

THE HUMAN EMBRYO *IN VITRO*

The Human Embryo In Vitro explores the ways in which UK law engages with embryonic processes under the Human Fertilisation and Embryology Act 1990 (as amended), the intellectual basis of which has not been reconsidered for almost thirty years. McMillan argues that in regulating ‘the embryo’ – that is, a processual liminal entity in itself – the law is regulating for uncertainty.

This book offers a fuller understanding of how complex biological processes of development and growth can be better aligned with a legal framework that purports to pay respect to the embryo while also allowing its destruction. To do so it employs an anthropological concept, liminality, which is itself concerned with revealing the dynamics of process. The implications of this for contemporary regulation of artificial reproduction are fully explored, and recommendations are offered for international regimes on how they can better align biological reality with social policy and law.

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CAMBRIDGE BIOETHICS AND LAW

This series of books – formerly called Cambridge Law, Medicine and Ethics – was founded by Cambridge University Press with Alexander McCall Smith as its first editor in 2003. It focuses on the law’s complex and troubled relationship with medicine across both the developed and the developing world. In the past twenty years, we have seen in many countries increasing resort to the courts by dissatisfied patients and a growing use of the courts to attempt to resolve intractable ethical dilemmas. At the same time, legislatures across the world have struggled to address the questions posed by both the successes and the failures of modern medicine, while international organisations such as the WHO and UNESCO now regularly address issues of medical law. It follows that we would expect ethical and policy questions to be integral to the analysis of the legal issues discussed in this series. The series responds to the high profile of medical law in universities, in legal and medical practice, as well as in public and political affairs. We seek to reflect the evidence that many major health-related policy and bioethics debates in the UK, Europe and the international community over the past two decades have involved a strong medical law dimension. With that in mind, we seek to address how legal analysis might have a trans-jurisdictional and international relevance. Organ retention, embryonic stem cell research, physician-assisted suicide and the allocation of resources to fund health care are but a few examples among many. The emphasis of this series is thus on matters of public concern and/or practical significance. We look for books that could make a difference to the development of medical law and enhance the role of medico-legal debate in policy circles. That is not to say that we lack interest in the important theoretical dimensions of the subject, but we aim to ensure that theoretical debate is grounded in the realities of how the law does and should interact with medicine and health care.

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CATRIONA A. W. MCMILLAN
University of Edinburgh



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For Dad.

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FOREWORD

Graeme T. Laurie

Professorial Fellow, Edinburgh Law School

It is with considerable pleasure and pride that I write the foreword for this monograph authored by Dr McMillan. As she indicates in the introduction to the work, her research was supported by a Wellcome Senior Investigator Award – *Confronting the Liminal Spaces of Human Health Research* – of which I had the privilege of being Principal Investigator (2014–2021, WT103360MA). This was the Liminal Spaces Project (www.liminalspaces.ed.ac.uk/). And, while it is an all-too-common feature of contemporary academia that researchers are held to account for their worth through numbers of publications, quality metrics, and research assessment exercises, there is still much that is not captured about the process of being involved in a research team and in producing a work of calibre such as this. Indeed, given that a central feature of the contribution of this work is to invite readers to consider the importance of *processual* regulation in dealing with the human embryo, I consider it fitting that I share with readers the experience for Dr McMillan and me in being supported by Wellcome in this project and in the *process* of producing this excellent monograph.

First, I want to signal our considerable appreciation of the flexibility that Wellcome funding affords. Because of this, I was able to employ Dr McMillan as a research assistant while she was undertaking her doctorate and also to provide partial funding support for the doctoral studies, even although this plan had not been part of the original proposal to the funder. This meant that Dr McMillan became a full member of the Liminal Spaces Project, and this was to the mutual benefit of Dr McMillan and the existing team in many ways over the ensuing years. Not only was Dr McMillan able to present and test her core ideas contained in this book at numerous international conferences, but she also benefitted from extensive and sustained interactions with other

members of the team who were also working with the anthropological concept of liminality that sits at the heart of this work. Our collective contributions were considerably enhanced as a result, and it is a testament to Dr McMillan's hard work and commitment that she was eventually appointed as Senior Research Fellow on the project. For those interested in metrics and meritocracy, all of this ultimately led to Dr McMillan securing a British Academy Postdoctoral Fellowship. It is important that these stories are told.

As to the present work, the contributions to scholarship are myriad and profoundly challenging to the ways in which law currently constructs the idea of the 'human embryo'. As a paradigm example of a liminal entity – neither one thing nor another, and 'trapped' in a state of in-betweenness betwixt proto-person and laboratory artefact – the embryo, as it is treated in law, is a perfect illustration of law's constant struggle in regulating human health research to deliver on the twin objectives of both protecting what is human and promoting scientifically sound, socially valuable research. Yet the particular contribution of this monograph goes beyond revealing the deep-rooted moral ambivalence that lies at the heart of the existing regulatory regime to suggest ways to move through and out of that permanent state of uncertainty. Indeed, many would argue that this is a regulatory state of unsustainable hypocrisy. It is here that Dr McMillan's insights through the lens of liminality – with its focus on recognising the importance of process and the processual and the need to move through and out of states of liminality towards clearly defined end points – throw into stark relief how law's bounded approach to regulation is at serious odds with the biological and processual realities of human development from its earliest stages. In seeking ways through and out of this impasse, Dr McMillan develops her notion of processual regulation, the contours of which are fully explored herein. Moreover, in the spirit of genuinely significant and impactful scholarship, it is important to recognise that this concept of processual regulation has value and application beyond the realm of the embryo and into other areas of human experience and regulation. We look forward to Dr McMillan's future scholarship in this regard.

But to remain with the current work, and as further indication of the value of being involved with an interdisciplinary team of scholars working in and around related concepts, it is also important to recognise how the Wellcome funding supported Dr McMillan to engage with projects and colleagues outside the legal realm to draw from parallel discourses about the ontology of the human embryo. In this regard, the Liminal

Spaces Project was a joint funder of the Uncanny Bodies Project that led to an anthology of fiction and non-fiction inspired by Freud, cyborgs, and the history of Edinburgh, published by Luna Press in 2020 (Edited by P. Goldschmidt, G. Haddow, and F. Mazanderani). Dr McMillan's involvement in this project considerably enriched the development of Part II of this book, which further contextualises law's ambivalence towards the embryo against other literatures – most particularly the 'gothic' – and relative to ongoing discussions about the 'uncanniness' of the embryo. Furthermore, in once again bringing a liminal lens to these literatures, the monograph helps us to get past the rather jarring 'So What?' question. It is by these means that the reader is brought to Part III where the legal, regulatory, and social implications of this research are fully explored.

In sum, Dr McMillan is to be commended for deftly weaving together an intricate patchwork of novel insights about the legal status of the embryo. As a stand-alone work in its own right, I recommend this book to a range of scholars and practitioners who are rightly concerned about how we should treat the embryo *right*. While there is manifestly no obligation to agree with the conclusions that are reached, I wager that Dr McMillan's analysis will be difficult to ignore in the ongoing debates, and I am confident that it will contribute significantly to how we see the human embryo *in vitro* in the future.

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I am grateful to Wellcome Trust for supporting this research as part of a senior research fellowship and PhD on the Senior Investigator Award entitled *Confronting the Liminal Spaces of Health Research Regulation* (WT103360MA).

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I consider myself very lucky to have carried out this research as part of the Liminal Spaces Project, alongside a team of brilliant colleagues and friends who I am grateful to for their encouragement over the past few years: Edward Dove, Agomoni Ganguli-Mitra, Isabel Fletcher, Emily Postan, Samuel Taylor-Alexander, Nayha Sethi, and Annie Sorbie. I especially thank Graeme Laurie, who led the project, without whom this work would not have been possible. I am particularly grateful for his dedication, support, and invaluable advice throughout.

Finally, I thank my father for his unwavering support and encouragement.

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ABBREVIATIONS

ART	assisted reproductive technology
AWT	artificial womb technology
CNR	cell nuclear replacement
ECHR	European Convention on Human Rights
ECtHR	European Court of Human Rights
ECJ	European Court of Justice
ESCs	embryonic stem cells
GMC	General Medical Council
HCSTC	House of Commons Science and Technology Committee
HFEA	Human Fertilisation and Embryology Authority
HRC Act	Human Reproductive Cloning Act 2001
ILP Act	Infant Life Preservation Act 1929
iPSCs	induced pluripotent stem cells
IVF	<i>in vitro</i> fertilisation
IVG	<i>in vitro</i> gametogenesis
MRT	mitochondrial replacement therapy
OAP Act	Offences against the Person Act (year as indicated)
PGD	preimplantation genetic diagnosis
SCR	stem cell research
UCP Bill	Unborn Child Protection Bill 1985
1803 Act	Lord Ellenborough's Act 1803
1967 Act	Abortion Act 1967
1967 Act (as amended)	Abortion Act 1967 (as amended by the Human Fertilisation and Embryology Act 2008)
1990 Act	Human Fertilisation and Embryology Act 1990
1990 Act (as amended)	Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008)
2008 Act	Human Fertilisation and Embryology Act 2008