



New research on the Human Fertilisation and Embryology Act 2008

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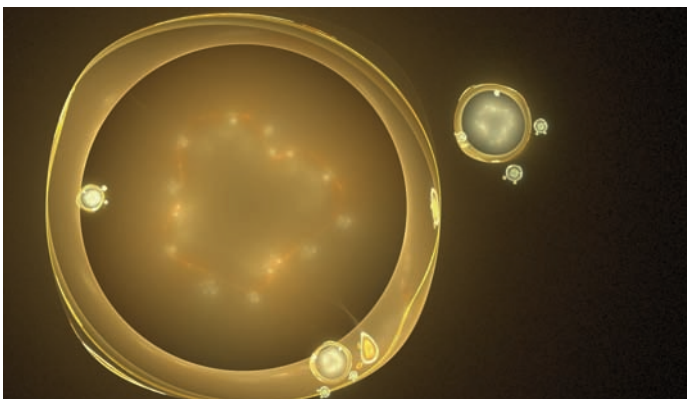
The Human Fertilisation and Embryology Act 2008 – implications for human embryonic stem cell research

I examine in detail three aspects of the Human Fertilisation and Embryology Act 2008 (particularly Part 1 and Schedule 2) of interest to human embryonic stem cell researchers: the sources of embryos for research, the permitted research purposes, and the regulation of embryonic stem cells post-extraction.

1. The sources of embryos for research

The broadening of the definition of a human embryo, along with the new definitions of human admixed embryos, have potentially widened the number and types of embryos upon which embryo research and stem cell derivation can occur. There is also the potential to undertake valuable research without the use of limited resources of human oocytes. However, the lack of appropriate regulation making powers creates the strong possibility that the definitions pertaining to human admixed embryos will quickly become out of date, and new primary legislation may be required.

The 'necessary use of embryos' provision is vital to maintain public confidence, but could also prevent further stem cell derivation where suitable alternative cell lines or sources of cell lines exist. Induced pluripotent stem cells represent an ethically acceptable source of pluripotent stem cells; as they become easier to create and maintain they may prevent the issuance of embryonic stem cell derivation licences where it is not possible to show that the use of embryos is 'necessary'.



2. The permitted research purposes

Schedule 2 of the HFE Act 2008 includes the provision allowing for basic research to occur, as well as more specific research provisions. The effect of extending research to 'serious medical conditions' for human embryonic stem cell research is that the field of research has been opened up, to areas which may not previously have been considered acceptable under the old research purposes (as contained in the HFE Act 1990).

3. The regulation of embryonic stem cells post-extraction

The HFE Act 2008 does not directly regulate embryonic stem cells. However, the Act does still affect the research which occurs with embryonic stem cell lines as it directly influences the Code of Practice of the UK Stem Cell Bank. The role of the UK Stem Cell Bank is to control access to, and research upon, stem cell lines. By following the permitted research purposes within the HFE Act, the UK Stem Cell Bank ensures that researchers are not able to circumvent the permitted reasons for destroying and researching upon human embryos.

Further reading

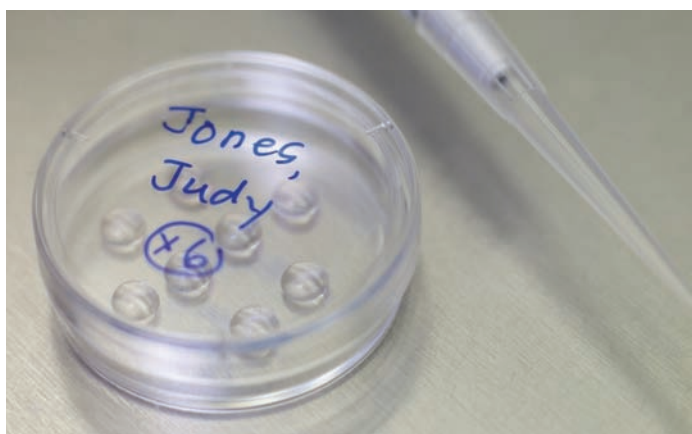
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Regulating IVF and pre-implantation tissue-typing for the creation of 'saviour siblings': a harm analysis

Introduction

My research reviewed the regulatory frameworks overseeing the delivery of assisted reproductive technologies (ART) in Australia and the UK. The research focuses on the specific regulatory issues surrounding the creation of 'saviour siblings' as a result of IVF and pre-implantation tissue-typing (PITT). The analysis of the regulatory frameworks is underpinned by a harm-based framework in order to establish whether there is any resulting harm to justify prohibition of the technology or limitation of its accessibility for this particular purpose.

Within the general field of ART regulation, the regulatory frameworks in place across Australia and the UK make reference to the importance of considering the welfare of the child who may be born as a result of reproductive technologies. This principle has generally been applied as a means of assessing whether there is any risk of harm to children born as a result of such technologies.



At the same time, there has been recognition of the importance of allowing reproductive choice and emphasis has been placed on preserving reproductive liberty, which should prevail except in cases where there is a serious risk of harm that will eventuate. For example, the Human Fertilisation and Embryology Authority (HFEA) has stated there should be a presumption in favour of reproductive choice unless serious harm will result to children who will (or may) be born following the provision of ART services. There is some conflict between these two underlying regulatory objectives and in the context of PITT, the regulatory response has taken a precautionary and restrictive response. The latter response is not necessarily consistent with the harm-based approach that has been adopted in many areas of ART regulatory policy.

Key findings

- Across Australia, the regulatory response to the specific issue of PITT is inadequate and is only addressed in detail by one State.
- Due to the imposition of statutory 'eligibility' criteria in some Australian jurisdictions, the accessibility of PITT services is indirectly limited. In those States, such services are only available in cases where the couple seeking treatment services is also seeking to use pre-implantation genetic diagnosis (PGD) to prevent transmission of a genetic condition.
- Although initially, PITT was not addressed by the legislative framework in the UK, the accessibility of the technology was restricted by the HFEA in a precautionary manner and was only available where the couple sought PGD services to prevent the transmission of hereditary disease.
- In the context of PITT, the HFEA has stated that its initial approach was focused on assessing the 'welfare of the child' in this context. However, arguably, there was no serious risk of harm to children born as a result of PITT to justify the limitations that were evident in the initial policy.
- Although the HFEA has emphasised that reproductive decisions should be given priority unless a significant risk of harm is present (thus, there is clear evidence of a harm-based approach), the reasoning evident in much of the Authority's policy has taken a slightly utilitarian approach and has placed emphasis on the benefit that may result to the existing sick child in the saviour sibling context.
- A harm-based approach is focused on analysing the harm that may result to children born following PITT (and also arguably the 'harm' that may result to society) and is not necessarily concerned with weighing up the risk of harm with the benefit to the existing sick child.
- A number of the regulatory requirements imposed in the context of PITT are restrictive and are not necessarily consistent with a harm-based approach.

Further reading

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Hype, hybrids and the re-construction of governance of embryo research in the UK

Introduction

The Human Fertilisation and Embryology Act 2008 was the culmination of a process of political debate stretching back over the preceding five or six years. In so far as the scientific community was closely involved in the process at the start, it was pushing, tentatively, for a liberalisation of the regulatory regime, a more 'research-friendly' structure. Consonant with the scientists' hope that they might be able to nudge the regulations in a more liberal direction, broad support for the principle of research using fully human embryos was evident throughout the debates leading up to and on the Bill, and in one way **the 2008 Act is more permissive (if not liberal) than its predecessor**, in the sense that it allows a wider range of research activities than the HFE Act 1990. Overall however, attempts to liberalise the regulatory structure failed: the character of the HFE Act 2008 is substantively similar to the HFE Act 1990, and formally speaking the underlying philosophy of the 2008 Act is the same as the 1990 Act, which was based on the work of the Warnock Commission in the 1980s.

But beyond the similarities there are also some differences. My research examines the reconstruction of the governance of embryo research and also the vexed issue of hype and medical research by looking at the question that dominated the recent debates: the creation for research of hybrid embryos; that is, embryos combining human and animal material (later termed admixed human embryos). I consider **the mixed assessments and motivations of the broad coalition established to promote hybrid embryo research** in the run up to Parliamentary debates in 2007 and 2008 (culminating in a very public Prime Ministerial endorsement of the importance of the research), and use this to shed light on the **confusions and disappointment evident when prominent scientists failed to attract funding for the research** shortly after Parliamentary approval was given.

A deliberative process?

The renewal of the HFE Act was presented and to a degree conducted as a deliberative process. As one might expect from the writings of Rawls and others this encouraged all the protagonists to move away from arguments based on core principles and world views to stressing a limited set of arguments. Specifically, in relation to research, **the protagonists were pushed to debate admixed human embryos because that was the main issue on which the process appeared to 'allow' debate.**

Framing is inherent to deliberative processes. In theory to a degree and in practice certainly pluralism has its limits. The most significant feature about both the HFEA consultation on hybrids in 2007 and the broader legislative consideration of the issue was **the framing of the debate in the light of existing legal and policy frameworks**. With an eye to this, attention has tended to focus on the exclusion of 'Pro-Life' views from the debates in the sense that their contribution was discounted in advance (opponents of hybrid embryo research who also opposed all human embryo research were regarded as 'the usual suspects'). However, those who do not see the need for specific governance arrangements for embryo research and specifically **those who saw no need to be concerned about research using hybrid embryos were also excluded**. Further, the deliberative process tended to select scientists who thought the work was scientifically important and perhaps medically useful, as it was by stressing the importance of the work that a counterweight was created to the ethical concerns of those critical of the work.

Conclusions

In practice, the construction of what we might call the representative scientists' view, that hybrid embryo research should be controlled by a competent authority to reflect the ethical seriousness of the undertaking but allowed in principle on account of its importance to developing cures for human diseases, was not obvious, since most of those who dissented from this package were less visible. However, **behind the scenes many were alternatively bemused or annoyed at the terms of the debate, both ethical and scientific**. It is against this background that we can best understand the rise and also the subsequent fall of hybrid embryo research.

Further reading

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Malcolm Smith will shortly submit his PhD thesis, undertaken at Queensland University of Technology, Australia, examining regulatory aspects of IVF within Australia and the UK for the creation of 'saviour siblings'. Malcolm is currently employed within the Legal Services Department at Imperial College Healthcare NHS Trust. Email Malcolm.Smith@imperial.nhs.uk



John Gillott is a PhD student with Innogen at The Open University, where his research is titled: 'The changing governance of science? A critical inquiry into the contemporary politics and governance of research as explored through the human tissue and embryo cases in the UK.' John worked most recently as Policy Officer at the Genetic Interest Group. Email J.M.Gillott@open.ac.uk

This research briefing was prepared in conjunction with a workshop organised by the ESRC Genomics Policy and Research Forum, held on Thursday 8 October at the ESRC Genomics Network Conference 2009, Welsh Assembly, Cardiff. This workshop brought together new research on the Human Fertilisation and Embryology Act 2008 from current PhD students and recent PhD graduates, from the ESRC Genomics Network and beyond.

This briefing was written by John Gillott, Natasha Hammond-Browning and Malcolm Smith, and edited by Christine Knight, Policy Research Fellow, ESRC Genomics Policy and Research Forum.



The Genomics Policy and Research Forum is a novel ESRC-funded initiative dedicated to the development of links between social scientists and scientists working in the contemporary life sciences, and the connection of research in this area to policymakers, business, the media and civil society. The Genomics Forum is based at the University of Edinburgh and is part of the **ESRC Genomics Network (EGN)**, a major ESRC investment spanning five of the UK's leading universities examining the development and use of the science and technologies of genomics. The EGN includes three ESRC-funded Genomics Centres – **Cesagen**, **Egenis** and **Innogen** – as well as the Genomics Forum.

For further information visit www.genomicsnetwork.ac.uk/forum, or contact:

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