

Institution: Queen's University Belfast		
Unit of Assessment: 30 – Philosophy		
Title of case study: The ethical approval of mitochondrial replacement therapy		
Period when the underpinning research was undertaken: 2012 to 2018		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s): David Archard	Role(s) (e.g. job title): Professor	Period(s) employed by submitting HEI: 01.06.2012 - to 01.02.2018
Period when the claimed impact occurred: August 2013 to July 2020		
Is this case study continued from a case study submitted in 2014? No		
<p>1. Summary of the impact</p> <p>In December 2014 the UK Parliament approved regulations allowing the licencing of mitochondrial replacement treatment, a pioneering medical intervention to prevent the transmission from mother to child of extremely serious genetic conditions. As the only philosopher on the Human Fertilisation and Embryology Authority (HFEA) Professor Archard played a significant role in the process that led to the approval of these regulations.</p> <p>He also played a central role, as Chair of the HFEA's Statutory Approvals Committee, in establishing the procedures (including the standing orders and decision trees) to be used by the HFEA when assessing individual applications for mitochondrial replacement treatment.</p>		
<p>2. Underpinning research</p> <p>The HFEA is an independent regulator with sole authority for the statutory review of fertility treatment and human embryo research throughout the United Kingdom. Its role is to protect patients and the public interest, to drive improvement in treatment and research, and to provide information to the public and policymakers about treatment and research.</p> <p>Professor Archard's appointment as the only moral philosopher on the HFEA between 2005 and 2016 was made in recognition of his internationally distinguished research in moral, legal, and political philosophy. His published research since his appointment at QUB in June 2012 confirms his reputation and distinctive role within the Authority. This research also supplies key and original insights with direct relevance to his work on the Authority. These concern the responsible regulation of procreation, the role of best interests in making decisions about future children, and the nature and role of philosophers in collective decision-making in non-ideal circumstances.</p> <p>A key constraint in the regulation of fertility treatment is the welfare and interests of any future child. Ensuring that any new regulation meets this constraint requires interpreting what the vague and ill-defined principle of <i>acting in a child's best interests</i> demands in the given context. Professor Archard has developed authoritative and ground breaking research on this topic, including work on how to determine the proper limits of the best interests principle in the context of regulating reproduction, and how it should be weighed against other principles applicable in that context (such as the presumptive rights of parents, and considerations of the public good) [outputs 3,4 and 5]. That research was materially relevant for his work with the HFEA that resulted in their recommendations to Parliament on the licencing of mitochondrial replacement</p>		

treatment, and in shaping the detailed procedures to be used when making decisions about individual licencing applications.

Archard has also published leading research into the proper role of normative theorists in developing and implementing public policy. Applied normative theorists trying to change law and policy in the light of their own theory must acknowledge that any such changes can only be managed in non-ideal contexts [Outputs 1 and 2]. He argues, crucially, that philosophers must make decisions conjointly with non-philosophers and in circumstances where the views of any individual philosopher need not have any especial or determinative weight. Archard is only one Member of the HFEA but his distinctive contribution as the sole philosopher is acknowledged. His research on 'moral compromise', the 'moral authority' of the philosopher, and complicity in non-ideal collective decision-making, directly contribute to the manner in which he discharged his roles in the process leading up to the licencing of mitochondrial replacement treatment.

3. References to the research

1. D. Archard, 'Moral compromise', *Philosophy*, 87:341 (July 2012): 403-420 — doi:10.1017/S0031819112000265
Contribution to a leading peer-reviewed journal
2. D. Archard, 'Dirty hands and the complicity of the democratic public', *Ethical Theory and Moral Practice*, 16:4 (August 2013): 777-790 — DOI 10.1007/s10677-012-9387-y
Contribution to a leading peer-reviewed journal
3. D. Archard, 'Children, Adults, Autonomy and Well-Being,' in A. Bagattini and C. Macleod (eds.) *The Nature of Children's Well-Being: Theory and Practice* (Dordrecht: Springer, 2014): 1-14. ISBN: 978-94-017-9252-3
Chapter in invited volume with international contributors
4. D. Archard, 'Regulating Responsible Reproduction,' in Catherine Stanton, Sarah Devaney, Anne- Maree Farrell and Alexandra Mullock (eds.) *Pioneering Healthcare: Essays in Honour of Margaret Brazier* (London: Taylor & Francis, 2015): 223-230 — doi:10.4324/9781315716107
Chapter in invited volume with international contributors
5. D. Archard, 'Family and Family Law: Concepts and Norms', in Elizabeth Brake and Lucinda Ferguson (eds.) *Philosophical Foundations of Children's and Family Law* (Oxford: Oxford University Press, 2018): 59-72. ISBN: 9780198786429.
Chapter in invited volume with international contributors

4. Details of the impact

Professor Archard has played a significant role in the processes that have made Mitochondrial treatment (MRT) available to patients in the United Kingdom — both those that resulted in Parliamentary approval for licencing such treatments, and those leading to the approval of licences in individual cases. He did so as the sole philosopher on the HFEA,

“Archard is in charge of one of the most delicate of public policy decisions. Parliament felt it could legislate to allow [MRT] because of the state of the science and the confidence it had in the expert regulation of the HFEA. [He] contributes greatly to the expertise of the HFEA and the treatment options of many people with serious inherited conditions; few philosophers could so directly demonstrate that their training had such an impact.”[Ref 5.4]

Parliamentary approval of regulations allowing the licencing of MRT

MRT can only be provided in the UK under licence. Before that could happen Parliament had to debate and approve regulations allowing such licences to be granted. Professor Archard played an integral role in developing the HFEA (in its role as the relevant licencing body) recommendations submitted for Parliamentary debate in 2014 on the form these regulations

should take, and thus significantly affected the content of the regulations subsequently approved by Parliament. That role was highlighted in the Parliamentary debates on the regulations:

- Lord Turnberg commented during the **House of Lords debate** (24th Feb 2015) “Remember that the HFEA is no pushover. It has in its membership not just three scientists and a clinical geneticist but three patients who have gone through IVF, a barrister, a *professor of philosophy*, a bishop and a national security adviser. That is quite an interesting mix but not one likely to be easily moved by faulty argument. It is they and their scientific advisory panel who will be assessing applications when these regulations come into force in October.” [Ref 5.1 emphasis added]
- In the **Commons debate** (3rd February 2015) it was noted by Dr Julian Huppert, then MP, that “we should be proud to be leading the world in medical treatments and [of the fact] thatwe can provide some of the best ethical safeguards in the world”. Andrew Miller (then MP and Chair of the House of Commons Science and Technology Select Committee) stated: ‘The ethical basis on which science is conducted in this country is world leading’. [Ref 5.2]

These remarks are generally commendatory of the HFEA but Professor Archard plays a particular and central role, as a moral philosopher, in the shaping and protection of these ethical safeguards and the ethical role of the HFEA,

“David’s contribution was to carefully and patiently describe and evaluate the significance of a variety of objections to [MRT] and communicate his thoughts to Authority members with quite disparate intellectual backgrounds... [This included:] Explaining notions of inter-generational justice and how germ line interventions such as [MRT] can still be justified; Discussing the status of the mitochondrial donor in the context of broader considerations of biological relatedness and personal identity; Elaborating on conceptions of risk in respect of technological innovation in medicine and answering wider questions related to regulation and societal implications of germ line interventions.” [Ref 5.3]

Professor Archard also played a key role in its **public consultation** on the safety, efficacy, and moral integrity of MRT [Ref 5.1]. Drawing on his own research on the ethical nature of the family and the status of children, Professor Archard both advised on the appropriate terms in which to represent publicly the major ethical issues, and contributed to drafting the consultation material. In doing so he helped frame the resultant debates in a way that undercut and defused the principal moral concern — which was summarised in the press and media as the ‘threat’ of ‘three-parent babies’,

“Without [Archard’s] experience in a range of topics in assisted reproduction, allied to his philosophical expertise and communication skills, the HFEA would not have been able to navigate [the issue] with the same dexterity, flexibility, authoritativeness and, I think, wisdom.” [Ref 5.3]

Licensing of MRT

Since Parliament approved the regulations allowing licensing of MRT fourteen licences have been granted by the HFEA’s Statutory Approvals Committee. To grant these licences the HFEA needed to develop detailed standing orders, regulations, and decision trees to be used when making decisions about individual applications. As Chair of the Statutory Approvals Committee Professor Archard took the lead developing the details of the regulatory scheme:

“Archard has been central to that work. He has guided our deliberations on a range of difficult policy issues ... [he] has brought to bear his philosophical training combined with a rare appreciation of what will work in public administration and clinical treatment. Our deliberations and final regulatory scheme are far better for his contribution.” [Joint letter from the Chair of the HFEA and Chief Executive of the HFEA, Ref 5.4]

“He has brought this experience to bear in delivering a licensing procedure that distinguishes between the particular risk of an embryo inheriting abnormal mitochondrial

DNA from its mother and the significant risk of serious disease arising in that individual as a consequence.” [Letter from Member HFEA, Ref 5.3]

In order to complete this work, and in recognition of the key role he could thereby play (as Chair of Statutory Approvals Committee and as Deputy Chair of the HFEA) to advise the Authority’s Chief Executive and Chair on critical issues, his membership of the HFEA was extended beyond the normal statutory limit of ten years. He is to date the Member with the most years of service on the HFEA (2002-2016). The HFEA’s role both in the licensing and regulation of mitochondrial replacement treatment has been cited by both the Nuffield Council on Bioethics and in the press as a model for best practice when considering any new therapeutic biotechnological processes [Ref 5.6]

“The HFEA and its characteristically careful, deliberative approach to these difficult matters of great public interest (and media attention) has been the envy of numerous countries around the world that have struggled to deliver consensus or even a coherent plan for future progress in this area. David has played a pivotal role in the success story of the HFEA and mitochondrial donation.” [Letter from Member HFEA, Ref 5.3]

5. Sources to corroborate the impact (indicative maximum of 10 references)

1. Hansard Report of House of Lords debate, 24th Feb 2015, Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015
[https://hansard.parliament.uk/Lords/2015-02-24/debates/15022465000540/HumanFertilisationAndEmbryology\(MitochondrialDonation\)Regulations2015](https://hansard.parliament.uk/Lords/2015-02-24/debates/15022465000540/HumanFertilisationAndEmbryology(MitochondrialDonation)Regulations2015)
2. Hansard Report of Parliamentary debate, 3rd February 2015, Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015
<https://publications.parliament.uk/pa/cm201415/cmhansrd/cm150203/debtext/150203-0002.htm>
3. Letter from Member HFEA, who is also a Member of the Nuffield Council on Bioethics, leading molecular geneticist and Chair of expert panel convened by HFEA at request of Government to review the latest evidence on the safety and efficacy of the two mitochondrial donation techniques.
4. Joint letter from Chair of the HFEA and Chief Executive of the HFEA.
5. Summary of consultation process conducted by the HFEA:
https://www.hfea.gov.uk/media/2618/mitochondria_replacement_consultation_-_advice_for_government.pdf
6. Reports citing the HFEA’s model for licencing as the best practice approach to the consideration of radical new therapeutic biotechnological processes: Nuffield Council on Bioethics 2018 Report ‘Genome editing and human reproduction’ 2018 Report
<http://nuffieldbioethics.org/project/genome-editing-human-reproduction> – chapter 5 (Conclusions and Recommendations); The Guardian
<https://www.theguardian.com/commentisfree/2015/sep/06/banning-genome-editing-is-not-the-answer> ; The Economist <https://www.economist.com/leaders/2015/08/22/editing-humanity>