Regulation of Assisted Human Reproductive Technologies in Ireland: Current, Emerging & Future Ethical, Legal & Societal Considerations.

Workshop Report



Workshop Date: 24th & 25th April 2025

Venue: Maynooth University.

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Introduction

On 24th and 25th April 2025, <u>Prof Aisling McMahon</u> and <u>Alanna Kells</u> (PhD Candidate), School of Law and Criminology, Maynooth University, hosted a multi-disciplinary workshop examining the 'Regulation of Assisted Human Reproductive Technologies in Ireland: Current, Emerging & Future – Ethical, Legal and Societal Considerations' in Maynooth University.

Over the course of two days, the workshop brought together over 20 leading national and international speakers drawn from a range of academic disciplines and practice, including law, business, health, social sciences, ethics, embryology and clinical fields. The workshop focused on examining ethical, legal and societal issues related to the regulation of emerging assisted human reproductive technologies in Ireland. In this context, it focused on the recently adopted Health (Assisted Human Reproduction) Act 2024 which was signed into law in Ireland on 2nd July 2024, and awaits commencement at the time of writing (June 2025). This Act provides for a tailored legal and regulatory framework for assisted human reproduction in Ireland, including providing for the establishment of a new regulatory body: the Assisted Human Reproduction Regulatory Authority (AHRRA) in Ireland.

The workshop focused on two key aspects of the legal framework in this context: First, it considered the Health (Assisted Human Reproduction) Act 2024 including how it will interact and sit within existing legal, constitutional and regulatory frameworks in Ireland. Speakers also considered how various provisions within this Act will address existing ethical, legal and societal issues (ELSI) related to assisted human reproductive technologies, including in the context of surrogacy, and around the use, storage and donation of gametes (egg and sperm) and embryos. Alongside this, the workshop featured papers examining ELSI related to emerging assisted human reproductive technologies, including gametogenesis, mitochondrial donation technologies, ectogenesis etc. Discussions considered a range of ethical, legal and societal challenges related to such emerging technologies, how these issues are being considered in other jurisdictions such as the UK, and the implications of these for the Irish context, including for the operation of the Health (Assisted Human Reproduction) Act 2024 (once commenced).

The event was attended by approx. 30 people over two days and featured insightful timely discussions with leading experts in the field. This report provides a brief overview of the main papers and topics discussed over the two days.





Workshop Day One - 24th April 2025 Welcome and Introduction to the Workshop

To start the workshop, Prof Fergus Ryan (Head of School of Law and Criminology, Maynooth University) offered an opening address and welcome to the conference attendees. He then reflected on the historical developments around the regulation of assisted human reproduction in Ireland, and highlighted the significance of the adoption of the 2024 Act.

Following this, Prof Aisling McMahon (School of Law and Criminology, Maynooth University) provided an introduction to the workshop topic and aims, and a brief overview of the current evolving legal landscape in Ireland with reference to the Health (Assisted Human Reproduction) Act 2024, which awaits commencement at the time of writing (June 2025). She provided a brief overview of the history of the development of this Act, and the current legal framework in Ireland. She also discussed key considerations around how this Act will operate commenced within the broader legal and regulatory framework in Ireland, including, the need to consider its interaction with a range of other national and legal sources such as existing national legislative frameworks, constitutional law, European Union law, human rights law and broader regulatory frameworks etc. Following this introductory session, day one proceeded over three main sessions each featuring papers examining the ethical, legal and societal issues related to the regulation of assisted human reproduction and emerging technologies in this field.



Prof Fergus Ryan, Maynooth University.





Session One – Children & Family Rights and Interests in the Regulation of Assisted Human Reproductive Technologies in Ireland: Examining Existing and Emerging Frameworks

Session one was chaired by Prof Edward (Ted) Dove (School of Law and Criminology, Maynooth University) and speakers in this session considered topics related to the protection of the interests of the child and family within Ireland's legislative and constitutional framework applicable to assisted human reproductive technologies. This included a consideration of how the existing framework and the new Health (Assisted Human Reproduction) Act 2024 (once commenced) will address ethical and legal issues arising and challenges remaining.



Prof Ted Dove, Maynooth University.



Dr Lydia Bracken, University of Limerick.

It featured papers from three speakers. The first paper was delivered by Dr Lydia Bracken (School of Law, University of Limerick) who examined 'The entrenchment of the sexual family form in the Health (Assisted Human Reproduction) Act 2024'. Dr Bracken highlighted key provisions within the new Act which she argued entrench the conception of the sexual family - a nuclear family with a mother and father. She explored the implications of this, including around entrenching gendered views in the assisted human reproduction (AHR) context, and for access to AHR services.

Following this, Dr Brian Tobin (School of Law, University of Galway) delivered a paper entitled 'Establishing the Child's Legal Parentage under the 2024 Act: Compliant with International Best Practice in the Verona Principles?' Dr Tobin focused on how the 2024 Act will apply in the surrogacy context. He put forward a series of gaps between current provisions in the Act including around the operation of consent in the surrogacy context, and international best practice, under the Verona principles.



Dr Brian Tobin, University of Galway.



Dr Andrea Mulligan, Trinity College Dublin.

Finally, Dr Andrea Mulligan (School of Law, Trinity College Dublin) discussed the 'Constitutional Aspects of Assisted Human Reproduction in Ireland'. Dr Mulligan considered the relevance of constitutional rights, including protections related to equality, marital privacy, the right to procreate, and the right to identity, to the AHR context in Ireland. She highlighted the important interpretative role of courts in this area, and implications for the regulation of assisted reproductive technologies.

Session Two: Donation, Use and Storage of Gametes and Embryos – Ethical, Legal and Societal Considerations and the 2024 Act.

Session two was chaired by Prof Aisling McMahon, (School of Law and Criminology, Maynooth University), and focused on ethical, legal and societal issues (ELSI) related to the donation, use and storage of gametes and embryos. Speakers considered how the 2024 Act will likely address such issues and challenges remaining. Discussions also considered the implications of the current law and emerging frameworks for clinical practice in the field.

First, Dr Neil Maddox (School of Law and Criminology, Maynooth University) discussed 'Human Gametes and Irish Law: The Impact of the Health (Assisted Human Reproduction) Act 2024' which examined how the 2024 Act (once commenced) will govern the storage and use of gametes (egg and sperm) and key ELSI emerging including, in the context of preservation of gametes. Following this, Dr Claire McGovern (School of Law and Criminology, Maynooth University) considered 'Posthumous Assisted Human Reproduction under the Health (Assisted Human Reproduction) Act 2024' which examined the framework under the 2024 Act for the use of gametes (or embryos created using these) following the death of a gamete provider. She highlighted how the Act addresses certain ELSI, and challenges remaining including around the consent framework. Following this, Prof Mary Wingfield (Former Consultant National Maternity Hospital and Clinical Director of Merrion Fertility Clinic, Associate Clinical Professor, Obstetrics & Gynaecology, University College Dublin) discussed 'Assisted Human Reproduction Legislation in Ireland: A Clinical Perspective', and Dr Aoife Campbell, (Merrion Fertility Clinic) considered 'Assisted Human Reproduction in Ireland: An Embryologist's Perspective'. Prof Wingfield and Dr Campbell offered important insights around how the 2024 Act would operate in clinical and laboratory practice contexts, and how it will likely address ELSI that may arise. Both speakers also highlighted challenges remaining, including challenges related to emerging scientific/clinical developments and how these will be provided for by the applicable legal framework. All speakers highlighted the need for ongoing multi-disciplinary dialogue within the field to address ethical and legal issues particularly given advances in AHR technologies.



Image Left to Right: Dr Neil Maddox, Dr Aoife Campbell, Prof Mary Wingfield, and Dr Claire McGovern.

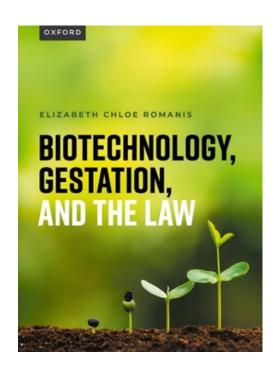




Session Three - Book Symposium: Chloe Romains, Biotechnology, Gestation and the Law Oxford University Press, 2024)

The final session of the first day took the form of a book symposium chaired by Alanna Kells (PhD Candidate, School of Law and Criminology, Maynooth University) which featured a talk by the book author Dr Elizabeth Chloe Romanis (Durham Law School, Durham University) about her recently published book: *Biotechnology, Gestation, and the Law* (Oxford University Press, 2024).

As highlighted in the book's introductory material -"Biotechnology, Gestation and the Law presents the first comprehensive ethico-legal analysis of the nature of gestation and of technologies enabling gestation, offering a concept analysis grounded in ontology, phenomenology, politics, and law. The first three chapters develop a transdisciplinary approach for identifying and exploring the ethical issues raised by uterus transplantation and ectogestation. This addresses the ontological and legal confusion about what gestation is, how we should classify procreative technologies in relation to gestation, and why it is important to have precise classification. remaining chapters use this framework to undertake a rigorous examination of pressing socio-legal implications of transplantation uterus ectogestation: who has access to technologies enabling gestation and under what circumstances? Who is/are the parent/s when novel forms of gestation are used? How do these technologies disrupt our notions of reproductive biosex and are they tools of emancipation from gendered roles? This book, and the original conceptual lens it sets out, forges a new direction for legal and social reform directed at addressing the harms of constructed gendered procreative and parenting roles."





Dr Elizabeth Chloe Romanis, Durham University.





As part of the book symposium, Dr Romains gave a short talk introducing key arguments in her book. Following this, Prof Mary Donnelly (School of Law, University College Cork) acted as a discussant for the book and provided a thoughtful reflection on core themes within the book, and how Dr Romain's conceptualisation of gestation and emerging assisted human reproductive technologies within the book could offer insights for considering emerging issues and challenges within the broader field. These talks were followed by a discussion on such core themes and emerging ethical, legal and societal issues arising within the assisted human reproduction field more generally between the author and audience.



Prof Mary Donnelly, University College Cork.





An Overview of Day Two - 25th April 2025

Session One: Current & Emerging Ethical, Legal and Societal Issues related to Disputes over Use/Storage of Embryos, Financialization of Fertility Services & Regulation of Ectogenesis.

Day two began with a session that considered current and emerging issues in assisted human reproduction focusing on three distinct areas, namely on legal approaches to storage and use of embryos including where disputes arise; on ethical, legal and societal issues (ELSI) related to financialisation of the fertility and AHR field; and ELSI arising in relation to emerging ectogenesis technologies. The session was chaired by Dr Neil Maddox (School of Law and Criminology, Maynooth University).

The first paper was delivered by Natasha Richardson (PhD Candidate, School of Law and Criminology, Maynooth University) who discussed 'Unsettled Futures: Legal Approaches to Using, Storing and Discarding Embryos under Ireland's Health (Assisted Human Reproduction) Act 2024.' Natasha considered how the 2024 Act addresses questions around the storage and use of embryos in the assisted human reproduction context. She considered how the principle of 'consent' will likely be applied under the Act where there are disputes over the use of stored embryos, and outlined potential ethical and legal issues arising.



Natasha Richardson, Maynooth University.

Following this, Alanna Kells (PhD Candidate, School of Law and Criminology, Maynooth University) examined 'Ectogenesis and the Margin of Appreciation under the ECHR: Anticipatory Gaps in Irish Reproductive Regulation.' Alanna considered the regulation of ectogenesis (the gestation of a fetus outside the body) and highlighted that whilst ectogenesis is not currently possible, developments suggest it may be possible in future. She noted ectogenesis is not covered under the current Act, and analysed Alanna Kells, Maynooth University. how Irish courts or the European Court of Human Rights principles might apply in this context.





Dr Lucy van de Wiel, Kings College London.





Finally, Dr Lucy van de Wiel (Department of Global Health & Social Medicine, Kings College London) examined 'Eggs and Equity: Finance and the Future of Fertility'. Her paper considered the increasing financialisation of assisted human reproductive services, and fertility services, including egg freezing. She compared the development of in vitro fertilisation to current assisted human reproductive services, and noted the increasing role of for-profit entities, including in the establishment of fertility clinics. Dr van de Wiel highlighted a range of important ELSI.

Session Two: Regulating Emerging Assisted Human Reproductive Technologies: Regulating Mitochondrial Donation Technologies, Gametogenesis and other Emerging Technologies

Session two on day two was chaired by Prof Mary Donnelly (School of Law, University College Cork) and continued discussions on the regulation of emerging assisted human reproductive technologies, and ethical, legal and societal issues which arise.

First, Prof Aisling McMahon (Maynooth University) discussed 'Regulating Emerging AHR Technologies & Uncertainties: Definitional Questions, Interpretative Spaces & Need for Principles Based Approaches'. She focused on the challenges for law in regulating emerging technologies, examining how developments in mitochondrial donation techniques in the AHR context, and stem cell based embryo model technologies in the research context, will fit within the 2024 Act (once commenced) and likely ethical & legal issues arising.



Prof Aisling McMahon, Maynooth University.



Dr Ilke Turkmendag, Newcastle University.

Following this, Dr Ilke Turkmendag (Newcastle Law Newcastle University) School, examined the 'Regulation of child's 'right-to-genetic-identity' in human reproductive technologies.' In this paper, Dr Turkmendag focused on the UK context which provides for the use of mitochondrial donation techniques in certain contexts. She then examined how questions around the child's right to an identity are considered within the context of mitochondrial donation with reference to information about the fact mitochondrial replacement techniques were and the used accessibility of donor information to children born.

Finally, Dr Laura O'Donovan (Sheffield Law School & Wellcome Trust funded, Future of Human Reproduction Project) delivered a paper on 'Regulating IVG in the UK: Navigating legal challenges and bioethical boundaries.' Dr O'Donovan provided an overview of emerging in vitro gametogenesis (IVG) technologies and then considered a range of ethical, legal and societal issues related to the regulation of IVG, emerging policy developments in the UK context and implications for the field more generally.



Dr Laura O'Donovan, University of Sheffield.





Session 3: Regulation of AHR Technologies: Regulatory Perspectives

The final session featured discussions on the regulation of assisted human reproduction and emerging considerations from a regulatory perspective. It included talks from representatives of the Health Products Regulatory Authority (Ireland) (HPRA) and the Human Fertilisation and Embryology Authority (United Kingdom) (HFEA). First, Anne Hayes and Jenny Cloherty (HPRA) discussed the "Regulation of Assisted Human Reproduction in Ireland: Role of Health Products Regulatory Authority" which highlighted the role of the HPRA in this area in Ireland, relevant European Union legislation, recent developments in the field, and emerging considerations. Following this, Peter Thompson, Chief Executive, HFEA, discussed 'Current and future challenges of regulating ART: A UK perspective' which provided an overview of the HFEA's role in the regulation of AHR in the UK, emerging issues, and likely future challenges for regulators. Following this, there was an insightful discussion with speakers and participants on the regulation of AHR.



Image Left to Right: Jenny Cloherty (HPRA), Anne Hayes (HPRA), Peter Thompson (HFEA), & Prof Aisling McMahon.

Workshop Close - Concluding Reflections

Professor Aisling McMahon closed the workshop thanking all participants and speakers, and reflecting on discussions. A key theme which emerged throughout the workshop was that the Health (Assisted Human Reproduction) Act 2024 is much welcomed in the Irish context. Relatedly, there was strong support in general for its commencement as soon as possible. Nonetheless, the effect of this Act on the AHR field in Ireland will depend on how it is interpreted once commenced. A range of ethical, legal and societal issues (ELSI) remain and other ELSI will likely emerge related to various provisions within the Act, depending on how these are interpreted. Moreover, given the fast pace of developments in the field, including the pace of technological developments, there is an ongoing need for meaningful multidisciplinary engagement with stakeholders and experts working on AHR. Such multidisciplinary engagement is vital to understand the likely impacts of legislative measures in practice, and to pre-empt future ELSI. Relatedly, as we await the commencement of the 2024 Act in Ireland, multi-disciplinary dialogue would benefit the development of any amending legislation (which is under consideration on certain aspects) and in the future operation of the AHRRA. The workshop closed with reflections on next steps for this group, including support for future meetings, and publications examining the ethical, legal and societal issues related to AHR with relevance to emerging policy discussions nationally and internationally.





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