority on this matter, some basic principles in the Act would be welcome. There has been extensive literature published on the welfare of children born through AHR (in particular the work of Professor Susan Golombok[1]) and much academic debate on whether welfare considerations may be used in practice to exclude or discriminate against certain categories of prospective parents. A positive statement in the Act to the effect that persons seeking AHR treatment should not be discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age is necessary to ensure that such discrimination does not take place under the guise of welfare of the child considerations.

6. Head 9 – Consent

i. Consent to treatment is a crucial aspect of all medical procedures. This Head provides that in para (1) consent shall be provided before treatment commences and shall cover all stages of treatment. This implies that consent is a once-off event rather than a continuous process as a person/couple proceeds through a variety of treatments over many months or years. This is problematic because the person receiving treatment may not recall details of a conversation months or years previously about the risks of treatment or about decisions made with his/her partner.

ii. Although para (e) refers to a refreshing of consent if the treatment changes or two years has elapsed, in my opinion this is insufficient to ensure valid consent for every intervention. Case law in other jurisdictions as well as in the Irish case of *Roche v Roche*[2], demonstrates the wisdom of seeking consent separately for each intervention and, at the very least, prior to embryo transfer.

iii. It is also unclear how the AHR provider may be expected to be aware of a change in circumstances such as a separation of husband and wife prior to embryo transfer unless informed of such by one of the parties. It would therefore in my view be more prudent to require consent in person by both parties prior to each intervention or, if this was deemed to be impractical, at the very least prior to embryo transfer.

[1] For example, Golombok S. *Modern Families: Parents and Children in New Family Forms* (2015) Cambridge University Press

[2] [2006] IEHC 359; [2009] IESC 82

7. Head 19 Non-commercial donation

i. This head prohibits the provision of payment or other reward for donation except for the reimbursement of reasonable expenses. It appears from the explanatory note that this would also preclude egg sharing which occurs when a woman who is already having IVF donates some of her eggs to the clinic where she is receiving treatment, usually in return for some free or discounted treatment. Egg sharing offers an option to some women who may struggle financially with the costs of IVF and although there are important issues for her to consider in relation to donation of some of her eggs, these can be adequately dealt with through counselling. In my opinion it is unnecessarily restrictive to exclude this option for couples who may need it, particularly in the absence of state funding of IVF.

8. Head 22 Storage

i. It is not stated whether gamete storage includes the storage of testicular or ovarian tissue for reproductive purposes in the future. This should be included.

ii. It is not stated whether a person under 18 years can consent to the storage of their own gametes. In most cases where a person under 18 is being treated for a medical condition such as cancer which might make it advisable to store his/her gametes for the future, there will be agreement about storage with the person's parents/legal guardians. However, there may be situations in which such a person might wish to store their gametes but the parents do not agree. Can a young person give consent to this without his/her parents?

iii. The age of consent to medical treatment in Ireland is generally understood to be 16 not 18 years. This is based on s.23 of the Non-Fatal Offences Against the Person Act 1997. Although there has not been any Supreme Court consideration of this provision in detail, particularly in conjunction with consideration of parental rights under the Irish Constitution, medical practice here has long adopted an interpretation of the 1997 Act to mean that a person aged 16 years can give their own consent to medical, surgical or dental treatment. This is evident in advice from agencies such as the Clinical Indemnity Scheme, Medical Council, Irish College of General Practitioners, Medical Protection Society, and the HSE National Consent Policy. It should be made clear, for young people and their treating doctors, that storage of gametes is to be regarded in the same way as other forms of medical/surgical treatment in this context.

iv. Para (7) provides that a person under the age of 18 years may have their gametes stored <u>without</u> their consent if the person's parents/legal guardians consent and storage is considered to be in their best interests. This Head does not distinguish between the *absence* of consent on the part of the person under 18 years and the *refusal* of consent by the person under 18 years.

v. If it is anticipated that parents may give consent in the absence of disclosure to the child/young person of the proposed extraction and storage of gametes, this raises ethical issues about deception and invasion of the child/young person's bodily integrity. It is also in conflict with Article 12 of the UN Convention on the Rights of the Child which provides: "States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child". This

provision means that children and young people are entitled under Article 12 to participate in decisions concerning them. The principle of participation by the child/young person in decision-making in an age-appropriate manner and format should be included in the Bill.

vi. The issue of refusal of treatment is more complicated as there is no legislative or judicial guidance in Ireland on whether a person under the age of 18 is entitled to refuse treatment and have such a refusal respected. It is difficult to imagine a scenario in which a young person who refused permission to have their sperm or eggs stored would have this overridden by their parents and a medical procedure imposed on them against their wishes. However, this seems to be envisaged by the wording of this Bill.

vii. Gamete retrieval and storage is not a treatment which is life-saving or necessary to preserve the health of the young person and therefore does not fall into the same category as surgical interventions or blood transfusions. As a matter of principle consent and refusal ought to be seen in the same way and the autonomy of the young person respected for both types of decisions. It is not ethically acceptable for adults to tell a young person of 16 or 17 years that their decision will only be respected if the young person is giving permission for a procedure and not if it is refusing permission for the same procedure. I submit that it would be an unjustifiable infringement of autonomy and bodily integrity if parents were authorised to override the wishes of a young person up to the age of 18 years in a matter so important and personal to that young person.

viii. The language of best interests is not appropriate in this context and has deliberately not been used in other recent legislation concerning decision-making by persons whose capacity may be in issue – Assisted Decision-Making (Capacity) Act 2015. The approach here should be to ascertain the will and preference of the young person following a process of communication of relevant information in age-appropriate language and format.

9. Head 24 Posthumous assisted reproduction (PAR)

i. Para (1) states that an AHR provider may provide PAR where the deceased person provided *his or her* consent for *his or her* gametes or embryo to be used after *his or her* death. This indicates that both men and women may provide consent to such use after death. However, para (1) (b) states that the gametes or embryo shall only be available for use by the deceased person's surviving partner where *she* will carry the pregnancy. Para (c) provides that *she* must have received counselling and given consent. This means that PAR is only possible for a surviving female partner of a deceased man or a surviving female partner of a deceased woman. PAR is therefore not possible for a surviving male partner of a deceased woman.

ii. These provisions are unnecessarily discriminatory and do not facilitate respect for the autonomy of the deceased. There is no justification or policy rationale given for enabling a woman to give consent to the use of her eggs after death only if she is in a same-sex relationship and not to allow her surviving husband/male partner to use those eggs/embryo created using the eggs to have a child with the assistance of another woman such as a surrogate.

iii. Given that Part 6 of the General Scheme envisages the possibility of a single person availing of surrogacy, it is inconsistent to exclude the possibility of a widowed man/surviving male partner using an embryo created with his gametes and those of his deceased wife/partner in a surrogacy arrangement (if this was consented to by his wife before her death). This man would instead be obliged to create a new embryo with donor eggs to be used in such a surrogacy arrangement.

10. Head 28 Consent for PAR

i. Head 28(4) sets out that consent for PAR must be in writing but it does not state for how long such consent will remain valid.

ii. Documentary evidence of consent is important for record keeping but other mechanisms of documenting consent should also be made available for persons with literacy or vision difficulties or otherwise unable to sign due to disability.

11. Part 6 Surrogacy

1. Introductory remarks

i. This Part provides for the regulation of domestic altruistic surrogacy in Ireland. Surrogacy raises complex legal and ethical issues on which there are many diverse views but it is important from a policy perspective to bear in mind that surrogacy is a present reality which requires to be dealt with from the perspective of ensuring respect and protection for all parties involved, particularly the rights and interests of children born to Irish citizens through surrogacy wherever that arrangement takes place. We know that many Irish people travel to other jurisdictions to avail of legal frameworks which facilitate the acknowledgement of their legal status as parents of their genetically related children born through surrogacy. These international surrogacy arrangements will continue after the introduction of this Act and I strongly recommend that this be dealt with in the Act and the legal rights of those children and their parents be protected.

ii. Concerns exist in relation to the potential exploitation of women of lower socio-economic class in other jurisdictions where they may not be given adequate information or medical care. However, it should not be assumed that simply because a woman is of lower socio-economic means that she is therefore unable to make a voluntary and informed choice to become a surrogate mother – this is a paternalistic and discriminatory position which does not reflect the reality in other modern developed countries in which surrogacy takes place with appropriate screening, counselling, legal advice and regulation. Many women in properly regulated surrogacy services express pride and gratitude for being able to help their families with better housing and education. By denying these women the opportunity to potentially better themselves, we condemn them to continued poverty instead of regulating surrogacy to ensure they are adequately informed and protected.

iii. The avoidance of potential exploitation will not be achieved by this legislation. Instead it forces intending parents to go abroad for surrogacy if they cannot find a woman in Ireland who is prepared to act as a surrogate for them or if they desire more certainty and protection of their rights as genetic parents than having to apply for a parental order

sometime after the child's birth which is contingent on the consent of the surrogate *and* her husband.

iv. Not all surrogacy arrangements should be considered as exploitative - in the UK women often offer to become surrogates to help those who cannot carry children themselves. Studies show that they are usually mothers who are motivated by a desire to help make a family for someone else. They are clear that the children they carry for the intending parents are not 'theirs' and they do not consider themselves to be exploited.

v. I welcome in principle proposals for authorisation of surrogacy agreements to ensure adequate counselling, consent, independent screening and advice to all parties has taken place. However, under Head 37 this approval process is carried out by the regulatory authority which has no legal authority to grant legal parentage to the intending parents and therefore its role is limited to a check-list monitoring that adequate preparations and discussions have taken place prior to AHR treatment taking place to commence the pregnancy. This means that a second process is required after birth to transfer parental rights to the intending parents, at least one of whom is the genetic parent of the child. I submit that a more meaningful, efficient and effective protection of rights would take place if the approval process was a judicial one which also served to transfer parental rights prior to the birth of the child, as discussed further below.

2. Gestational surrogacy only

i. This Bill facilitates certain forms of surrogacy only, namely gestational/ IVF surrogacy where the surrogate does not have any genetic relationship with the child. Indeed, this is the usual form of surrogacy in most cases as the intending parents will, if they can, provide the embryo themselves. However, it means that in circumstances where the intending mother is unable for medical reasons to provide the eggs, she and her partner must also find an egg donor who is willing to donate. It is not stated what the policy rationale is for the restriction of surrogacy to gestational only.

ii. I submit that the introduction of a third woman into the conception of the child is unnecessary and not consistent with the best interests of the child in circumstances where the surrogate mother is willing to give valid consent to the use of her own eggs in the arrangement. It may also be contrary to the best medical interests of the surrogate mother who will go through embryo transfer rather than the simpler, less invasive and less risky procedure of insemination.

3. Parentage of children born through surrogacy

i. The Commission on Assisted Human Reproduction (2005) recommended (by majority) that the child born through surrogacy should be presumed to be that of the intending parents. This recommendation, which I support, was based on the 'intent of reproduction', i.e. legal parentage should be based on what all parties intended from the outset of the arrangement (which is that the intending parents would be the legal parents). When the surrogacy arrangement is entered into, the intending parents (one or both of whom are the genetic parents) do not create an embryo to donate to the

surrogate mother to have a child of her own. Neither does the surrogate mother want to have a child of her own created through the use of another couple's gametes. All parties are agreed that the child will be that of the intending parents and all are committed from the outset to achieving this end. The Commission was of the view that the legal framework should recognise and implement that joint intention as this was considered to be consistent with the prioritisation of the best interests of the child as well as protection of the rights of the genetic parents.

ii. Studies of surrogate mothers commonly show that surrogates do not consider the children they bear to be theirs and do not wish to be regarded as the legal mothers of those children. For example in a study carried out by the Family and Child Psychology Research Centre, City University, London[3] the researchers concluded that that "[T]he findings of the present investigation suggest that surrogacy has generally been a positive experience for those surrogate mothers interviewed, and fail to lend support to claims regarding the potentially negative outcomes of surrogacy for surrogate mothers. For example, none of the women in the present study had any doubts about their decision to hand over the child to the commissioning couple. In line with previous findings which showed that surrogate mothers tended to distance themselves from the foetus, the results of the present study indicated that surrogate mothers may view the child they are carrying as not theirs, thereby facilitating relinquishment." In addition, the study concluded that "Although it may be assumed that genetic surrogate mothers would be more likely to feel a special bond towards the child, this was not found to be the case."

iii. The proposed court mechanism to transfer parental rights to the intending parents six weeks after birth is imposed by the fact that the Government clearly adopts the position that the birth mother is the legal mother irrespective of any genetic link with the child. In other jurisdictions which provide for judicial pre-authorisation of surrogacy arrangements such as California, New Hampshire and Greece, legal parentage is accorded to the intending parents prior to birth, thus providing clarity and certainty from the moment of birth of the child as to who its legal parents are and avoiding the requirement for further legal processes which can cause unnecessary delay, worry and financial cost.

iv. The General Scheme is similar to the provisions contained in the English Human Fertilisation and Embryology Act 2008. Therefore, it is important to learn from the case law, academic commentaries and numerous calls for reform that have been made in the UK in recent years.[4] Rather than repeat those same mistakes with a high human cost for families and children, we should devise a rational, evidence-based framework that provides couples with a realistic opportunity to become parents through surrogacy in Ireland rather than travel overseas to avail of less desirable and perhaps more legally risky arrangements elsewhere.

[3] Jadva et al, "Surrogacy: the experiences of surrogate mothers", *Human Reproduction* Vol.18, No.10 pp. 2196-2204, 2003

[4] See for example, the Report of the Surrogacy UK Law Reform Project https://www.kent.ac.uk/law/research/projects/current/surrogacy/Surrogacy%20in%20the%20UK%20Report%20FINAL.pdf

v. In California, legislation was introduced in 2012[5] to provide guidance relating to the manner in which surrogacy agreements must be executed, when medical procedures can be commenced, and where parental establishment cases may be filed to clarify for courts what constitutes a properly executed surrogacy agreement, and to help protect all parties to the agreement—surrogate, intending parents and child—from potential exploitation. This law

- Requires that intending parents and a surrogate be represented by separate legal counsel.
- Requires notarization of gestational surrogacy agreements.
- Requires the execution and notarization of an agreement prior to the administration of medications used in assisted reproduction or any embryo transfer procedure.
- Requires the parties to a gestational surrogacy agreement to attest, under penalty of perjury as to their compliance with these provisions.
- Provides that a gestational surrogacy agreement executed in accordance with these provisions is presumptively valid.

vi. In relation to establishing legal parentage between intending parents and the resulting child, the law:

- Permits intending parents to establish parentage prior to the child's birth.
- Permits intending parents to establish parentage prior to the child's birth and permits the filing of the parentage action in the county where the child is anticipated to be born, the county where the surrogate or intending parents reside, the county where the agreement was executed, or the county where the medical procedures were performed.
- Requires that a copy of the gestational surrogacy agreement be filed with the court as part of the parentage action.
- Seals records of the agreement to all except parties except the intending parents, surrogate, their attorneys and the state Department of Social Services.

vii. The significance of this procedure is that the court issues an order establishing a parent-child relationship either before or after the child's birth. Subject to proof of compliance with the legislation, the court order establishes the parent-child relationship of the intending parents identified in the surrogacy agreement and establishes that the surrogate, her spouse, or partner is not a parent of, and has no parental rights or duties with respect to, the child or children. The court order is sent to all parties including the hospital where the surrogate will deliver so that there is no room for ambiguity in terms of parental responsibility as soon as the child is born.

viii. In New Hampshire[6] the surrogacy arrangement must be judicially preauthorized. Evaluations and counseling of the parties must be conducted prior to impregnation of the surrogate. Such evaluations shall include home studies of all parties; the surrogate, the intending mother and the intending father. All parties must have attained 21 years of

[5] Assembly Bill No. 1217

[6] New Hampshire statute RSA §§ 168-B:1 to -B:32

age. It is stipulated that the intending mother must be physically unable to bear a child. The eggs must come from the surrogate or the intending mother. The surrogate must have had at least one prior delivery. If the surrogate is 35 or older, a genetic counseling is necessary for taking up surrogacy. The statute also prescribes a residency requirement of 6 months for either the gestational mother or the intended parents. The agreement must be submitted in the form of a petition to Probate Court, where a hearing is scheduled within 90 days after such filing. At the hearing, the probate judge validates the surrogacy agreement after meeting with the parties, reviewing the agreement's terms and conditions, verifying that all the required counseling and appropriate evaluations have occurred and, finally, determines whether everything shall be ultimately in the best interest of the resulting child. The birth mother has the right to take all healthcare decisions concerning the foetus. Once parental rights are transferred to the intending parents, they have a duty to support the child. The child born under surrogacy shall always be considered the legitimate child of the intending parent. Fees for surrogacy as negotiated between the parties are limited to medical expenses, lost wages, insurance, legal costs, and home studies. New Hampshire laws prohibit fees for arranging a surrogacy contract. There are also provisions addressing issues of the contract being breached or terminated.

ix. Under the General Scheme of the Irish Bill, a parental order may only be made with the consent of the surrogate and her husband, unless she is deceased, lacks capacity to give consent, cannot be located or for any other reason the court considers relevant. Therefore, if the surrogate and her husband do not give consent and decide to retain custody of the child, she will remain the legal mother of the child, can receive payment of expenses etc. from the intending parents and presumably can seek a court order for maintenance of the child against the genetic parents. The genetic father may only apply for legal guardianship of the child, which is not automatic and will be decided on the basis of the child's best interests. In rare situations of conflict between the surrogate and the intending parents, the court may well decide that the child's best interests would be better served by being raised by the surrogate and her family to the exclusion of the intending parents. This is inherently unjust and imposes significant stress on intending parents who in many cases have tried for many years to have a child, are the full genetic parents of this child and with whom they will not have any relationship despite being fit and proper persons to be parents.

x. I would strongly recommend the adoption of a judicial pre-authorisation model similar to California or New Hampshire which ensures independent judicial scrutiny of the arrangement, oversight of the voluntariness of all parties, and the prioritisation of the best interests of the child which in almost all surrogacy cases will be to be regarded as the legal child of its intending (genetic) parents from the moment of birth.

xi. Time periods: Head 47 (6) specifies that an application for parental order shall be made not less than six weeks and no later than 6 months after the child's birth. What will this mean in practice? Will a hospital facilitate the intended parents taking the baby following its discharge from hospital? Who will make medical decisions for the child prior to the date on which the application is heard? Head 46 states that in order for the child to live with the intending parents from birth, the surrogate must give her consent but it is not clear whether a hospital would facilitate the intending parents removing the child from the hospital in circumstances where they have no legal relationship to the child. It would be preferable to follow a model such as that in New Hampshire where the declaration of parentage is made prior to birth and there is no doubt regarding the child's parentage

after delivery. This ensures that the child's best interests are prioritised and that custody and care of the child is situated with its intended parents.

4. Payment:

i. Payment of surrogate mothers continues to be an issue that provokes much debate. As proposed in the General Scheme, many countries ban payment to surrogates, which effectively ensures there are not enough women who are willing to become surrogates or that payments are made 'under the counter'. In these countries, surrogates tend more often to be related to or be personal friends of the commissioning couple, and they are willing to go through treatment, pregnancy and labour for their family member or friend. They are only allowed to receive reasonable expenses.

ii. It is important to note that familial relationships can also be emotionally coercive and surrogacy can potentially cause confusion in family relationships later in the child's life unless managed well. For those who do not have a willing family member or friend or for those who would prefer not to involve their families in this way, surrogacy may not be a real option unless they travel to countries such as the Ukraine or another jurisdiction where surrogacy is currently facilitated. Thus, if the aim of the Scheme is to prevent exploitation of women, it does not achieve this objective, it simply ensures that the exploitation does not occur within Ireland.

iii. Although the Scheme does make provision for reasonable expenses to be paid, my concern relates to situations in which this provision is breached. The consequences of transgression are extremely harsh and result in potential criminal prosecution with significant penalties (Heads 36(4) and 86(3)), as well as loss of eligibility to apply for a parental order. (Heads 47(1) and 48(1)). In circumstances in which the intending parents are refused a declaration of parentage and the surrogate mother does not wish to retain custody of the child, what is the outcome for the child? In the absence of a parentage order, the birth mother and her husband will remain the unwilling legal parents of the child. They may abandon the child who then goes into state care awaiting fostering or adoption despite having genetic parents who wish to have care and custody of the child and who may be fit and loving parents.

iv. It is important to note that the fact that they may have paid money to a surrogate mother does not render the intending parents any less suitable to raise their own genetic child and no inferences to that effect should be made. If a court were asked to decide on the parentage of a child in such circumstances, the court would be obliged to prioritise the best interests of the child irrespective of whether the provision relating to payment was breached. The alternative would be unthinkable as it would result in depriving the child of a legal relationship with its genetic parents and placing it in state care. This may be in breach of the child's right to private life and, in particular, the right to personal identity, under Article 8 of the European Convention on Human Rights as demonstrated by cases such as *Mennesson v France*[7].

v. Therefore, in my opinion these provisions of the proposed Bill are deterrent in nature only and will be likely to be ignored in practice. Judges should not be forced to make legally correct decisions that do not promote the welfare of the child, or decisions which,

[7] App no 65192/11 (ECtHR, 26 June 2014). Also *Labasse v France* App no. 65941/11 (ECtHR, 26 June 2014).

to achieve the paramount aim of protecting welfare, circumvent the law.[8] These provisions should be removed from the draft Bill and intending parents should not be precluded from applying for parentage orders in respect of their children. This issue would be avoided if a judicial pre-authorisation mechanism was adopted such as that in New Hampshire as the court would approve payment to the surrogate mother during the pregnancy and make a declaration of parentage before the child is born. Importantly, the Act states that non-compliance will not affect determinations of parenthood. I recommend a similar provision here.

vi. This issue has been the subject of case law in England. For example in *Re X and Y* in 2008[9] which involved a couple who conceived twins with a Ukrainian surrogate mother who was paid £23,000. The High Court ultimately agreed to authorise the payments (notwithstanding public policy against commercial surrogacy) because the intended parents had behaved responsibly, the surrogate had not been exploited and the welfare of the children demanded it as they would otherwise be 'stateless and parentless'. Similarly the case of *Re L* in 2010[10] relates to a commercial surrogacy agreement made in Illinois, USA. Although the agreement was wholly lawful under the law of Illinois, it was unlawful under the 2008 Act in England because no payments other than reasonable expenses are lawful in England and in this case it was clear that payments in excess of reasonable expenses were made. Hedley J said that 'reasonable expenses' remains a somewhat opaque concept. The approach he adopted is to treat any payment described as 'compensation' (or some similar word) as prima facie being a payment that goes beyond reasonable expenses. He stated that he must weigh the balance between public policy considerations relating to payment and the child's welfare decisively in favour of welfare. He said "It must follow that it will only be in the clearest case of the abuse of public policy that the court will be able to withhold an order if otherwise welfare considerations support its making."

vii. I submit that these provisions should be re-considered in light of the case law above as the same difficulty will arise in Ireland where a couple seek a declaration of parentage in circumstances where more than 'reasonable expenses' have been paid. Irish law should learn from the mistakes of other jurisdictions which have attempted to criminalise intending parents who have a child through surrogacy. Such an approach will drive surrogacy underground or abroad, a result which is clearly not in the best interests of children. If the government really wishes to pursue a child-centred policy in relation to surrogacy, then a more realistic regulatory framework is required which attempts to encourage Irish intending parents to enter regulated surrogacy agreements in Ireland subject to appropriate regulation and protections for all parties involved, particularly the child. I submit that the legislation in New Hampshire provides a clear, effective and appropriate model in this regard.

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[8] Surrogacy in the UK, Report of the Surrogacy UK Law Reform Project https://www.kent.ac.uk/law/research/projects/current/surrogacy/Surrogacy%20in%20the%20UK%20Report%20FINAL.pdf page 6

[9] [2008] EWHC 3030 (Fam)

[10] [2010] EWHC 3146 (Fam)

25: Professor Martin Clynes

Information about person making the submission

Martin Clynes B.Sc, Ph.D. is Emeritus Professor of Biotechnology at Dublin City University, and until 2015 was Director of the National Institute for Cellular Biotechnology at DCU.
He is author or coauthor of over 200 peer reviewed papers and 3 books in cell and molecular biology.He has supervised more than 70 Ph D.s to completion in these areas of biology.
He has a particular interest in cell culture as applied to cancer, diabetes and ocular disease research and in the technology and Ethics involved in Assisted Human Reproduction, Stem Cells, Gene Therapy and related technologies
Information on his research is available at www.nicb.ie or by inputting Clynes M into the U.S. National Institutes of Health on-line library, Pub Med (Google search for Pub Med, no password needed)

INTRODUCTION

The draft document for the Assisted Human Reproduction Bill 2017 is, in general, excellent and comprehensive and this legislation is urgently needed

However, writing as a scientist who has been monitoring the scientific developments and regulatory and ethical debate around the AHR area for many years, I want to draw your attention to a few areas where I believe the Bill needs to be refined or improved

Broadly my comments relate to:

Access to information for children resulting from donor gametes or surrogacy

Use of embryos in research and related topics

Embryonic Stem Cells

Induced pluripotent stem cells

Mitochondrial replacement and Gene Editing

Some new developments not covered in the Bill

1. PART 2–GENERAL PRINCIPLES AND STATUS OF THE EMBRYO

The Bill quite properly seeks to give priority to the interests of children born as a result of AHR, and alsoto respect the interests of parents, donors, surrogates and society in general. **It unfortunately omits reference to the interests of the embryos generated in vitro by AHR processes**.

Please note that I am in favour of availability of IVF to parents for whom this is the best option, and I accept that at the moment that, in the use of this technology, there will inevitably be some unused or supernumerary embryos, and some loss of embryos. However, the status of embryos as human beings has to be carefully considered.

Each embryo is a unique human individual, Eggs and sperm are not individuals – they can be considered as body parts, the property of their parents.
Once an egg is fertilised by a sperm, however, you have for the first time the complete DNA programme or blueprint or instruction manual, half from each parent, but now together in one cell, that fully specifies the new individual. In a marvel of self-assembly that one cell goes on autopilot, reading the instructions coded in its DNA, developing to become a fully formed baby in eight or nine months.The early embryo is part of the whole life story of every individual.
The fact that the embryo is a new unique individual human is a scientific fact, not a matter of opinion (although that fact was fully understood only as we came to understand the role of DNA as the code for life, in the 1950s, and it still hasn't percolated into the general consciousness of society, partly because we can't see DNA or embryos , so for many people their reality remains difficult to grasp – nevertheless it is true)

People sometimes introduce the concept of "personhood" and define away the rights of the embryo by citing characteristics like self-awareness, feeling pain etc– but the fact is that our mental construct of personhood is built around adult characteristics – it is a pre-scientific concept built on Greek and Roman Philosophy from more than two millennia ago and really applies only to older children and adults, and how these philosophers saw them differing from animals and inanimate objects..

In AHR/IVF we have used technology to bring these new unique human individuals into existence: I suggest to you therefore that the State and society as a whole have a duty of care to protect them. Ignoring this fact, as the current draft largely does, may indeed be convenient, and make it easier to draft regulations now - but it doesn't make the problem go away. If you ignorereality and science now, it will come back to biteour society as the field develops and becomes more complex. It is really important to get the basic principles right in the first piece of legislation– otherwise as the field develops we will be drawn into an ethical quagmire.

Can I emphasise that this is a separate issue from the abortion debate?
When an embryo is growing within the mother's womb, legislation has to consider the rights both of the mother and of the unborn child, which are sometimes in conflict – hence the current abortion debate.
(If the embryo were not a human individual there would be no clash or rights and nothing to debate about).
In AHR, in contrast, we have complete power over the embryo, in a culture dish or a freezer, and no competing maternal rights arise until the embryo is implanted in a woman's womb.

Society therefore has a duty to protect these embryos, as they are human individuals. I accept that it is inevitable that some embryos will die in the IVF process as a whole, but I submit that this should be minimised insofar as is possible , and that this should be among the core principles of the Bill, along with Children's rights, Parents' informed consent etc

Finally, may I make a legal/scientific point which I believe is often misunderstood. I followed the case of Roche vs Roche with interest, and indeed I was called as an expert witness for Mrs Roche. The High Court, subsequently confirmed by the Supreme Court ,ruled that the term "unborn" in the 8th amendment did not cover IVF embryos in vitro, and that Constitutional protection for the embryo came into effect only following implantation in the wall of the mother's womb at about day 14. But the judgement was at pains to point out that the Judiciary were deciding on that point of constitutional law only. They were making no judgement on whether or not IVF embryos should have legal or constitutional protection. I submit to you, as outlined above, that Science, through our knowledge of DNA, has the clearest answer to that question = a very clear YES.

2. PART 3 - GAMETE AND EMBRYO DONATION

As discussed in no. 1 above, an IVF embryo, is clearly, by any scientific criterion,, a new human individual.

I therefore suggest that the proposed legislation should be modified as follows:

adoption of embryos

1. If the parents decide that they do not wish to use all of their frozen embryos, then these embryos should be available for adoption and parental consent should not be necessary. Eggs and sperm are body parts and are properly described as the property of the female and male donors respectively. In contrast, once the embryo is formed, it is a human individual in its own right and cannot be considered as the property of the parents. The concept that any human being could be the property of another would be a reversion to slavery and additionally contravene the recent change in the Constitution in relation to Children's rights. Of course, the parents have first call on implantation and storage, but if they do not wish to pursue such an option, the remaining embryos must ethically be available for adoption.

destructive embryo research

2. For the same reason I propose that it is unethical to allow frozen embryos to be used for research, including research to generate embryonic stem cells. Destructive research on embryos should not be permitted: nor should research on embryonic stem cells. Early human embryos are already new human individuals. It is unethical to consider them as objects, (as might be legitimately the case for eggs and sperm with donor consent), which can be destroyed at will for research purposes.

It could be argued that if unused they will die anyway, but you could make the same arguments for lethal experiment on patients with dementia , and these would obviously be completely unacceptable – I submit that we just don't have any right to destroy another human individual, and long-term cryopreservation in a properly monitored freezer (as would be used to store embryos intennded for implantation) seems to me to be the only respectful option, and a minor additional cost for a lucrative industry. Perhaps a future generation will have an answer to this problem of how to deal ethically with these embryos. We don't really have such an answer now.

Egg freezing is ethically preferable to embryo freezing

3. While recognising that embryo freezing may need to continue for some time, I suggest that the regulations should encourage egg freezing rather than embryo freezing as a route to allow repeat implantation if the first attempt is not successful. This approach reduces the number of human embryos generated with the associated ethical dilemmas and problems. Using newer freezing approaches such as vitrification, the efficiency of IVF using egg freezing is improving constantly and approaching equivalence to embryo freezing.

Leftover ova can be donated to other couples, used for research or even discarded, if neither of the previous 2 options is appropriate in a specific case, without serious ethical problems

3. PART 5 - PRE-IMPLANTATION GENETIC DIAGNOSIS AND SEX SELECTION

I suggest that this section of the Scheme requires some modification to respect the humanity of the embryos, including those with a 'debilitating disease'. It is better to screen gametes than embryos whenever that is possible.

I accept the need and intent of the section, although I suggest that the term on p.79 "a high risk of shortened life expectancy" needs to be changed significantly to something like "a very high risk of death before 6 months of age" – otherwise it could be used to screen out people with likelihood of/genetic predisposition to eventually developing a disease like muscular dystrophy or cancer but who can potentially enjoy many years of life.

Screening of eggs or sperm carrying disease or without required HLA markers does not pose ethical problems. Screening of embryos does, because it involves rejecting many embryos..

Therefore, I suggest the text of the Bill should permit testing of embryos only where effective screening of sperm and ova is impossible (although currently this is the case for many tests, the situation is likely to change with advances in analytical technology).

For the reasons outlined in the previous section, I suggest that embryos which fail screening should be stored, not used for destructive research or discarded

4. PART 6 - SURROGACY, ACCESS BY CHILDREN TO INFORMATION ON DONOR AND VICE VERSA

I think that some additions are necessary in relation to the proposed Register and how it is used in several ways:

1. The new Agency should have an obligation to inform the child on reaching age 18, in relation to the information that it holds about the child and the donor. The agency should not await an application from the child who might not even be aware that a donor was involved. It is essential that the children have this information in order to limit the risk of half-sibling mating, and in order to have maximum information on their biological parents' medical histories.

2. The donor should have an obligation to provide a detailed medical history and family medical history which should be deposited anonymously but with reference number in the Register , and systems should be in place to facilitate and encourage updating of health information through the Donor's lifetime.

3. The donor should have a reference number which will be disclosed to the child; this would allow two children of donations, who might be contemplating having a child together, to check more easily if they have a common donor.

4. While the anonymity of both child and donor must be protected, unless voluntarily surrendered, the agency should have the duty to pass on in either direction requests for information, and requests to meet.

5. PART 7 -EMBRYO AND STEM CELL RESEARCH

Embryonic stem (ES) cells and induced Pluripotent stem (iPS) cells

Embryonic stem cells are derived by destroying living human embryos. It is therefore unethical to make such cells and I would also argue that use of the cells should not be permitted by law either, since such use inherently encourages the destruction of further living embryos.
As well as being unethical, research using human embryonic stem cells is not necessary. It is becoming increasingly clear that most and probably all information that could be derived from research using ES cells could equally well be obtained from research using iPS cells

These Human pluripotent (embryo-like) stem cells (hiPSC) can be obtained by relatively simple genetic manipulations in culture of adult tissues,and since no destruction of a human individual is involved, they do not carry the same ethical challenges. They seem to have the same or very similar potential as embryonic stem cells for treating disease, although this is still very much a research goal and widespread application of either type of stem cell in the clinic is still quite a time away – the field was greatly overhyped in the early years of this century.

Also please note that in spite of all the promises made over the past 20 years about cures for diseases from embryonic stem cells **all currently approved stem cell treatments use adult stem cells, not embryonic stem cells.**

iPS cells (Induced pluripotent stem cells) should not in general be dealt with in this Bill

I suggest that induced pluripotent stem cells should not come under the terms of this Act at all, except if they are to be used to generate embryos in vitro, which should be prohibited under this act, for the same reasons that generating embryos for research is prohibited

My reasoning for proposing this is as follows:

1. IPS cell technology has nothing to do with assisted human reproduction and therefore is not properly a topic to be regulated by this act. There is no father, no mother, no donors, no fertilization. IPS cells are simply the creations of technology starting with adult cells.

2. Making iPS cells involves inserting certain genes into adult human cells which reprogramme the cells to behave like early embryonic cells. These reprogrammed cells can then be used in research to study how pluripotent stem cells develop into different tissues of the body.
As far as clinical applications are concerned, the iPS cells also have the potential, like embryonic stem cells, to be developed into making replacement tissues for transplantation.

3. The research use of the cells does not require any further regulations. It is straightforward biological research. The clinical applications and transplantation are already covered by a variety of European and national laws and regulations (e.g. Tissue Directive) and would have to be done under license by the HPRA. It will only complicate matters to have dual legislation with the cells if it is also regulated under the Assisted Human Reproduction act.

4. Including IPS cells in the act(other than to ban any attempt at creation of human embryos using iPS cells) would be an unnecessary barrier to research and because of the position of the HPRA in regulating clinical use, further coverage in the act is duplication and will be unnecessary and irrelevant. The only relevant statement that could be included in the Act would be to say that the use of iPS cells to produce Human Embryos is prohibited.

Mitochondrial Replacement and Gene Editing

The prohibition on mitochondrial replacement and Gene Editing is indeed appropriate on safety grounds given our current state of knowledge.

The field is moving rapidly, however, and it might be appropriate to indicate that the prohibition might be amended if international studies demonstrated safety (in particular for the children) and ethical rules were not breached (e.g. in some forms of mitochondrial

transfer two embryos are created, one to be destroyed; this form of mitochondrial replacement should not be allowed)

I also suggest that it might be stated that Gene Editing of somatic cells and the germline to eliminate a deleterious mutation could, subject to proof of safety, be permitted,

but not for "enhancement" or similar purposes.

IF this technology develops and is shown to be safe in such circumstances it would be a pity to deprive families harbouring genetic diseases of the opportunity to remove the harmful mutations from their germlines.

6. NEW DEVELOPMENTS

The whole field is developing rapidly

Even in the week when I was writing this submission, two new important papers were published, one showing how human eggs could be matured in culture prior to fertilisation;

Another showing extended life in an artificial womb for premature lambs

It might be useful if the act referred to such developments in a general and indicated that some may fall under the remit of the HPRA, others in the remit of the new AHR Agency, or possibly some potentially under both agencies, with jurisdiction decided on a case by case basis.

JCH 404

PI-001 Rev 2

REPROMED
Fertility Matters

ReproMed Ireland
5th Floor Northblock
Rockfield
Balally
Dundrum
Dublin 16

February 15th, 2018

Joint Committee on Health
Leinster House
Kildare Street
Dublin 2

Re: Submissions to The Joint Committee on Health regarding the General Scheme of the Assisted Human Reproduction Bill 2017

Dear Sir/Madam,

I write to you as a healthcare professional who has served for 25 years the sub-fertile population in Ireland. My representation herein is on behalf of all Clinics in the ReproMed Group which are licensed in Ireland by the HPRA to provide Assisted Human Reproduction (AHR). These include my clinics in Dublin, Kilkenny, Limerick, Cork, and Galway.

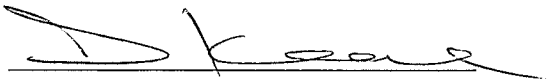
The recently published draft legislation governing the activities of those of us who operate licensed fertility clinics is worrying to me because it lacks insight on a number of levels. I offer my availability to consult with the Oireachtas Health Committee on this important body of work. I believe this call by the Oireachtas for communications is timely offering an opportunity to deliver a better format of the proposed legislation.

The introduction of legislation with fine details of permitted clinical practice stated in the body of the Act is inappropriate. Minutiae should be reserved for operating guidelines to be regularly updated and regulated by the Assisted Human Reproduction Regulatory Authority (AHRRA). The rationale for this suggestion is that the medical field of Reproductive Medicine and Endocrinoly, and associated research is evolving very rapidly. Technologies, diagnostics, treatments and success rates are dynamic and ever improving. To nominate restrictions and standards in legislation hampers the ability of our proposed regulatory system to evolve without protracted legislative delays. It would be better that rules and regulations are

introduced through the AHRRA which could be more readily updated by consensus if and when required.

I realise that suggestions at this advanced stage of drafting the Bill are going to require review of the wording and format of the proposed legislation. I urge that you pause and take stock of the recent submissions to the Joint Health Committee on the General Scheme of the Assisted Human Reproduction Bill 2017 by the Irish Fertility Society, and Institute of Obstetricians and Gynaecologists. I have seen both of these submissions and believe these represent the general consensus of the majority of interested parties in Ireland. Please enter into a consultative process with AHR service providers such as my Group to produce much more productive legislation which will better serve our society, patient population and service providers.

Yours sincerely,



Declan Keane
MSc MBA CSci MIBMS
Director and Senior Clinical Embryologist

February 7, 2018

Submission to the Joint Oireachtas Committee on Health

We refer to the General Scheme of the Assisted Human Reproduction Bill. Our particular concern is what the provisions relating to surrogacy.

Our organisation, Stop Surrogacy Now, is an international movement consisting of women and men of diverse ethnic, racial, religious, cultural, sexual orientation and socio-economic backgrounds from all regions of the world. We are not a religious organisation, many of our members are not religious, and many of us come to this issue from a feminist perspective.

A few of our notable leading signatories are:
Sylviane Agacinski, Feminist philosopher, France
Kajsa Ekis Ekman, author of *Being and Being Bought: Prostitution, Surrogacy and the Split Self,* Sweden
Dr. Renate Klein, FINNRAGE, Australia
Gary Powell, LGBT activist and campaigner, U.K.
The Swedish Women's Lobby, The European Women's Lobby and LeCorp

We come together to voice our shared concern for women and children who are exploited through surrogacy contract pregnancy whether commercial or non-commercial. We ask that Ireland join with other countries [LIST A FEW] in prohibiting surrogacy in all forms.

Together we affirm the deep longing that many have to be parents. Yet, as with most desires, there must be limits. Human rights provide an important marker for identifying what those limits should be. We believe that surrogacy should be stopped because it is an abuse of women's and children's human rights.

Surrogacy often depends on the exploitation of poorer, minority women. In many cases, it is the poor who have to sell and the rich who can afford to buy. These unequal transactions result in consent that is under informed if not uninformed, low payment, coercion, poor health care, and severe risks to the short- and long-term health of women who carry surrogate pregnancies.

The medical process for surrogacy entails risks for the surrogate mother and the children born via the assisted reproductive technologies employed. Children born of assisted reproductive technologies,

which are usually employed in surrogacy, also face known health risks that include: preterm birth, stillbirth, low birth weight, fetal anomalies, and higher blood pressure. A surrogate pregnancy intentionally severs the natural maternal bonding that takes places in pregnancy-a bond that medical professionals consistently encourage and promote. We believe that the practice of commercial surrogacy is indistinguishable from the buying and selling of children. Even when non- commercial (that is, unpaid or "altruistic"), any practice that subjects women and children to such risks must be banned.

We stand together asking national governments of the world and leaders of the international community to work together to end this practice and Stop Surrogacy Now.

The Stop Surrogacy Now Coalition
100+ Original Signers (see http://www.StopSurrogacyNow.com)
6,600+ additional signers from 160+ countries
Leading NGO signatories who represent tens of thousands of members

GENERAL SCHEME OF THE ASSISTED HUMAN REPRODUCTION BILL

COMMENTS AND RECOMMENDATIONS CONCERNING DONOR-CONCEIVED CHILDREN

By the Iona Institute
and Dr Joanna Rose

'Science has given us something new: families that are designed, from the start, to have only a single parent; to have quite a few parents; to have two parents, only one of whom is biologically related to the child, the other of whom is not biologically related, with a third party out there who is biologically related, but often, unknown...parental roles are being divided up and divvied out, outsourced and re-shuffled and even deleted.'

Lisa Mundy, 'Everything Conceivable: How Assisted Reproduction is changing men, women and the world', p.96

'Should science do everything that science can do?'

Prof Dervilla Donnelly, Chair of the Commission on Assisted Human Reproduction, Commission on Assisted Human Reproduction Report, p.11

Introduction

THIS submission on the General Scheme of the AHR Bill has been written with the help of Dr Joanna Rose. Dr Rose is herself donor-conceived and has campaigned in the UK for the rights of donor-conceived people such as herself to have their rights to genetic kinship and identity properly protected under law. She won a landmark case in the British courts that brought an end to anonymous egg and sperm donation.

As the quote from Lisa Mundy above indicates, when Assisted Human Reproduction (AHR) uses donor eggs, sperm and embryos in order to help individuals wishing to have children, we are embarking on what amounts to a massive experiment with the lives of children.

The General Scheme overall is incredibly complex and far-reaching. We could comment on the use of embryos for research, on surrogacy, on posthumous conception, on the creation of 'saviour siblings' for the express and totally instrumental purpose of harvesting stem cells and bone marrow from them for the purpose of helping an ill sibling.

For the purposes of this submission, however, we will restrict ourselves solely to the issue of donor gametes and the ethical implications of donor-conception, especially for the children thus conceived.

Donor-conception and the devaluing of the natural ties

Donor-conception, by its very nature, devalues the importance of the natural ties and the General Scheme very much goes along with this, paying only scant regard to them.

It allows that only one 'intending parent' should have a biological link to the child. They can do so by gestating the child in their own womb, or by providing a gamete. As an example, a single man

availing of AHR would have to provide his own sperm. He would have to then find a woman willing to provide him with an egg and another willing to carry his baby (the surrogate mother).

This resultant child would be raised by his or her natural father, but the tie to the other biological parents, namely the genetic mother (the egg donor), and the birth mother (the surrogate) can be cut with the full blessing of the law.

The proposed Bill does abolish anonymous gamete donation, but by the time the child is 18, what is the likelihood that the child, now an adult, will ever have a proper relationship with his or her sperm donor father or egg donor mother? This will be especially the case if the donor is from overseas, which is quite likely. Sperm used in Irish clinics tends to be imported from Denmark. (See "Ireland's IVF children: an identity crisis?", Irish Times, July 22, 2017).

This willingness on the part of the proposed law (and the Children and Family Relationships Act before that), to see the natural ties cut is quite remarkable given what we now know about the lengths adopted children – no matter how well loved they were by their adoptive parents – often go to find their natural parents, especially their mothers.

But adoption differs from donor conception (or 'Donor-Assisted Human Reproduction' (DAHR) as it is also called) in one very crucial respect. In the case of adoption, the natural tie has been broken by circumstance in most cases. With DAHR it is broken by deliberate design.

The proposed Bill seems to have learnt almost nothing from the experience of many adopted people in their search for their genetic kin. For the reasons already given, the prohibition on anonymity will amount in many cases to little more than a nod to the natural ties.

In addition, we are now in a position to learn from the experience of donor-conceived people themselves, many of whom are now adults. As with adopted people, many never go looking for their genetic kin, but many do, and their experiences must be seriously considered. Some donor-conceived people are against all donor-conception.

Given how little importance the General Scheme gives to the natural ties, can it really be said that the General Scheme has the 'best interests' of children at heart?

Adult autonomy view underlies the Scheme

Indeed, far from having the 'best interests' of children at heart, it would seem that what is really to the fore in the Scheme is the wishes and desires of 'intending parents.'

The use of the term 'intending parents' is very telling in this regard. Throughout the Scheme, the 'intending parent' is given far greater standing than the biological parents (the gamete and embryo donors). It is the person who wishes to be a parent who counts, not the natural parents.

This is extremely adult-centred. The natural parents are not considered by the proposed law to be the parents unless they intend to be. The child may have an entirely different view, of course, which is the case with many donor-conceived children. They might well regard their natural parents as their parents, whatever those parents, or the law, intended. The natural parents of a child *are* its parents, no matter what the law says, or what the intention of the adult(s) is.

We can also see how adult-centred the Scheme is by the way it treats the issue of family structure, that is the form of family the child will be raised in. Will the child be headed by a married opposite-

sex couple, a married same-sex couple, a cohabiting couple (opposite-sex or same-sex), a single man, or a single woman?

The underlying philosophy of the Scheme is that the number of parents, the sex of the parents, and whether they are married or not, is entirely irrelevant to the welfare of the child. This is quite aside from the issue of deliberately cutting the natural tie to at least one parent, which donor-conception also inevitably involves and the identity issues this can create.

Our overarching recommendation:
minimise the damage to children caused by deliberate disruption of genetic kinship ties

We take the view that family structure matters (we can provide supporting material for this claim if called on). We also take the view that the natural ties matter far more than the General Scheme allows.

However, we realise that in these two respects, the die appears to be cast. Therefore, the recommendations that follow seek to minimise the possibility that donor-conceived children will suffer in the future from having their genetic kinship ties deliberately disrupted and kept hidden from view until at least the age of 18.

We hope the Health Committee will look seriously at our recommendations, which put the interests of donor-conceived people, not intending parents, to the fore.

The recommendations that follow are not exhaustive, but if implemented, they would have the effect of at least lessening the damage that will be caused to some children by having their genetic kinship ties deliberately disrupted, something that is facilitated and permitted by the proposed AHR law and by the Children and Family Relationships Act.

Recommendations

- **Counselling**

Those wishing to avail of donor-conception, and those who wish to donate gametes should be required to receive counselling. The counselling should be independent of, and if need be paid for, by the AHR clinics. There is too much of a conflict of interest if the clinics both pay for and provide the counselling.

The counselling should discuss not only infertility issues, but the identity issues many donor-conceived children will in the future face. Prospective donors should be informed about the possibility that in the future their donor offspring may seek to make contact with them and wish to form a relationship.

- **Tracing genetic kin**

It must be made as easy as possible for donor-conceived children to find their genetic kin, both their genetic donor-parents and genetic half-siblings. It must be borne in mind that one sperm donor can have many children, both in Ireland and overseas. Donor-conceived children should be enabled to trace their genetic kin both in Ireland and overseas. This should be the responsibility of the Assisted Human Reproduction Regulatory Authority (AHRRA).

- **Assisting existing donor-conceived people**

While the proposed Bill will end donor anonymity, it does not do so retrospectively. The AHRRA should help donor-conceived people to trace their genetic kin (which is to say, their natural families), and also provide counselling where necessary. Although adoption in the past was closed, great efforts are made to help parents and children find each other.

- **Use the term "donor parent", instead of "donor"**

The term 'donor' on its own does not properly capture the genetic relationship of the donor to the child created via the donated gamete. It would be better to use the term 'donor parent', or even better, 'donor mother' or 'donor father'.

- **Use the term "gestational mother" or "birth mother" instead of "surrogate"**

Similarly, the term 'surrogate' doesn't properly capture the vital role of the surrogate in the child's life. It would be better and more accurate to speak of "gestational mother' or even 'birth mother'.

- **Use the term 'intervention' instead of 'treatment'**

To speak of fertility 'treatment' implies that the infertile person will be cured. Sometimes those presenting to AHR clinics for donor-conception will not be infertile at all. A single man or woman, for example, wishing to have a child via DAHR is likely not infertile as such. They can provide an egg and/or a womb, or sperm. But they need someone else's womb or gamete to have a child. 'Treatment' here is a misnomer. A better word might be 'intervention'.

- **Minimum age of the donor parent should be 25**

Donating a gamete that may result in a child is a profound act that must be properly understood in all its implications. For this reason, a donor must be mature enough to grasp these implications and therefore we recommend a minimum age for a donor parent of 25.

- **Limit on number of families created by a single donor parent should be four worldwide**

The Scheme says the number of families created via one donor parent should be four. This limit must apply to families created in other countries as well, so the number is four in total. The genetic kinship networks of a donor-conceived child should not be overly complex and members of that network too difficult to trace. Ensuring this limit is adhered to should be the responsibility of the AHRRA, working with the clinics.

- **Prohibition on gamete donation from close family members is too narrow**

'Close family members' in the Scheme refers to those very closely related by blood. It does not exclude other blood relations, for example first cousins, or relations by marriage, for example, brothers and sisters-in-law. If the sperm of a brother-in-law was used, the "uncle" of the child would, in fact, be the biological father.

Is it fair on the child that the one person is both the 'uncle' and the biological father of the same child? It is unprecedented in human history to deliberately blur the roles of the different members of a family in this way and therefore the definition of 'close family members' needs to be broadened to include members by marriage as well.

- **It must be ensured that gametes obtained from overseas have been not commercially purchased**

The Scheme proposes to prohibit paying gamete-donors commercial fees, paying them only 'reasonable expenses' instead. It will have to be ensured that 'intending parents' or clinics have not paid commercial rates for eggs or sperm obtained from overseas. This should be the responsibility of both the clinics and the AHRRA.

- **Intending parents, like donors, should undergo a health check**

Donor parents are required to receive a health check. So should intending parents to ensure they are healthy enough to raise a child. They should also undergo a psycho-social assessment in the same way as would-be adoptive parents.

ENDS

Submission on General Scheme of the Assisted Human Reproduction Bill 2017

About TENI

TENI is a non-profit, non-governmental organisation supporting the trans community in Ireland. TENI seeks to improve the situation and advance the rights and equality of trans people and their families. Our vision is an Ireland where trans people are understood, accepted and respected, and can participate fully in all aspects of Irish society. Despite recent advances, Ireland remains a place where it can be difficult for trans people to lead safe, healthy and full lives. TENI is dedicated to ending transphobia, including stigma, discrimination and inequality and continues to advocate for social, political and legal recognition of trans people in Ireland.

Gendered Language

Instances in the Bill where gendered language may exclude trans people in the Assisted Reproduction Bill 2017:

- Head 2 – Interpretation
- Head 6 – Provision of AHR Treatment
- Head 10 – Embryo Transfer
- Head 16 – Limits on the use of donated gametes and embryos
- Head 24 - Posthumous assisted reproduction (PAR) procedures involving gametes or embryos
- Head 27 - Recognition of the deceased person as a parent of the child
- Head 35 – Interpretation
- Head 38 – The surrogate
- Head 39 – The intending parents
- Head 41 – Surrogacy agreements and reasonable expenses
- Head 61 - Prohibition of modification of the human genome

Individuals who have accessed the Gender Recognition Act 2015 may not fulfil definitions of the terms woman and man contained within the legislation. This may prevent them accessing necessary health and reproductive care. It is imperative when looking at reproductive care that trans people who have accessed gender recognition are also covered by the full breadth of the legislation.

By using the terms woman and man, legally recognised men and women are excluded from the rights afforded to pregnant people in this legislation. It is also assumed that a surrogate is female.

TENI recommends that provision be made within the legislation to ensure that explicit references to ‘woman’ or ‘women’ in the context of assisted human reproduction should be amended to ensure the inclusion of any individual who may become pregnant.

TENI recommends that the Minister ensures the Bill is inclusive of all trans people and that legislative provisions ensure full access to reproductive care as necessary.

Discrimination and Equality Proofing

Head 17 (1) - Access to gamete and embryo donation for AHR purposes.

> "Access to gamete donation for use in AHR treatment procedures shall be permitted for people irrespective of their gender, marital status or sexual orientation where the AHR treatment procedure is provided in accordance with the provisions of Part 2 of this Act."

TENI recommends that the term 'gender' in paragraph (1) is ammended to include gender identity, gender expression and sex characteristics.

• "gender identity" refers to each person's internal and individual experience of gender, which may or may not correspond with the sex assigned at birth, including the personal sense of the body (which may involve, if freely chosen, modification of bodily appearance and/or functions by medical, surgical or other means) and other expressions of gender, including name, dress, speech and mannerisms;

• "gender expression" refers to each person's manifestation of their gender identity, and/or the one that is perceived by others;

• "sex characteristics" refers to the chromosomal, gonadal and anatomical features of a person, which include primary characteristics such as reproductive organs and genitalia and/or in chromosomal structures and hormones; and secondary characteristics such as muscle mass, hair distribution, breasts and/or structure.

30: Virus Health

Introduction

Our submission is the work of a multi-disciplinary team, comprised of doctors, embryologists, nurses and compliance specialists, all actively working in fertility.

As a group we welcome the introduction of legislation that extends beyond the technical regulations for the laboratory set out in the EU Tissue and Cell Directive. We recognise the importance of the legislation and look forward to establishing a relationship with the future regulating body.

We are confident that the storage requirements for gametes and embryos, the guidelines for genetic testing, the Welfare of the Child provision and other parts of the Bill will greatly improve patient experience, and are in keeping with the aim of the act; to safeguard "the health and wellbeing of children born as a result of such treatments and to women who receive such treatments."

We do however have a duty of care to our patients, and believe that certain aspects of the legislation may have consequences for their treatment and their future families. We have outlined the points in the following document and ask that they be taken into consideration prior to approval of this Bill.

We have also included a number of points where we would like clarification, to ensure not only our compliance with the legislation, but also that the best and most appropriate treatment options are available to patients.

Our response is presented in accordance with the sections of the Bill, and headings and subsections have been included accordingly.

Part 1 Preliminary & Part 2 General

A service provider is referenced as a "person" rather than a clinic. We would request clarification of who exactly will be licenced.

Head 6

This provision excludes potential candidates from non-medical (social) egg freezing as there is no reasonable expectation of subfertility in this group.

Subsection 2(b)
We would request clarification of the national standards in relation to disproportionate risk of health of the woman or child. We would be supportive of a multi-disciplinary case by case review of high risk patients to determine and counsel them regarding the risks of AHR and pregnancy so they can make an informed decision regarding their care.

Subsection 2(c)
We are supportive of the welfare of the child provisions and welcome the planned guidelines and instructions.

Subsection 3
We would strongly advise that the age for treatment is reduced to 18, the legal age of adulthood in Ireland.

Subsection 4
It is our belief that limiting treatment to patients 47 years or younger is discriminatory. In keeping with international practice and UK guidelines we would suggest that the age limit is determined by the age of natural menopause, which is 50.6 years. It is worth noting that 153 patients over the age of 47 years in the last 5 years have attended Sims for egg donation treatment. 50% of those patients achieved a pregnancy as a result of treatment. Notwithstanding the children who would not have been born had this legislation been in place at that time, even the unsuccessful couples would have been denied their constitutional right to attempt to have a family. We feel strongly that this is the most punitive aspect of the proposed legislation.

Subsection 5
The restrictions on treatment for men are unclear and may prove difficult to enforce. Without clear guidelines for approving or refusing treatment the intention of this statement may not be enacted. This restriction will significantly impact on oncology patients and their potential treatment.

Head 7 Welfare of the Child
We are in agreement with the approach put forward in the general scheme

Head 8 Counselling

We understand and accept the guidelines established for counselling and will work to facilitate the requirements in the near future.

We do have some concerns over the mandatory nature of counselling which many patients do not wish to undertake. We are very supportive of the role counselling plays in the provision of AHR but feel that this should be encouraged and patient directed, not mandatory.

Head 9 Consent
We would like to request clarification regarding the use of embryos for training purposes as opposed to research. Does the term research as used in the bill include the use of gametes and embryos for training?

It is stipulated that written request is required to revoke consent; we would like to confirm that treatment may be delayed on receipt of a verbal request.

Head 10
We are very supportive of the move towards single embryo transfer but are happy that there is scope for individual assessment for each patient depending on their circumstances and needs.

Part 3 Gamete & Embryo Donation

Head 12
Embryo Donation: for surplus embryo donation the embryo donors would not have undergone the level of screening required for donation under the statutory instruments.

Subsection 1(b)
This section provides a minimum age of 18 to be a donor. We are requesting clarification as previous sections required the patient to be 21 to engage in any AHR treatment.

Subsection 3
We would like to request clarification regarding the use of embryos for training purposes as opposed to research. Does the term research as used in the bill include the use of gametes and embryos for training?

Head 13 Embryo Donation for the use of AHR or Research

We would like to seek clarification regarding the creation of embryos solely for donation. Is this prohibited? We understand that supernumerary embryos may be used for the treatment of infertile couples where both donor egg and sperm are needed and can also be used for same sex female couples where there is also a need for an egg donor. Given that there is provision for double donation in these circumstances then we would propose that "double donation" (both egg and sperm donation) be facilitated for those couples who would remain childless without such a resource.

Head 16 Limits on the Use of Donated gametes and embryos

Subsection 4(a)

This section stated it is prohibited to use sperm provided by more than one man per treatment cycle. Does this apply if oocytes are separated at retrieval and fertilised in separate dishes, with only embryos from one dish transferred per cycle? In this instance traceability is fully maintained throughout the cycle and intending parents would be aware if a child was conceived using partner or donor sperm.

Subsection 5(b)

Embryos created can no longer be used in the event of the death of the donor. We feel strongly that as donors can't withdraw consent once embryos have been created, embryos created should be suitable for use following the death of the donor.

Head 17 Access to Gamete & Embryo Donation

Subsection 3(a)

We believe that this subsection is discriminatory to men as it does not provide for the use of a surrogate, restricting their treatment options.

Head 19 Non-commercial Gamete & Embryo Donation

We would suggest that reasonable expenses for the donor be extended to include compensation for loss of working hours where appropriate.

Head 21 Disclosing Medical Information

We feel this section provides clear guidelines for all medical practitioners, and will be beneficial in ensuring appropriate care is provided.

Head 22 Storage of Gametes & Embryos
We are supportive of this provision, and agree that storage limits are a necessity. We would like clarification regarding the application of this provision; will it be applied retrospectively? If these limits are applied to existing embryos and gametes will the time frame begin from the date of freeze/creation or from the date the provision becomes law?

Subsection 9
We would like a definition of reasonable efforts to contact a patient; the number of attempts and the methods required to be considered reasonable.

We are also requesting clarification of the extension period. Will it be a standard length, e.g. 5 years? Can patients apply for more than one extension or will extensions be limited?

Will the same timelines apply to oncology patients or will an extended storage period be available to them without application?

Part 4 PAR

Head 24

Subsection 1(b)
We are concerned that this may be discriminatory towards male patients seeking treatment as it states the surviving partner must carry the pregnancy. This does not allow for surrogacy in the event the surviving partner is male.

Subsection 1(d)
We would suggest that the automatic one year delay to treatment is overly prescriptive. We would prefer to see treatment available to the patient once they have received appropriate counselling and clearance from a qualified counsellor**.**

Head 27
This provision states the surviving partner must carry the pregnancy. It does not make provisions for surrogacy in the event the surviving partner is male.

Part 5 PGD

We are accepting of the guidelines provided and believe the matter has been addressed sensitively and thoroughly.

Part 6 Surrogacy

Head 36
We would like to confirm that clinics will not be able to facilitate patients who request the shipment of their embryos abroad for the purposes of surrogacy. Does this mean that the only option available to patients is domestic surrogacy?

Does this also prohibit the routine fertility testing of couples thinking of travelling abroad for surrogacy if such an option is not available to them in Ireland, e.g semen analysis, or blood tests?

Does this also prohibit AHR providers from giving information to couples about surrogacy options abroad?

We would ask if there is any exceptions considered for oncology patients where a domestic surrogate is not available. Will this provision be replied retrospectively to oncology patients who have created embryos and plan to travel abroad for the purposes of surrogacy?

Head 42 Advertisements for Surrogacy
Given the other requirements set out in the legislation such as the prohibition of commercial surrogacy we do not understand the restrictions on advertising for surrogates.

We would propose the establishment of a state agency, similar to existing organisations within the UK and other countries that help identify surrogates for patients. This service will be essential for Irish patients in light of the prohibition on international surrogacy.

Part 8 Assisted Human Reproduction Regulatory Authority

We welcome the establishment of the AHRRA.

Current oversight is provided from a cell and tissue perspective by the HPRA. We are concerned that having 2 separate regulators will result in work duplication for both the organisations and providers. We would propose putting all regulatory oversight under one organisation such as in the UK with the HFEA.

We would also suggest that the board membership include a member who is currently actively working within the area of AHR.

How will AHRRA be funded? Our concern is that there will be an additional cost to patients.

31: Waterstone Clinic

WATERSTONE CLINIC

CENTRES FOR REPRODUCTIVE HEALTHCARE

Submission on behalf of Waterstone Clinic

To the Joint Committee on Health regarding the General Scheme of the Assisted Human Reproduction Bill 2017

This document was prepared by Dr John Waterstone, Medical Director of the Waterstone group of clinics and current President of the Irish Fertility Society. Dr Waterstone has made a submission to the Joint Committee on Health on behalf of the Irish Fertility Society (IFS) and has also contributed to the submission made by Prof. Mary Wingfield on behalf of the Institute of Obstetrics and Gynaecology.

Background to expertise in Assisted Reproduction (AR)

A graduate of both the Science (Genetics) and Medical Faculties of Trinity College, I have worked in Assisted Reproduction for over 30 years. I trained initially in London with Professor Robert Winston, a pioneer of fertility surgery, IVF and Pre-implantation Genetic Diagnosis. I also served as an inspector for the Human Fertilisation and Embryology Authority (HFEA) in the UK. I represented the IFS on the steering group set up to implement the European Tissues and Cells Directive (EUTCD) in Ireland. Having worked in the NHS for 13 years and in the HSE for the past 10 years, I believe that I am qualified to provide useful insights into the proposed legislation.

Primary concerns re the proposed legislation

Our detailed commentary is included at Appendix 1. The main areas in the proposed legislation I feel need to be addressed are as follows:

Statutory Legislation VS Guidelines

There are huge variations in regulatory legislation all over the world and while I acknowledge that it is difficult to create the perfect legislation, especially in case of controversial issues like gamete and embryo donation or surrogacy, the focus of some aspects of the proposed legislation in the draft bill is inappropriate. ***Certain of the clinical issues outlined, would be best addressed in guidelines formulated by the new regulatory authority, the AHRRA in conjunction with clinicians or expert advisors.*** Matters such as the number of embryos to be transferred at a time, should be the subject of such practice guidelines rather than statutory legislation. ***The latter mechanism is too inflexible to allow evidence based alteration of practice to take place as new techniques emerge and attitudes change in this dynamic area of medical science.*** There should also be some leeway for doctors to make decisions based on the particular needs of individual patients.

Functions of the AHRRA

The Joint Committee needs to be aware that ***Irish AR units are already licensed and regulated very strictly under the EU Tissues and Cells Directives***. The Health Products Regulatory Authority (HPRA) is the competent authority, carrying out inspections every two years at a minimum. Comprehensive quality management systems are in place and every AR treatment carried out must be individually licensed. At this stage, after a decade of regulatory activity, the HPRA has accumulated valuable practical experience with regard to inspecting IVF units. ***We need to avoid any unnecessary duplication of licensing and inspection activity which will inevitably involve cost for the patient and taxpayer.*** A way might be found to merge the activities currently carried out by the HPRA with those of the proposed new AHRRA, developing a single regulatory body which applies both the EUTCD and the AHRA. The HPRA already collects a significant amount of data on each licensed clinic on an annual basis. I propose that their ***remit be extended to collating and auditing success rate data and the monitoring of clinical practice***. Clinics falling short of standards and producing success rates significantly below average should be warned and if necessary have their license withdrawn in order to protect the general public against spending money in a clinic with suboptimal success rates. Additional scientific and medical expertise would need to be drafted in to guide and manage such activity.

The role of the AHRRA should also include the protection of patients against the use of unproven and expensive tests and treatments. This is a specific area of concern, particularly when the current trend is for the fertility sector to be owned and controlled by venture capital funds located outside of Ireland. We see frequent prescribing of natural killer cell (immunotherapy treatment), for example or IMSI, which add unnecessary cost for the patient for no proven benefit. These should be controlled more vigorously. The Human Fertilisation and Embryology Authority (HFEA) in the UK, appeared ineffectual when dealing with ***expensive adjuvant ('add on') tests, treatments and services that are not proven to be of benefit***. The new AHRRA should have the authority and remit to control and prevent such activity.

Anonymous and Identifiable Donor conception

The fundamental problem for many sub-fertile couples is poor egg quality, most often the result of advancing age. AR treatments have only a limited ability to compensate for this problem and many such couples are unable to achieve a pregnancy without egg donation. Egg donation is a wonderful application of IVF treatment which brings joy and fulfilment into the lives of many couples who would otherwise have remained childless. The availability of donor eggs in many European countries has been limited for decades by a reluctance to financially compensate donors. 'Reproductive Tourism' has resulted with couples travelling to other jurisdictions (particularly Spain, the Czech Republic and the USA) where donor eggs are more readily available. More recently, common sense has started to prevail and in 2011 the UK (previously a vociferous opponent of any remuneration) relaxed its rules and now permits a payment per donation. I believe it is unreasonable to expect a donor to undertake IVF treatment for no financial compensation. ***Reasonable expenses should be allowable for altruistic***

donors and surrogates who make it possible for couples who would otherwise have remained childless to enjoy the fulfilment of family life.

Attitudes relating to the anonymity or identifiability of donors also vary hugely across different jurisdictions. Spain and the Czech Republic enforce anonymity, the UK enforces identifiability, while the USA allows either. Virtually all sperm donated and used is imported from Denmark and anonymous donors greatly outnumber identifiable donors.

Waterstone Clinic has a support programme in place for patients who go abroad for egg donation treatment. We have a duty of care to couples who require gamete donation and forcing identifiable donation will inevitably reduce the availability of donors. ***I believe couples should have a choice of using anonymous or identifiable donors.*** Creating legislation that is too restrictive is not productive, it would a be far better approach to have openness around gamete donation, not least for medical reasons, and to produce best practice guidelines that can be amended as cultural practices change over time.

Waterstone Clinic has had an in-house known donor programme since 2006, where intending patients receive donated eggs from a friend or more commonly a sister. We also carry out embryo donation on an anonymised basis. This is where a couple having had fertility treatment, have now completed their family but still have embryos cryopreserved. They choose to donate (always in our experience anonymously) to another couple. It is the case that most donors will not be prepared to donate unless the process is anonymous; ***an absolute ban on donor anonymity (as in Parts 2 and 3 of the CFRA) would prevent an altruistic act taking place.*** I recommend that points 2 and 3 of the CFRA be replaced by acceptable and workable legislation as part of the AHRA.

National Donor-Conceived Person Register

The interrelated but separate issues of anonymity, information about donors, 'telling', avoidance of unwitting consanguinity, donor autonomy and financial compensation of donors are complex; they have not been discussed sufficiently. It is the case that donor conceived children can be 'told' without revealing the identity of the donor. Similarly, a wealth of medical and non-medical information about a donor can (and should) be made available without identification. We feel strongly that these issues should be governed by guidelines provided by the Regulatory Body rather than by Statutory Legislation.

Parts 2 and 3 of the CFRA are unacceptably coercive with regard to the State forcing information regarding donor origin on 18 year olds, sometimes against the wishes of parents. Even in the UK, where donor anonymity was banned in 2005, the government, after a consultation process, decided not to introduce any legal measure to force parents to tell their children that they were donor conceived, believing this to be a matter best encouraged through good practice rather than compulsion.

Parts 2 and 3 of the CFRA threaten the rights of Irish citizens to privacy and reproductive autonomy. They would, if implemented, be open to constitutional challenge. The DOH has already conceded that patients (more than 1000 per year) can continue to travel to Spain, Czech Republic and the USA for anonymous egg donation

so that the donor conceived person's register, should it ever materialise, would be hopelessly incomplete.
I suggest that this element of the legislation be scrapped and replaced by legislation which Irish citizens constitutional right to privacy and autonomous reproductive choices.

Restrictions on number of embryos to be transferred
Our clinic finds the suggestion that no more than two embryos should ever be transferred to be completely out of touch with reality. IVF treatment is expensive and in general, success rates for older women are modest because of poorer egg quality. In these cases, it may be appropriate to transfer three embryos where the embryos appear to be of suboptimal quality and where there is a negligible chance of multiple pregnancy. For such women, transferring only two embryos would significantly reduce the chance of pregnancy and would be unethical.

~~**Areas not addressed in the legislation**~~

Funding of AR
How is the proposal to provide state funding for treatment going to be dealt with as there is no reference to this in the Bill?

Cryopreservation Services
Provision must be made for fertility preservation for oncology/medical reasons. This service should be funded and made available for patients to avail of in the fertility clinic of their choice. The current service provided in Dublin only is not a good service for patients.

Preimplantation Genetic Diagnosis (PGD) services should be supported financially.
PGD is a complex form of IVF, where couples who know they are at genetic risk for a serious condition such as Cystic Fibrosis or Huntington's Chorea take a proactive approach to their situation by pursuing IVF with PGD in order to avoid passing on that heritable disease. Waterstone clinic having achieved the first live births in Ireland after PGD has developed significant clinical expertise in this area. We would welcome dialogue in relation to financial support and clinical indemnity. We feel PGD deserves to be funded by the State as it is capable of preventing a lifetime of illness for children.

PGS services should be included and monitored.

Genetic Counselling

The number of clinical geneticists and experienced genetic counsellors in Ireland is totally inadequate and the situation must be addressed. Waiting times for an initial consultation with a consultant geneticist may be as long as one year. This results in delay for patients considering PGD treatment and may impact significantly on their ability to conceive. If the State insists on patients seeing a geneticist prior to PGD treatment then the State must ensure that adequate geneticist positions are funded to meet the requirement of Head 34.

The views expressed above are focused on protecting the patient and optimising the success of ART treatment. It is imperative that the Department of Health agrees to a consultative process with stakeholders in relation to AR legislation. I would urge the committee to acknowledge the importance of the matters outlined and make provision for discussion and engagement with clinicians working day to day with patients trying to have a family.

John Waterstone
Medical Director

Appendix 1

Our comments combined with group comments on individual Heads and Subheads

Head 2 - Definition of AHR

"assisted human reproduction (AHR)" means all treatment or procedures that involve the handling of gametes and embryos for the purposes of establishing a pregnancy;"

Comment: Intrauterine insemination (of sperm) should be included here and should be governed by the proposed legislation. We therefore suggest the following definition of AHR: 'All treatments or procedures that involve the handling of gametes or embryos for the purpose of establishing a pregnancy'

"embryo" means a human embryo formed by the fertilisation of a human egg by a human sperm;

Comment: We refer to the World Health Organisation (WHO) definition which defines an embryo as the product of the division of the zygote to the end of the embryonic stage, eight weeks after fertilization. (Zygote: a diploid cell resulting from the fertilization of an oocyte by a spermatozoon, which subsequently divides to form an embryo). It is imperative to differentiate between this internationally accepted definition of an embryo (up to 8 weeks' gestation) and the preimplantation or *in-vitro* embryo. We suggest using the term preimplantation embryo for the purposes of this Bill.

"gamete" means,

(a) a human sperm, which is formed in the body of and provided by a man, or
(b) a human egg, which is formed in the body of and provided by a woman.

Comment: We suggest the definition of gametes be simply either a human sperm or a human egg. It is unnecessary to say 'in the body of or provided by a man/woman', and this

Head 5: General Principles (p15)

Subhead 1: *In all decisions regarding the provision of assisted human reproduction (hereafter referred to as AHR) treatment, due regard shall be given to the health and wellbeing of children born as a result of such treatments and to women who receive such treatments.*

Comment: the explanatory note on page 15 refers to 'children born as a result of AHR should not be exposed to greater medical or psychosocial risk than children conceived without AHR. How will this be assessed?
Again at Head 6 explanatory note 2 on page 17 states' that the AHR treatment provider will have to consider the welfare of the child as set out in Head 7 in making the final decision on whether to provide AHR treatment.

We would have concerns that there appears to be a general principle of placing the onus on the AHR treatment provider to assess the risk to any offspring by providing AHR treatment. We feel that this cannot be agreed to and is unnecessarily onerous and unworkable.

Head 6 – Age Limits for treatment with own gametes

Subhead 3: AHR treatment shall not be provided to persons who are under the age of 21 years.
Comment: We agree that the lower age limit for AR treatment should be 21 years.

Comment: We feel that the upper age limit for AR treatment for a woman should be 50 years when donor eggs are involved considering that women will (rarely) become pregnant naturally up to this age. When women are using their own eggs the issue concerns the probability of success which becomes unacceptably low beyond age 45 years. The lack of any specific upper age limit for men is remarkable, discriminatory and must be the subject of discussion.

We feel that all of these age limits should be the subject of practice guidelines and not statutory legislation.

Head 7 – Denial of AR Treatment

The responsibility placed on individual AR clinicians of making decisions concerning the denial of AR treatment to certain patients – either on the grounds of the health status of prospective parents or concerns about welfare of the child – are too onerous. In practice, if children are to be protected, such decisions are best made by a collective rather than by an individual. IFS members are adamant that decisions about refusal to provide treatment must be backed up by an ethics committee and that the whole process must be supported by statutory legislation.

Head 8 – Counselling

Sub Head 1: *All intending parents wishing to undergo AHR treatment shall be provided with counselling from a counsellor who delivers services on behalf of the AHR treatment provider.*

Comment: We do not accept that counselling should be mandatory for all patients undergoing AR. Well-adjusted patients who are comfortable about the AR treatment planned for them and who are not unduly stressed should not be forced to undergo counselling any more than should individuals who are attempting to conceive naturally. Counselling should obviously be available for all patients at all units - as is the situation currently. Counselling should be mandatory only for patients considering treatment involving donor eggs, donor sperm, donor embryos, surrogacy or posthumous conception. Specialist genetic counselling must be provided for patients before they make decisions about Preimplantation Genetic Diagnosis.

International research suggests that counselling should be *offered* but significant numbers of patients do not require counselling. This is also our experience. This is in keeping with guidance from international bodies such as the HFEA (Human

Fertilisation and Embryology Authority, UK) and ESHRE (European Society for Human Reproduction and Embryology).
Guidelines published by ESHRE in 2015 and titled 'routine psychosocial care in infertility and medically assisted reproduction—a guide for fertility staff' make 120 recommendations for good practice – mandatory counselling is not recommended.

Head 9 – Consent (p22)

Subhead 6(a): *The AHR treatment provider shall retain the original of each consent or revocation or alteration of consent given to the provider under this Act, and*

Comment: Given the growing use of electronic records we suggest that the original signed consent or alteration of consent may be scanned and stored electronically with shredding of the paper consent.

Head 10 - Number of Embryos Transferred

Comment: The suggestion that no more than 2 embryos can ever be transferred is unacceptable to us. The decision about whether to transfer 1, 2 or 3 embryos is a clinical one and can only be made on the day of transfer when embryo quality can be evaluated. The task of AR doctors and scientists is to maximise success rates while keeping adverse outcomes associated with multiple pregnancies to an acceptable minimum. We aspire to elective single embryo transfer (replacing only one embryo when two or more are available) and we have policies in place to promote ESET. However, the proposed limit of 2 would be unreasonable for older patients with poor quality embryos, as it would make their low chance of success even lower. This principle remains the same whether treatment is being funded by the State or by the patient herself. We feel that the number of embryos which can be transferred should be the subject of practice guidelines and not of statutory legislation.

Head 12 – Age limits for Gamete Donors

Subhead 1 (b): *A person, may donate his or her gametes to be used in providing AHR treatment to one or more other people if he or she has attained the age of 18 years,*

Comment: We are comfortable with a lower age limit of 21 for gamete donors and feel that an upper age limit of 37 rather than 35 should be used for egg donors; our known donor egg donation programme is successful and operates with an upper age limit of 37. It is also the case that good quality supernumerary embryos derived from 37-year-old eggs and which might be donated to another patient have a good chance of producing success. This is particularly relevant for egg donation from one patient to another within same sex female couples; this service is already available in our clinic. We feel that age limits for donors should be governed by AHRRA guidelines and not by statutory legislation.

Subhead 7 (a): *In providing his or her consent to the donation of his or her gametes, under subheads (1), (2) or (3) a person shall, in the context of subheads (1) and (2), specify the AHR treatment procedures that his or her gametes may be used in,*

Comment: The requirement for the donor of gametes to specify which AHR treatment procedures may be used is likely to be cumbersome and unworkable as new procedures evolve rapidly and may not have been listed in the original consent. It would be preferable for the donor to specify any particular procedure to which they do not consent, having due regard to equality legislation.

Subhead 7 (b): *In providing his or her consent to the donation of his or her gametes, under subheads (1), (2) or (3) a person may, in the context of subhead (3), specify the types of research that his or her gametes may be used in,*

Comment: Again this requirement is cumbersome and likely to be unworkable. We propose that research should be allowed as long as it has been approved by a State Research Ethics Committee and complies with the Helsinki Convention.

Head 14 – Parentage and non-anonymity in the context of gamete and embryo donation

Comment: We have ethical difficulties complying with such non-anonymity because such conditionality will dissuade some potential donors from donating. We suggest an alternative mechanism where identification of the donors is a possibility – but only if requested by both parties (the donor and the resulting child). We have ethical difficulties implementing the Donor Conceived Persons Register either in all cases or in cases involving in-house known egg donors (e.g. sisters) or in cases involving anonymous egg donation which has taken place in other jurisdictions. We feel that both anonymous and identifiable are ethical and should be permitted.

Head 19: Non-commercial gamete and embryo donation for AHR procedures or research (p55)

Comment: As donation is an altruistic act we would favour a modest compensatory payment similar to that in the UK (£35 for sperm donation and £750 for egg donation). These limits should not be specified in the Act but should be determined by the regulatory authority from time to time. Provision needs to be made for egg sharing and also for expenses involved in donating supernumerary gametes and embryos. Counselling should be provided prior to any egg sharing arrangement.

Head 22 - Maximum storage period for gametes and embryos

Comment: We consider the periods of 10 years for eggs and 5 years for embryos to be too short. Young cancer patients might store eggs or sperm for 20 years before being in a position to attempt pregnancy. For embryos the HFEA in the UK started out with a 5-year limit but subsequently, after consultation, increased the limit to 10 years. At the same time, we welcome the support provided by the proposed legislation for units with regard to disposing of gametes or embryos abandoned by patients who have failed to respond to repeated communications. This whole issue requires discussion between the DOH and IFS / IOG representatives to arrive at a wise solution which protects the interests of all parties concerned. We feel that limits on storage should be the subject of guidelines from the AHRRA.

General comment: it should be clarified/specified that this includes the storage of ovarian or testicular tissue with a view to subsequent reproduction using eggs or sperm from that tissue.

Head 27 – Recognition of the deceased person as a parent of the child

We consider the 3-year limit between death and the subsequent birth of a child to be too short. One of our units has treated a patient who had 2 children by PAR; under the proposed legislation the second of these children would be treated differently to the first, with regard to legal parentage and inheritance rights. This matter requires discussion.

Head 28: Consent, provision of information and counselling (p73)

Subheads 1 (c) and 2 (c):

> *(1) A consent from a deceased person to the use of his or her gametes, or an embryo created using his or her gametes, for the purposes of PAR shall—*
> *(c) Specify the treatments arising as part of PAR for which he or she consents to his or her gametes, or an embryo created with his or her gametes, being used after his or her death. (2) A consent from a deceased person to the posthumous retrieval of his or her gametes for use in PAR shall—*
> *(c) Specify the treatments or uses arising as part of PAR for which he or she consents to his or her posthumously retrieved gametes, or an embryo created using his or her gametes, being used after his or her death.*

Comment: See previous comments re Head 12, Subhead 7 (a) and (b). It is not recommended that specific treatments be specified by any person in relation to frozen gametes or embryos as ART treatment changes at a rapid rate and it might be that treatments become available that would not have been foreseen by the deceased. We suggest that an alternative is for the person to have consented to treatment that might be necessary to lead to a pregnancy (or some such wording).

Head 29: Interpretation (Part 5) (p78)

Comment: Regarding the definition of "life-limiting disease". Some life-limiting diseases present in adulthood. Use of the word 'child' is confusing and we suggest it be replaced with the word 'offspring'.

Head 30: PGD

Comment: PGD is a complex form of IVF, where couples who know they are at genetic risk for a serious condition such as Cystic Fibrosis or Huntington's Chorea take a proactive approach to their situation by pursuing IVF with PGD in order to avoid passing on that heritable disease. Waterstone clinic having achieved the first live births in Ireland after PGD has developed significant clinical expertise in this area. We would

welcome dialogue in relation to financial support and clinical indemnity. We feel PGD deserves to be funded by the State as it is capable of preventing a lifetime of illness for children.

Head 34: Consent, provision of information and counselling (p86)

Subhead 3 (b) and (c):

> *(b) Prior to giving his or her consent under paragraph (a) the person in question shall have been provided with information about the disease in question and the procedure to be carried out from a geneticist, including information about the potential risks and implications involved, and*
> *(c)(i) Separately from and subsequent to the provision of information referred to in paragraph (b), the person giving his or her consent shall have received counselling from a genetic counsellor.*

Comment: AHR providers should certainly ensure that patients considering PGD or PGS are sufficiently informed and counselled. However, we state categorically that the provision of genetic services in this country is totally inadequate. Access to the services of geneticists and genetic counsellors is extremely difficult. We suggest that counselling by either a geneticist or genetic counsellor, in conjunction with the AHR Unit's medical and counselling staff, would be sufficient in many cases. Again, this type of detail should be the remit of the regulatory authority.

Head 36: Surrogacy permitted under this Act (p91)

Subhead 1(a): *Surrogacy may be permitted under the following circumstances—*

> *(a) it is domestic surrogacy,*

Comment: The need for surrogacy in Ireland will not be met by domestic surrogacy i.e. Surrogates resident in Ireland. Irish patients will continue to travel overseas and will bring their children back. The legal situation of these children and their intended parents must be secured.

Subhead 2: *Subject to subhead (3), it is prohibited for any person to intentionally provide a technical, professional or medical service that is to facilitate or give effect to a surrogacy agreement not permitted under subhead (1).*

Comment: It would be unethical for a doctor to refuse medical care to a patient/s who is having treatment overseas, even if that treatment involved surrogacy abroad. It would be a breach of the patient/doctor relationship for a doctor not to be able to advise patients on treatments available abroad.

It is possible that some couples will have embryos frozen in Ireland and may wish to transfer these to another jurisdiction for surrogacy. The authors have already been involved with some such cases. If person/persons are able to use their embryos for treatment, they should not be precluded from taking them abroad for such treatment. Under international law (EU Directives) all clinics are required to assist in order to import or export gametes or embryos.

Head 37

Comment: The requirement to have all consents and arrangements for surrogacy in place before approval by the AHRRA is sought, is arduous. This is a lot of time, expense and emotional investment if approval is not granted? Provisional / full approval at an earlier stage, subject to fulfilment of conditions would be fairer to patients.

Head 38: The surrogate (p96)

Subhead 1(d): *A woman may act as a surrogate as part of a surrogacy agreement under Head 36 only if she is 47 years of age or under at the time of the embryo transfer as part of the surrogacy agreement,*

Comment: The upper age for surrogacy should be 40 years. As the surrogate will not have the benefit of keeping the child, her health and wellbeing need protection and the risks of pregnancy increase significantly after 40.

Head 42: Advertisements for surrogacy (p105)

Comment: This prohibits the advertisement by any means, to seek a surrogate or offer services as a surrogate, or facilitating such an arrangement. This seems inappropriately restrictive. While we completely agree that no person should be induced or coerced, there should be a facility where information on such arrangements can be accessed by and provided to any interested parties. For example, notices on fertility clinic websites should be permitted, or leaflets summarizing the legislative framework (once enacted).

Head 43: Requirement for counselling and independent legal advice (p106)

Comment: The surrogate's spouse, civil partner or cohabitant should also be seen by a counsellor and he/she should also receive legal advice.

Head 44: Information to be provided to and recorded by the Regulatory Authority in relation to a surrogacy agreement (p107)

Subhead 1(a, b, c): *Prior to giving his or her consent to the surrogacy agreement, the surrogate and each intending parent involved shall be informed—*
(a) that the surrogate will be the legal mother of any child born as a result of the surrogacy agreement,
(b) that the surrogate's husband, if she has one, will be presumed to be the legal father of any child born as a result of the surrogacy agreement unless the contrary is proven on the balance of probabilities as set out in section 46 of the Act of 1987, and a declaration under section 35 of the Act of 1987 that he is not that child's father is granted,

(c) that an intending parent will not automatically be the legal parent of any child born under the surrogacy agreement,

Comment: See our major observation 12. It needs to be clarified what will happen if the intending parents decide not to pursue a Court order, particularly in a case where the child is born with a disability.

Head 51: Interaction of the National Surrogacy Register and the register of births (p128)

Subhead 3: *Where a person who has attained the age of 18 years applies for a copy of his or her birth certificate, an tArd-Chláraitheoir shall, when issuing a copy of the birth certificate requested, also inform the person that further information relating to him or her is available from the National Surrogacy Register.*

Comment: As previously noted by the Institute of Obstetricians and Gynaecologists in relation to the Children and Family Relationships Act of 2015, the imparting of information regarding their mode of conception to individuals at or after the age of 18 which their parents may not have told them is irresponsible and dangerous from a mental health perspective, particularly in the case of psychologically vulnerable individuals. This degree of relay of unsolicited information is not the international norm, even in countries where open disclosure of conception-related information is advocated.

Head 67 - Functions of AHRRA - perceived omissions

Comment: We feel that a function of the AHRRA should be to protect patients against financial exploitation associated with unproven additional tests and treatments.

A function of the AHRRA should be to regulate fertility treatments such as ovulation induction and IUI (which are currently uncontrolled but, just as is the case for IVF, can generate multiple pregnancies). Currently Clomid is used by GP's and general gynaecologists in an unregulated manner. Many triplet pregnancies have resulted over the years. The AHRRA should implement guidelines to make ovulation induction safe.

We agree that an additional function of the AHRRA, namely a responsibility to follow up children born after AR with regard to birth abnormalities and also to adverse outcomes related to multiple pregnancy is necessary. To this end, we recommend that thought be given to delegating this function of the AHRRA's remit to the National Perinatal Epidemiology Centre headed up by Prof. Richard Green. Audit in this way would allow outcomes after AR conception to be compared to outcomes after natural conception.

Head 76 – Membership of the board of the AHRRA

We are concerned about the exact composition of this board. We wonder if (2) should read "*all 11 members shall be appointed by the Minister and* ***all*** *shall be people* ....."

We feel that the composition of the board is of vital importance in order for the AHRRA to fulfil its role effectively. We feel that the composition of the board needs to be more specific. We suggest that the Minister might seek nominations for board membership from the IFS.

We propose that the membership of the board includes amongst the 11 members the following personnel:

- At least one Medical Consultant with a minimum of 5 years' experience in Assisted Human Reproduction
- At least one Clinical Scientist with a minimum of 5 years' experience in Assisted Human Reproduction
- At least one consultant gynaecologist not involved in AR
- A nurse / midwife with a minimum of 3 years' experience in Assisted Human Reproduction

The Minister should ensure that at least 50% of the Board Members have experience in the area of AHR, whether in Ireland or abroad, from a regulatory or service provision point of view.
The lack of direct experience of current practices is evident in the legislation already passed (CFRA 2015) and this Draft Scheme. We do acknowledge the provision for the establishment of Committees (Head 79), covering Appeals / Scientific and Ethics.

Pathways to Parenting: Proposals for Reform

BRIEFING DOCUMENT

LGBT Ireland*

Introduction

This Briefing Document addresses selected areas of significant concern to LGBT parents and their children in Ireland in the areas of donor-assisted human reproduction ("DAHR") and surrogacy and proposes legal reforms to address those issues.

The reforms that are proposed in this Briefing Document are based on protecting the best interests of the child and are informed by reference to the rights of the child under the United Nations Convention on the Rights of the Child (UNCRC), the European Convention on Human Rights and Article 42A of the Irish Constitution. It is argued that the best interests of the child are met through laws that recognise the reality of life for the child and that ensure that the child can be fully cared for by the adults whom he or she regards as parents. For children raised in gay and lesbian families, this means that the children should have the opportunity of acquiring a legal relationship with both intended parents and those parents should have all of the legal tools necessary to care for the child. Moreover, it is argued that children who are born through DAHR or surrogacy must not be disadvantaged when compared to other children due to their mode of conception or due to their parents' marital status or sexual orientation. Unfortunately, there are a number of provisions in Parts 2 and 3 of the Children and Family Relationships Act 2015 ("CFR Act"), once commenced, and the Assisted Human Reproduction Bill 2017 ("AHR Bill"), once enacted, that will operate to treat certain children less favourably than others. These issues are not only of concern to children born to same-sex parents, but to many other children who are born through DAHR and surrogacy.

It is acknowledged that the child's right to identity is of upmost importance in DAHR and surrogacy and so the provisions of the CFR Act that allow children to access information about their origins provide important safeguards for the right to identity. However, it is important to acknowledge at the outset that upholding the child's right to identity does not require that a

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gamete donor, who has no desire or intention to play any role in the child's life, should be recognised as a legal parent. The reality of the child's actual family relationships must be legally recognised and protected and should drive the legislative response. The reforms proposed in this Briefing Document are designed to achieve this.

KEY RECOMMENDATIONS:

1. Where a child is conceived through non-clinical DAHR, procedures should be in place to recognise the second intended parent as a legal parent.
2. A retrospective application for a declaration of parentage in cases of DAHR under section 20 of the CFR Act should be possible where a known donor was used.
3. To ensure that the second intended parent is recognised as a legal parent in cases where she provides her egg to enable the conception of the child, the words "unless the donor of the gamete or embryo is the spouse, civil partner or cohabitant of the mother" should be added to all sections of the CFR Act that currently provide that "a donor of a gamete [or embryo] that is used in a DAHR procedure is not the parent of a child born as a result of that procedure."
4. The Government should consider possibilities for recognising DAHR conducted abroad after Parts 2 and 3 of the CFR Act are commenced.
5. Provisions should be enacted to retrospectively recognise the legal parentage of children born through surrogacy before the AHR Bill is enacted.
6. The AHR Bill should provide recognition of the legal parentage of children conceived through surrogacy conducted outside of the State after the AHR Bill is enacted.
7. Pre-conception court orders should be provided for in the AHR Bill to provide approval of the surrogacy arrangement *and* to determine the parentage of the child before conception takes place with no requirement for a parental order to be obtained after the birth of the child.

LGBT Ireland is aware that there may be a perception that that adoption is a viable option to address some of the issues discussed in this Briefing Document. We do not share this view. Adoption was not designed to be used in cases of DAHR or surrogacy and does not accurately reflect the reality of the family relationships created through those processes. Adoption requires that the parents are assessed in terms of their eligibility and suitability to parent a child with whom they already have a parent-child relationship and when an adoption order is made, the

child is issued with an adoption certificate to replace the birth certificate. Moreover, the partner of the legal parent can only engage in second-parent adoption where the child has lived with the second parent and the birth parent for a continuous period of not less than two years.[1] As such, there is a two-year waiting period before second-parent adoption can be used. Where the child is less than two years of age, only joint adoption is possible whereby the birth parent would be required to give up his or her existing parental rights in order to jointly adopt with the second parent. This is an overly complicated and unnecessary process. For these reasons, adoption should not be seen as a "solution" to issues arising in DAHR and surrogacy: the appropriate way to address the issues is through amendment of the Children and Family Relationships Act 2015 ("CFR Act") and/or the Assisted Reproduction Bill 2017 ("AHR Bill").

1) Known donor outside of a clinical setting:

Non-clinical procedures are currently excluded from the parentage provisions in the CFR Act. The result is that children conceived through DAHR outside of the clinical setting do not have a legal relationship with the second intending parent at birth. Children conceived through DAHR outside of the clinical setting are therefore disadvantaged when compared to children conceived through DAHR in a clinic by virtue of the circumstances of their conception.

a) Case Study:

Elaine (birthmother) and Jenny conceived their baby girl at home, using sperm donated by Jenny's brother. They had no problem conceiving and did not need any clinical intervention. Their donor is happy to give consent to both women being recognised as the legal parents.

As their baby is only 3 months old, Jenny is unable to seek guardianship under the CFR Act 2015 as the child is less than 2 years old. Therefore, as the law currently stands she has no legal relationship to her child and is unable to establish a legal relationship until her daughter is two years old.

b) Possible Legal Solution

Married opposite-sex couples currently benefit from a presumption of paternity in favour of the husband of the birth mother. There is no equivalent presumption for married same-sex couples. To accommodate married same-sex couples and civil partners and to ensure that they

[1] Adoption Act 2010, s 37(b) as amended by Adoption (Amendment) Act 2017, s 18.

are not disadvantaged when compared to married opposite-sex couples, the Civil Registration Act 2004 should be amended to allow both intended parents to be registered as the legal parents of a child who has been born following a non-clinical DAHR procedure. This could be facilitated through a mechanism along the lines of that in section 22 of the Civil Registration Act 2004, as amended by section 6 of the Civil Registration (Amendment) Act 2014 (not yet commenced) allowing the joint registration of the intended parents in the following circumstances:

a) The intended parents must provide the registrar with a statutory declaration stating that they are the mother and intended parent of a child born following a DAHR procedure; that they have recorded the identity of the gamete donor and transmitted the relevant information to the National Donor-Conceived Persons Register; that the donor did not intend to be recognised as a legal parent and that they have evidence exhibiting this which will be provided to the registrar.
b) The female couple shall provide the registrar with the name and last known contact details of the gamete donor.
c) Upon receiving the statutory declaration from the female couple, the registrar shall make all reasonable efforts to give notice in writing to the donor requiring him, within 28 days, to attend before a registrar, at the office of the registrar or such other (if any) convenient place in the registration area concerned, as may be specified by the registrar in the notice, and there to inform the registrar if he agrees that he is not the father of the child.
d) The donor shall complete a statutory declaration agreeing that he is not the father of the child.
e) Where the registrar receives both statutory declarations and is satisfied that details concerning the donor have been transferred to the National Donor-Conceived Persons Register, s/he shall register the intended parents as the legal parents on the child's birth certificate.
f) Where the registrar is unable to make contact with the donor but is satisfied based on the statutory declaration provided by the intended parents that the donor is not the father of the child, s/he shall register the mother and second intended parent as the legal parents on the child's birth certificate.

For cohabiting couples (who are not married or civil partners), or where there is a dispute as to the parentage of the child in respect of the above, where a child is conceived through non-clinical DAHR, the second parent should be able to apply to court for a declaration of parentage after the birth of the child to establish his or her parentage. To protect the rights of the donor, he should be joined to the application and his consent required before the declaration can be granted (unless the consent is unreasonably withheld). The application should also be grounded on evidence establishing that the donor consented to the use of his or her gamete and did not intend to be recognised as a legal parent at the time of the DAHR procedure; and evidence that all relevant details concerning the donor and the procedure have been transmitted to the National Donor-Conceived Persons Register.

These procedures will allow the second parent to be legally recognised in cases of non-clinical DAHR but would also require the intended parents to take precautions to protect the child's rights and best interests at the time of the conception.

c) Examples in other Jurisdictions

Other jurisdictions have addressed the issue of non-clinical DAHR by extending a statutory presumption of parentage to some couples. In the United Kingdom, a statutory presumption of parentage operates in favour of same-sex married couples and civil partners (but not cohabiting couples) in cases of donor insemination. As such, the spouse or civil partner of the birth mother is automatically regarded as the child's second legal parent regardless of whether the procedure takes place in a clinical or non-clinical setting. The presumption applies unless it is shown that the second parent did not consent to the procedure at the relevant time.[2] In British Columbia, a person who is married to, or in a marriage-like relationship with, the child's birth mother at the time when the child was conceived is deemed to be the child's parent unless it is shown that he or she did not consent to be recognised as such.[3]

2) Known donor in a clinical setting in respect of a child conceived before Parts 2 and 3 of the CFR Act are commenced

For children who were conceived prior to the commencement of Parts 2 and 3 of the CFR Act, parentage may be retrospectively allocated to an intended parent not previously recognised as

[2] Human Fertilisation and Embryology Act 2008, s 42.
[3] Family Law Act 2011, s 27.

a legal parent through application for a declaration of parentage under sections 21 or 22 of the Act. In order for the declaration to be granted, the donor must have been and remain unknown to the intending parents at the time of the application.[4]

The requirement that the donor must be unknown raises issues as "unknown" is not defined in the legislation. It is unclear whether it means that the donor must be unidentifiable or identifiable but not yet identified. This approach penalises couples who chose to use a known donor in order to safeguard their child's right to identity. It means that where the child's right to identity was prioritised, the child is subsequently deprived of his or her right to be cared for by the intended parents as the second parent cannot subsequently obtain the declaration of parentage.

a) Case Study

Jane (birthmother) and Sarah have an 18-month-old baby boy, Jake. Jake was conceived in a fertility clinic using sperm provided by an identifiable donor. Jane and Sarah want Jake to know about his origins and so they have obtained identifying information about the donor so that they can educate Jake about his genetic background in an age-appropriate manner as he grows up. The women have never met the donor but know his name and last known address. Jane is the birth mother of Jake and is recognised as the legal mother. After Parts 2 and 3 of the CFR Act are commenced, Sarah will be unable to obtain a declaration of parentage listing her as the second legal parent because a known donor was used.

b) Possible legal solution

Section 20(d) of the CFR Act should be amended to make it possible to apply for a declaration of parentage in cases where a known or identified donor was used. Where a known donor was used, the law should provide that s/he is to be joined to the application for the declaration of parentage and his/her consent required before the declaration can be granted. Where the donor cannot be located, the court should have the power to dispense with his/her consent. This could be facilitated by amending section 20(d) of the CFR Act to provide along the lines that:

> "at the time referred to in paragraph (c) the person, other than the mother of the child, who provided a gamete that was used in the DAHR procedure, consents to the making of the

[4] Children and Family Relationships Act 2015, s 20(1)(e).

declaration of parentage unless—

(i) he or she is deceased or cannot be located, or the court finds that the consent is unreasonably withheld; or

(ii) the person who provided the gamete was the spouse, civil partner or cohabitant of the mother and was the only intending parent of the child at the time that the DAHR procedure was performed."

The court should only dispense with the donor's consent where it is in the best interests of the child to do so. Where the child is capable of forming his or her own views, the views of the child should be ascertained and given due weight having regard to the age and maturity of the child in the application for the declaration of parentage.

3) Reciprocal IVF

Reciprocal IVF (where a female couple conceive using the non-birth mother's egg and a sperm donor) is not regulated under the CFR Act. As a result, it is unclear as to whether the partner of the birth mother would be recognised as a legal parent or whether she is classified as a donor.[5]

a) Case Study:

Ranae and Audrey have a two-year-old daughter Ava and are expecting a second child. Ranae is the birth-mum of Ava and is carrying their second child. Both children were conceived using Audrey's eggs and donor sperm: "In our mind, that meant that the baby would truly be a part of both of us."

As the birth-mother Ranae is the legal mother of Ava. Audrey will be unable to apply for a parental order under Section 20 of the CFR Act, as she is classified as a known donor under the Act. When their new baby is born she will be unable to establish guardianship of the child for 2 years.

b) Possible Legal Solution

To ensure that the second intended parent is recognised as a legal parent in cases where she

[5] See further: Lydia Bracken, "In the Best Interests of the Child? The Regulation of DAHR in Ireland" (2016) 23 *European Journal of Health Law* 391.

provides her egg to enable the conception of the child, the words "unless the donor of the gamete or embryo is the spouse, civil partner or cohabitant of the mother" should be added to all sections of the CFR Act that currently provide that "a donor of a gamete [or embryo] that is used in a DAHR procedure is not the parent of a child born as a result of that procedure." These words should be added to sections 5(5), 5(7), 6(3)(d), 7(b)(i), 9(3)(c)(i), 11(3)(d)(i), and 13(b)(ii) of the CFR Act and any other section where the latter phrase appears.

Where children have already been born following reciprocal IVF, the second parent should be able to apply for a declaration of parentage naming her as the second legal parent. In line with the recommendations under Heading 2 above, section 20(d) of the CFR Act should be amended to remove the requirement that the donor must have been and remain unknown in order for the declaration of parentage to be granted. Instead, the section should provide along the lines that

> "at the time referred to in paragraph (c) the person, other than the mother of the child, who provided a gamete that was used in the DAHR procedure, consents to the making of the declaration of parentage unless—
>
> (i) he or she is deceased or cannot be located, or the court finds that the consent is unreasonably withheld; or
>
> (ii) the person who provided the gamete was the spouse, civil partner or cohabitant of the mother and was the only intending parent of the child at the time that the DAHR procedure was performed."

This will mean that where a woman has provided her egg to enable the conception of a child that was carried by her spouse, civil partner or cohabitant, she can subsequently be recognised as the second legal parent.

c) Examples in other Jurisdictions

In the United Kingdom, paragraph 5 of Schedule 3 of the Human Fertilisation and Embryology Act 1990 provides that consent to donor insemination is not required for "the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services."

4) Fertility treatment accessed abroad

Section 20 of the CFR Act provides that an application for a retrospective declaration of parentage may be made in respect of a child conceived before Parts 2 and 3 of the Act are commenced who was conceived by DAHR performed in the State or outside the State. For children born after Parts 2 and 3 are commenced, the procedure must be performed in the State.[6]

This provision raises particular issues for persons who already have a child conceived following a DAHR procedure performed in a foreign clinic in circumstances where the clinic is storing embryos for that couples' future use. Once Parts 2 and 3 of the Act are commenced, the parentage provisions in the CFR Act will not apply where the couple use the stored embryos to conceive a child as a result of a DAHR procedure conducted abroad.

a) Case Study

Sue and Teresa initially attended a Dublin clinic for AHR treatment, but when significant fertility issues were identified, they had to look abroad for further treatment options. They were very lucky, and their daughter was born in early 2018. As she was born before the CFR Act commences, Teresa will be able to apply for a retrospective declaration of parentage naming her as a legal parent. However, the couple have a number of embryos in storage in the UK clinic. If the couple use these embryos in order to conceive a genetic sibling for their daughter, they will not be able to apply for parentage under the CFR Act.

It is unclear whether it may be possible to apply for parentage if they transfer the existing embryos to an Irish clinic and carry out embryo transfer here. There would be a significant cost involved in this and it would mean leaving a clinic where they had a very positive experience, and a medical team with whom they have established trust, both very important elements within the AHR process.

b) Possible Legal Solution

The CFR Act recognises that couples who already have a child born through DAHR may wish to conceive a genetic sibling for the child. Sections 26(5) and 26(6) of the CFR Act allow Irish DAHR facilities to use gametes or embryos acquired prior to the commencement of Parts 2 and 3 even where the acquisition does not meet the criteria in sections 26(1) or 26(2)(a). Gametes

[6] Children and Family Relationships Act 2015, s 4.

can be used for three years following commencement and there is no stipulated time limit for the use of previously acquired embryos. Where a couple has already engaged in a DAHR procedure in a foreign clinic, a similar three-year amnesty should apply to allow them to conceive a child through DAHR in the foreign clinic using gametes already acquired and there should be no time limit on the use of embryos stored at a foreign clinic. The couple should be able to apply for a declaration of parentage in Ireland to recognise their parentage following the birth of the child. This could operate along the lines of the existing sections 21 and 22 of the CFR Act.

In respect of future procedures, the Government should consider entering into bilateral agreements with countries that offer DAHR treatment to Irish couples whereby Ireland agrees to recognise the parentage of children conceived by DAHR to Irish couples outside the State so long as this meets criteria equivalent to that in the CFR Act. This will ensure that the parentage of children conceived through DAHR abroad can be established.

5) International Surrogacy

Under the AHR Bill, only domestic surrogacy will be permitted after the legislation is enacted. There is no provision in place to recognise the parentage of children who were/are born through surrogacy before the Bill is enacted and commenced. It must be acknowledged that the exclusion of international surrogacy will not prevent couples from accessing services abroad. In these cases, Ireland must remain cognisant of the case law of the European Court of Human Rights which establishes that it is contrary to Article 8 ECHR to refuse legal recognition of children's legal relationships with their genetic parent in cases of international surrogacy, even where surrogacy is prohibited under domestic law.[7]

The child has no control over the circumstances of conception and should not be disadvantaged by virtue of the fact that he or she was conceived by surrogacy abroad. It is argued that it is in the best interests of the child for his or her relationship with the intended parents to be legally recognised. As the UK courts have acknowledged:

> "is almost impossible to imagine a set of circumstances in which by the time the case comes to court, the welfare of any child (particularly a foreign child) would not be gravely

[7] *Mennesson v France*, app. no. 65192/11, 26 September 2014; *Labassee v France*, app. no. 65941/11, 26 September 2014.

compromised (at the very least) by a refusal to make an order [transferring parentage to the intended parents]."[8]

a) Case Study

Laurence and Eddie have six-year-old twins, which they conceived using a surrogate mother in the UK. Eddie is the legal parent of the twins. The woman who was the surrogate for the couple is in regular contact with the family and is happy to consent to Laurence being recognised the twins' legal parent.

One of the children has significant health issues and needs regular medical attention, and while Laurence does have guardianship of both children this does not recognise his parental relationship to them, which has huge implications for the family, as Eddie explains here "I have a little boy with a rare genetic disorder which will mean he will need care AFTER his other dad's guardianship ends when he's 18."

b) Possible Legal Solution

Retrospective:

Provisions should be enacted to retrospectively recognise the legal parentage of children born through surrogacy before the AHR Bill is enacted. These provisions should mirror those in sections 20, 21 and 22 of the CFR Act that allow for the retrospective recognition of legal parentage where children were conceived by DAHR before Parts 2 and 3 of the CFR Act were commenced.

Prospective:

The AHR Bill should provide recognition for the legal parentage of children conceived through surrogacy abroad after the AHR Bill is enacted. The provisions should allow the parents to apply for a declaration of parentage/ parental order in Ireland after the birth of the child so long as the foreign surrogacy meets conditions set out in the Irish legislation eg. that the surrogacy was gestational and non-commercial etc.

[8] *Re X and Y (Foreign Surrogacy)* [2008] EWHC 3030 (Fam).

c) Examples in other Jurisdictions

The United Kingdom adopts a post-birth model of parentage in surrogacy whereby the surrogate is recognised as the legal mother at birth and the intended parents can later apply for a parental order to transfer parentage to them. As a result, the UK law does not recognise birth certificates issued abroad in cases of surrogacy that automatically allocate parentage to both intended parents. Instead, the intended parents must still apply for a parental order from the UK courts when they return to the jurisdiction with the child. The UK courts have adopted an approach whereby the parental order will almost always be granted (as it is in the best interests of the child to do so), unless there is the "clearest abuse of public policy"[9] in respect of how the international surrogacy arrangement was conducted. As Fenton-Glynn notes:

> "In this way, the English courts have transferred legal parenthood to the commissioning parents, despite breaches of law including large payments to surrogate mothers, as well as to agents and mediators, applications outside the time limit, deception of the Foreign Office, and lack of truthful information about the surrogate mother."[10]

The UK courts recognise that once the child has developed a relationship with the intended parents, it is almost always in the best interests of the child to transfer parentage to the intended parents.

6) Domestic Surrogacy

The AHR Bill proposes to introduce a post-birth model of parentage in surrogacy, similar to that in the UK, but with the additional requirement that the surrogacy must be pre-authorised by a new Assisted Human Reproduction Regulatory Authority. A major difficulty that arises with this delayed model of parentage is that, at the time of the child's birth, at least one of the intended parents will not be recognised as a legal parent and cannot be recognised until the time that the parental order is granted. The application for the parental order cannot be made earlier than six weeks and not more than six months after the child's birth.[11] This approach leaves the child in a vulnerable position as he or she is cared for from birth by the intended parents, one of whom will not have any legal parental responsibility or decision-making powers

[9] *Re L (A Child)* (2010) 3146 (Fam).
[10] Claire Fenton-Glynn, "International surrogacy before the European Court of Human Rights" (2017) 13 *Journal of Private International Law* 546 at p 551.
[11] General Scheme of the Assisted Human Reproduction Bill 2017, Head 47.

for at least six weeks. Instead, the surrogate, as the legal mother, retains decision-making responsibility for the child until the time that the parental order is granted.

A post-birth model of recognition is currently adopted in the United Kingdom. Many experts and stakeholders have criticised the UK regulation of surrogacy and, as a result, the Law Commission of England and Wales is currently reviewing the area with a view to reforming the current surrogacy laws which were first enacted over thirty years ago.[12] Attitudes towards surrogacy have changed considerably in this thirty year period and so the Law Commission will propose reforms that are designed to accommodate surrogacy in the 21st century.

It might be assumed that the post-birth model of parentage offers protection to the surrogate by giving her the opportunity to change her mind about the transfer of parentage after the child has been born. A number of studies indicate that women who act as surrogates do not view the child as their own and do not struggle with the decision to transfer parentage to the intended parents.[13] It is also notable that in the United Kingdom, where the legislation gives the surrogate the opportunity to change her mind, there have only been three reported cases where disputes have arisen between the surrogate and the intended parents in relation to the transfer of parentage.[14] To give context to these figures, it should be noted that approximately 138 applications for parental orders were made in the UK between April 2011 and March 2012 alone, while 241 applications were made between April 2014 and March 2015.[15] Of course, there might be other disputes that do not come before the courts but these figures indicate that it is very rare that the surrogate will subsequently refuse to consent to the transfer of parentage. It should also be noted that a survey conducted in the UK in 2015 indicated that many surrogates do not want to be recognised as legal parents (with all of the responsibility that this carries) in the first place.[16]

Furthermore, the focus on protecting the surrogate in the Irish AHR Bill is inconsistent. Although the surrogate is given the opportunity to change her mind about the transfer of

[12] Law Commission, "Surrogacy" https://www.lawcom.gov.uk/project/surrogacy/
[13] Vasanti Jadva, "Surrogcy: Issues, concerns and complexities" in Golombok and others, *Regulating Reproductive Donation* (Cambridge University Press, 2016) at p 128.
[14] Natalie Gamble, "A better legal framework for United Kingdom surrogacy?" in Golombok and others, *Regulating Reproductive Donation* (Cambridge University Press, 2016), at p 148.
[15] CAFCASS, *Cafcass Study of Parental Order Applications made in 2013/14* (CAFCASS, 2015)
[16] Surrogacy UK, *Surrogacy in the UK: Myth Busting and Reform: Report of the Surrogacy UK Working Group on Surrogacy Law Reform* (Surrogacy UK, 2015).

parentage to the intended parents, the requirement for her consent to be provided to the parental order can be waived by the court where it is in the best interests of the child to do so.[17] In addition, Head 46 of the AHR Bill *requires* the surrogate to consent to the child living with the intended parents after birth; she has no discretion not to consent. This dilutes the claim that the objective of adopting the post-birth model of parentage in the AHR Bill is to protect the surrogate's interests.

The pre-authorisation requirement as set out in the AHR Bill is cumbersome as it essentially means that the surrogacy agreement must be approved twice: before conception by the Regulatory Authority and after birth by the courts. This is a lengthy and expensive process.[18]

a) Possible Legal Solutions

A pre-conception model of parentage would better protect the rights of all stakeholders in the surrogacy process than the post-birth model. Pre-conception court orders would provide approval of the surrogacy arrangement *and* determine the parentage of the child before conception takes place. The order would provide that the intended parents are to be recognised as joint legal parents at the time of the child's birth and that the surrogate mother is not recognised as a legal parent. This would ensure that both of the intended parents have full legal powers to care for the child from the moment of the child's birth and ensure that the child is legally integrated into his or her family from the moment of the child's birth.

b) Examples in other Jurisdictions

In South Africa, under the Children's Act 2005, surrogacy agreements must be validated by the High Court before the surrogacy is undertaken. Where the criteria for validation are met, the intended parents will be treated as the legal parents from the moment of the child's birth.[19] The surrogate mother does not acquire any parental status.[20]

British Columbia operates a similar pre-conception model of surrogacy except the Family Law Act 2011 provides that the pre-conception agreement will only take effect where, *inter alia* the

[17] General Scheme of the Assisted Human Reproduction Bill 2017, Head 48(2).
[18] See further Lydia Bracken, "The Assisted Reproduction Bill 2017: An Analysis of Proposals to Regulate Surrogacy in Ireland" (2017) 68 *Northern Ireland Legal Quarterly* 577.
[19] Children's Act 2005, ss. 292, 295, 297.
[20] See further Lydia Bracken, "The Role of the Best Interests Principle in Regulating Parentage in Surrogacy in Ireland" [2017] *International Family Law* 115.

surrogate "gives written consent to surrender the child to an intended parent or the intended parents" after the birth of the child.[21] The fact that the surrogate entered into the written pre-conception agreement to act as a surrogate or to surrender a child is not consent for the purposes of the post-birth surrender of the child but may be used as evidence of the parties' intentions with respect to the child's parentage if a dispute arises after the child's birth.[22] The surrogate is not recognised as a legal parent upon the birth of the child.

[21] Family Law Act 2011, s 29(3)(b).
[22] Family Law Act 2011, s 29(6).

ÚDARÁS UCHTÁLA na hÉIREANN
THE ADOPTION AUTHORITY of IRELAND

DATE:

RE: Freedom of Information Request 2018/18

Dear

I refer to your FOI request dated , regarding statistics on adoption applications to the Adoption Authority relating to surrogacy / DAHR.

As there is currently no legislative framework regarding surrogacy and DAHR, the Adoption Authority of Ireland have not been able to process any adoption applications which relate to surrogacy / DAHR. The Adoption Authority will not be in a position to process such applications until the Surrogacy and Assisted Human Reproduction Bills are commenced into law.

Should you have any queries regarding the above, please do not hesitate to contact me.

Yours sincerely

Corporate Services and Accreditation Unit
Email : corporate@aai.gov.ie

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19th May 2019

Ted McEnery

Joint Oireachtas Health Committee

Leinster House

Kildare St

Dublin 2

Dear Mr McEnery,

Legislation for Assisted Human Reproduction – Sperm & Egg Donation - Implications

I am writing to you with regard to the upcoming legislation for Assisted Human Reproduction in Ireland. As a Specialist Fertility Counsellor and Author, I have worked managing the Psychotherapy department for patients in The Lister Hospital, London and also previously in Sims IVF, Dublin. I currently work part-time in the area of fertility counselling support for couples and individuals. I now work independently, as this also means, I am not on the payroll of a particular clinic or hospital where I am providing implications counselling support to patients undergoing donation treatment.

As outlined, I have worked in the UK which is legislated for Identifiable donation only, and also work in Ireland, where to date both anonymous and identifiable donation treatment has been provided. I have wondered how things would progress within private health settings and with fertility consultants once this new legislation is introduced.

As we are aware Fertility Health Care yields millions of euros for those involved in its provision and I personally very much welcome the legislation and its intention to better serve patients, clinics and ultimately children born from the process.

Having worked in the industry for many years, in hospital and private settings, I am aware that many consultants approach the area of Donation (sperm, egg and embryo donation) with an ethical mindset, however, unfortunately we still have many clinics and consultants in Ireland promoting anonymous donation and additionally non-disclosure to children/adult children being encouraged to patients (particularly heterosexual couples).

Most recently, I am hearing an increasing number of patients being told by consultants that the eggs, "are just cells" and that there is no benefit to telling children they have been born with the help of donation. I believe this to be medically unethical – as in reality we were all just cells! However, it minimises the fact that actually it is one half of a person's identity.

Consultants are also encouraging their patients to attend Information Evenings on Anonymous egg and sperm donation, with their partner clinics, for example with Shady Grove in the US (see link below) and other clinics in Spain. These clinics only provide anonymous egg donation (non-identifiable).

https://www.shadygrovefertility.com/resources/calendar/ireland-dublin-donor-egg-seminar

https://www.shadygrovefertility.com/blog/treatments-and-success/anonymous-egg-donation-is-it-possible-to-protect-a-donors-identity/

In addition, patients are being told that the Irish government will soon have their details on file if they choose identifiable donation. This is taking a grain of truth and injecting a considerable element of fear, at a time when most couples and individuals are very vulnerable (choosing whether to move forward with donation or not usually after unsuccessful IVF or IUI treatment). The same information is often perpetuated by the clinic (for example in the blog from Shady Grove above).

Partner clinics promoting anonymous donation infer that otherwise, the donor or recipient may be left open to discovering each other e.g. via the internet! This is misleading – as we know the only person who can have any identifiable information is an adult donor child after due process. The identity of the donor (even if identifiable) and the identity of the recipient is never disclosed or could never be disclosed to each other. The only time this would change is if the donor is known to the recipient (not common and this is agreed by choice).

The new legislation does not cover the loop hole to ensure that Irish clinics or consultants are not facilitating anonymous donation with partner clinics abroad. I am very concerned about this and believe in the interest of the adult children who will be impacted most by anonymous donation, this needs to be rectified.

If it is not rectified we will be doing a total dis-service to the Irish adults of the future in 20, 30 plus years' time. We have already had a similar experience where we denied many adult children the right to know their identity, following adoptions in Ireland. The current generation of adoptees carry that burden and in my experience of working with adult children, it causes grave distress, often for a lifetime.

If clinics and/or consultants facilitate anonymous donation e.g. they provide all the treatment up to and after the sperm, egg or embryo is transferred, this should in my opinion be made illegal, as it is effectively facilitating anonymous donation, which will no longer be legal in Ireland. In such instances, the patient will only travel once to the clinic abroad for the anonymous sperm, egg or embryo transfer, all other treatment before and after, will be provided by the consultant/clinic in Ireland.

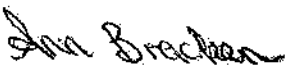
When legislation came into the UK, most clinics objected saying there would be no access to identifiable donors, this has not been the situation. Equally there are identifiable donors accessible to any clinic in Ireland, via for example, the European sperm bank or London sperm bank or egg donors via Altrui agency and in partnership with any other UK based clinic and also in the Ukraine. Therefore, it is not necessary and should not be lawful to partner up with clinics to facilitate anonymous donation.

As outlined, I am working completely independently of any hospital, consultant or clinic and have no personal gain in bringing this to your attention. My book on fertility treatment and donation was endorsed by Dr Alice Domar, Harvard University and Dr James Nicopoullos from The Lister Hospital, Chelsea, London. I am experienced in implications therapy provision for identifiable and anonymous donation and provide training in the area of fertility treatment support.

I am writing because I believe we need to respect the rights of adult children to have access to their identity, so important for medical reasons and/or for their human right to know this if desired. If denied, this will potentially affect them negatively and can also impact future generations of their family and they don't have a voice! It will not affect the consultant or even the parents - although it usually impacts negatively on family dynamics if they find out inadvertently and also if they have no access to any identifiable information as adults, should they want to.

Please, let's not leave another group of Irish adults with no access to their full (e.g. anonymous embryo) or partial identify (sperm or egg donation) and with no hope of ever being able to access it, as by turning a blind eye to this loop hole, it impacts them, their children and future generations.

Yours sincerely,



Ann Bracken