



The Bar Council

Law reform essay competition 2024: best GDL entry

'No nameless horrors': the case for regulating embryo models under the Human Fertilisation and Embryology Act 1990 by Christina Fleischer

1. Introduction

Human embryos, or approximations of them, can now be created from stem cells.¹ Scientists achieve this by extracting stem cells from embryos and cultivating them *in vitro*² into human embryo 'models', replicating many features of early embryonic development including a heartbeat and traces of blood.³ Research on such 'stem-cell-based embryo models' (SCBEMs) is not governed by current legislation, as SCBEMs are not considered 'embryos' for the purposes of the Human Fertilisation and Embryology (HFE) Act 1990,⁴ due to their a) physical dissimilarities with embryos, and b) inability to develop into a human being (see section 4 below). As SCBEMs are not governed by the Act, the field of SCBEM research falls outside the regulatory powers of the Human Fertilisation and Embryology Authority (HFEA),⁵ so is unregulated in the UK.

Researchers in the field want to keep it that way. In July 2024, a UK working group of experts released a world-first Code of Practice⁶ for the ethical use of SCBEMs in research, in an explicit bid to pre-empt legislation.⁷ The Code of Practice

¹ Hannah Devlin, 'Synthetic human embryos created in groundbreaking advance' *The Guardian* (London, 14 June 2023) <<https://www.theguardian.com/science/2023/jun/14/synthetic-human-embryos-created-in-groundbreaking-advance>> Accessed 05.08.2024

² Oxford English Dictionary, 'in vitro' definition: 'in a laboratory vessel, test tube, culture dish, etc.' <https://www.oed.com/dictionary/in-vitro_adv?tab=meaning_and_use#1218096250> Accessed 23.10.2024

³ Joanne Delange, 'Heartbeat and blood reportedly observed in human stem-cell-based embryo model' (BioNews, 26 June 2023) <<https://www.progress.org.uk/heartbeat-and-blood-reportedly-observed-in-human-stem-cell-based-embryo-model/>> Accessed 01.10.2024

⁴ As amended by the Human Fertilisation and Embryology Act 2008

⁵ HFEA, 'Modernising Fertility Law: Recommendations from the Human Fertilisation and Embryology Authority (HFEA) for changes to the Human Fertilisation and Embryology Act 1990' (2023)

⁶ Cambridge Reproduction and Progress Educational Trust, 'Code of Practice for the Generation and Use of Human Stem Cell-Based Embryo Models' (July 2024)

⁷ Roger Sturmey, 'Guidelines on lab-grown embryo models are strong enough to meet ethical standards — and will build trust in science' (*Nature*, 30.07.2024) <<https://www.nature.com/articles/d41586-024-02446-x>> Accessed 31.07.2024

recommended the creation of an SCBEM Oversight Committee to approve research proposals.⁸ This Oversight Committee would not enforce a set limit on how long SCBEMs can be cultivated in a lab, but instead review researchers' own proposals for *duration of culture*, which may vary according to the stated scientific objective.⁹ Although the decision to enforce no set limit has been criticised in some quarters, the Code of Practice has broadly been positively received, with little suggestion that it falls short of replacing legislation.^{10,11} However, in this essay, I will argue that the HFE Act 1990 should be updated to regulate SCBEM research, on the grounds of (i) ethical protections, (ii) legal consistency, and (iii) public interest considerations for regulating research (see section 5 below).

2. Introduction to the HFE Act 1990

The HFE Act 1990 was the first in the world to legislate for *in vitro fertilisation* (IVF) and embryo research, and in doing so became the basis of legislation in many other jurisdictions.¹² Several provisions of the Act derive from a report produced by philosopher Mary Warnock after the birth of the first IVF baby in 1978 sparked public debate about the status of the embryo.¹³ This 'Warnock Report' recommended a 'special status' in law for the embryo, which should nonetheless be balanced against the benefits of embryo research.¹⁴ The result was a proposed '14-day rule' stipulating that embryos may be cultivated in a lab for fourteen days after fertilisation. This rule was written into the HFE Act¹⁵ and remains the upper limit for embryo research in countries as diverse as China, Sweden, and Japan.¹⁶

3. Other jurisdictions

Despite its common origins, the wording of legislation around the world differs in respect to embryos. Accordingly, 'whether and how SCBEM research is regulated

⁸ Above, note 6, p.21

⁹ Above, note 6, p.11

¹⁰ Smriti Mallapaty, 'Lab-grown embryo models: UK unveils first ever rules to guide research' (Nature 'News', 03.07.2024) <<https://www.nature.com/articles/d41586-024-02171-5>> Accessed 01.10.2024

¹¹ Louise Vennells, 'Pioneering new Code of Practice on stem cell-based embryo models in research' (University of Exeter Research News, 04.07.2024) <<https://news.exeter.ac.uk/faculty-of-health-and-life-sciences/university-of-exeter-medical-school/pioneering-new-code-of-practice-on-stem-cell-based-embryo-models-in-research/>> Accessed 05.09.2024

¹² Peter Thompson, 'The HFEA at 30: Where do we go from here?' (2021) HFEA <<https://www.hfea.gov.uk/about-us/30th-anniversary-expert-series/the-hfea-at-30-where-do-we-go-from-here/>> Accessed 24.10.2024

¹³ Mary Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology' (1984), 'The Warnock Report'

¹⁴ Ibid, 11.25

¹⁵ Human Fertilisation and Embryology Act 1990 (as amended), s.41(1)

¹⁶ Kristin Matthews, Daniel Morali, 'National Human Embryo and Embryoid Research Policies: A Survey of 22 Top Research-Intensive Countries' (2020) 15(7) Regenerative Medicine <<https://www.tandfonline.com/doi/full/10.2217/rme-2019-0138>> Accessed 01.10.2024

depends haphazardly on the form of words used in embryo research legislation passed long before anyone had contemplated the creation of SCBEMs'.¹⁷ For example, the references to fertilisation in the statutes of Spain and Germany mean SCBEMs fall outside their remit; whereas Australia's statute accommodates 'any other process that initiates organized development', meaning SCBEMs are regulated in line with embryos.¹⁸

4. UK's definition of 'embryo'

4.1. Statute

The HFE Act's definition of 'embryo' originally included a reference to fertilisation: s.1(1)(a) used to read 'embryo means a live human embryo where fertilisation is complete'. This reference was removed in 2008¹⁹ following a 2003 decision by the House of Lords that the wording of s.1(1)(a) encompassed embryos created by a process other than fertilisation. The process in question was a cloning technology known as 'cell nuclear replacement' (CNR). In the 2003 decision, *Quintavalle*,²⁰ the House of Lords ruled that embryos created by CNR were covered by the wording of s.1(1)(a). The reference to fertilisation was nonetheless removed in 2008 and the section now reads 'embryo means a live human embryo'. This definition of 'embryo' has been described as 'imprecise'²¹ and 'frustratingly circular',²² as it contains the very word it is seeking to define. Rather than providing a definition, Millett LJ notes that s.1(1)(a) is more properly regarded as a restriction on the types of embryos covered, excluding non-human and non-living embryos.²³ The gaps in this 'definition' are therefore filled by case law.

4.2. Case law

The leading case on the definition is *Quintavalle* itself, which holds that the manner of an embryo's creation does not preclude it from being legally defined as such; embryos cloned in a lab using CNR share the legal categorisation of 'embryo' with those created through the fertilisation of human gametes. Rather, CNR embryos' indistinguishability from embryos created through fertilisation provided the

¹⁷ Emily Jackson, 'Regulating embryo models in the UK' (2024) 11(2) *Journal of Law and the Biosciences* <<https://academic.oup.com/jlb/article/11/2/lsae016/7716401>> Accessed 10.08.2024

¹⁸ Ana M Pereira Daoud et al, 'Modelling human embryogenesis: embryo-like structures spark ethical and policy debate' (2020) 26(6) *Human Reproduction Update* <<https://academic.oup.com/humupd/article/26/6/779/5876550>> Accessed 23.09.2024

¹⁹ By the Human Fertilisation and Embryology Act 2008, which amended the 1990 Act

²⁰ *R (Quintavalle) v Secretary of State for Health* [2003] UKHL 13, [2003] 2 A.C. 687

²¹ Amy L Foreman et al, 'Human embryo models: the importance of national policy and governance review' (2023) 82 *Curr Opin Genet Dev*

<<https://www.sciencedirect.com/science/article/pii/S0959437X23000837#bib14>> Accessed 02.10.2024

²² Philip Ball, 'A Turing Test for Embryos?' *Inquisitive Minds* (2023)

<<https://inquisitiveminds.bristows.com/post/102imgn/a-turing-test-for-embryos>> Accessed 23.09.2024

²³ *Quintavalle* [45], Millett LJ

reasoning for treating them akin; Millett LJ noted that CNR embryos 'are in all respects save the method of their creation indistinguishable from other embryos'.²⁴ A key aspect of this indistinguishability was their mutual capacity 'to develop and, if planted in a woman, to become a foetus and eventually a human being'.²⁵ *Quintavalle* thus developed two interrelated standards for a legal definition of 'embryo': a) physical indistinguishability from those already categorised as such; and b) capacity to develop into a human being.

In 2011, the legal definition of 'embryo' received further attention in *Brüstle v Greenpeace*,²⁶ a case in the European Court of Justice which sought to clarify the definition in respect of patent law. *Brüstle* held that stem cells 'capable of commencing the process of development of a human being' were 'included within the concept of 'human embryo'.²⁷ Like *Quintavalle*, this case supports a legal definition of 'embryo' for which the process of creation is irrelevant. Unlike *Quintavalle*, *Brüstle* takes no account of physical similarities, focusing solely on development potential. As Philip Ball comments, 'even an embryo model made of wood and glue would be an "embryo" for patent purposes if it acquired the capacity of developing into a human being'.²⁸

4.3. Application to SCBEMs

SCBEMs are not considered to have the capacity to develop into a human being 'if planted in a woman'.²⁹ Such implantation is broadly considered unethical, so has not been attempted, but experiments with animal SCBEMs of comparable complexity suggest that such an attempt would fail to result in a live birth.³⁰ SCBEMs are therefore not considered to reach the standard of development potential laid down in *Quintavalle* and *Brüstle*. Regarding *Quintavalle*'s second standard of physical indistinguishability, SCBEMs range in similarity to embryos, from 'non-integrated' SCBEMs, which recapitulate³¹ only some features of an embryo, to 'integrated' SCBEMs, which attempt to recapitulate an embryo's entire development.³² Although there are clear similarities between 'integrated' SCBEMs and embryos, SCBEMs have

²⁴ *Quintavalle* [49], Millett LJ

²⁵ *Quintavalle* [43], Millett LJ

²⁶ Case C-34/10 *Oliver Brüstle v Greenpeace eV*. [2011] ECR I-9821

²⁷ *Brüstle* [37]

²⁸ Above, note 22

²⁹ *Quintavalle* [43], Millett LJ

³⁰ Jie Le et al, 'Cynomolgus monkey embryo model captures gastrulation and early pregnancy' (2023) 30(4) *Cell Stem Cell* <[https://www.cell.com/cell-stem-cell/fulltext/S1934-5909\(23\)00080-2](https://www.cell.com/cell-stem-cell/fulltext/S1934-5909(23)00080-2)> Accessed 01.10.2024

³¹ Oxford English Dictionary, 'recapitulate transitive Biology' definition: 'to repeat (an evolutionary stage or process) during embryonic development' <https://www.oed.com/dictionary/recapitulate_v?tab=meaning_and_use> Accessed 20.10.2024

³² The International Society for Stem Cell Research, 'Guidelines for Stem Cell Research and Clinical Translation' (2021) Glossary, p.64 <<https://www.isscr.org/guidelines>> Accessed 07.08.2024

not reached the standard of CNR embryos in being ‘indistinguishable’ from embryos created from fertilisation. For these reasons, the HFEA has considered that SCBEMs are not covered by the HFE Act’s use of ‘embryo’.³³

However, SCBEMs are becoming increasingly similar to embryos; in September 2023, the first integrated model that recapitulated most of the known features of a 14-day embryo was reported in *Nature*.³⁴ As SCBEMs’ similarity to embryos increases, so does their likelihood of achieving the development potential to become a human. At some point, therefore, SCBEMs will reach a ‘tipping point beyond which greater similarity collapses into identity’.³⁵ Rather than leaving SBCEMs unregulated until they fall under the HFE Act’s use of ‘embryo’, I offer three arguments in support of updating the Act to accommodate SCBEMs instead.

5. Case for updating the HFE Act 1990 to accommodate SCBEMs

- 5.1. Under the current HFE Act, it is not illegal to implant an SCBEM into a human womb.³⁶ This is because the Act’s prohibition applies only to ‘embryos’, which embryo models are not: ‘No person shall place in a woman **an embryo** other than a permitted embryo’ (my emphasis).³⁷ If the Act is not revised, a scientist who chooses to embrace the reputational risks of bypassing the SCBEM Code of Practice could implant SCBEMs into female volunteers with legal impunity. This would amount to a form of human experimentation, as well as involving unknowable health risks for the female.³⁸ The Act must be reopened to address this issue.
- 5.2. Secondly, research on material containing even a single human cell is regulated by the Human Tissue Act 2004 and subjected to strict research protocols, showing that respect for even the smallest sample of human cellular material is enshrined in law.³⁹ Furthermore, the use of the embryonic stem cells from which SCBEMs are created is regulated by the HFE Act itself.⁴⁰ It is a legal absurdity for the resulting creation to remain unregulated and subjected to fewer restrictions than its source material and other human cells.

³³ Above, note 5

³⁴ Bernardo Oldak et al, ‘Complete human day 14 post-implantation embryo models from naive ES cells’ (2016) 622, 562-573 *Nature* <<https://www.nature.com/articles/s41586-023-06604-5>> Accessed 23.09.2024

³⁵ Ana M. Pereira Daoud et al, ‘The Closer the Knit, the Tighter the Fit’ (2021) 43(6) *Reproductive Biomedicine Online* <<https://doi.org/10.1016/j.rbmo.2021.08.031>> Accessed 08.08.2024

³⁶ Emily Jackson, ‘Regulating embryo models in the UK’ (2024) 11(2) *Journal of Law and the Biosciences* <<https://academic.oup.com/jlb/article/11/2/Isae016/7716401>> Accessed 10.08.2024

³⁷ Human Fertilisation and Embryology Act 1990 (as amended), s.3(2)(a)

³⁸ Above, note 36

³⁹ Human Tissue Authority, ‘Relevant material under the Human Tissue Act 2004’, <<https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004>> Accessed 07.08.2024

⁴⁰ Human Fertilisation and Embryology Act 1990 (as amended), s.3, and schedule 2, para 3

5.3. Finally, legislation for ethically sensitive research is beneficial both to the public and to scientists. As Mary Warnock commented in relation to the original HFE Act, 'everyone wants legislation: the general public so that they can be certain that no nameless horrors are going on, hidden away in laboratories; the scientific community so that they may be in a position to get on with their work'.⁴¹ Although public awareness of SCBEMs is still relatively low, there is evidence that Warnock's 'nameless horrors' are a concern among the informed. A recent 'public dialogue' on embryo research reveals fears of a 'Frankenstein' moment⁴² if scientists' work on SCBEMs remains unregulated, and found emotional and ethical responses to SCBEM features including the spinal cord and heartbeat.⁴³ Meanwhile, the same public dialogue found 'a high level of confidence in the current regulatory and legislative structures that surround early human embryo research.'⁴⁴ This public confidence is at least partially responsible for the remarkable lack of controversy surrounding embryo research and IVF in the UK since the HFE Act 1990. Scientists may fear regulation's restrictive effects on their research, but regulation can also demonstrably bolster trust and thus ensure its longevity. Therefore, for the sake of scientists as well as the public, ethically sensitive research on SCBEMs should be governed by legislation, rather than self-regulated by a voluntarily adopted Code of Practice.

6. What form should regulation take?

6.1. Definition

The first step is to define SCBEMs in s.1 of the HFE Act, after which specific provisions for SCBEMs may be inserted. Although I have been using 'SCBEM' as the term most broadly adopted in the UK,⁴⁵ it seems unwise to build the manner of creation ('stem-cell-based') into the Act, given the problems this has caused in the past.⁴⁶

⁴¹ Mary Warnock, 'Moral Thinking and Government Policy: The Warnock Committee on Human Embryology' (1985) *Health and Society* 63(3) <<https://www.milbank.org/wp-content/uploads/mq/volume-63/issue-03/63-3-Moral-Thinking-and-Government-Policy.pdf>> Accessed 23.08.2024

⁴² Human Developmental Biology Initiative, 'Public Dialogue on Research Involving Early Human Embryos' (2023), p.37

⁴³ *Ibid*, p.43, 46-7

⁴⁴ *Ibid*, p.22

⁴⁵ See Progress Educational Trust, 'SCBEM' <<https://www.progress.org.uk/glossary/scbem/>> and POST Briefing on SCBEMs, <https://researchbriefings.files.parliament.uk/documents/POST-PN-0716/POST-PN-0716.pdf>> Both accessed 22.08.2024

⁴⁶ The case in *Quintavalle* arose because embryos' manner of creation was needlessly built into s.1 of the Human Fertilisation and Embryology Act 1990.

The term ‘embryo model’ should be adopted instead, along with the following definition: ‘embryo model means a live human embryo model created by a process other than fertilisation, which is not intrinsically capable of developing into a human’. Like the Act’s definition of ‘embryo’, this avoids the interpretative pitfalls of defining terms, but instead serves to refine what may be understood as an ‘embryo model’. By excluding embryos created through fertilisation, the definition precludes the possibility that non-viable IVF embryos could be considered embryo models, which would be undesirable on public policy grounds.⁴⁷ The phrase ‘intrinsically capable’ prevents embryos from being redefined as embryo models on the basis of extrinsic capabilities, such as the lack of correct laboratory equipment. Finally, I have suggested a corollary of the case-law definition of ‘embryo’ in focusing on the embryo model’s capability to develop into a human.

As well as covering existing embryo models, this definition is broad enough to encompass future advances in embryology. New creations of technology that approximate an embryo, yet do not meet its legal definition, could fall under this definition and be regulated by provisions for embryo models. This definition is therefore effective in future-proofing the HFE Act and ensuring that the HFEA’s powers extend over new advances in embryology which fall short of being considered ‘embryos’ yet merit some level of ethical and legal protection.

6.2. Recategorisation

Scientists writing in *Cell* have proposed a human embryo model ‘Turing Test’ in two parts, which will prove useful in determining when an embryo model can be legally recategorised as an ‘embryo’. In part one, a human embryo model must ‘pass certain watersheds’ of human embryonic stages ‘efficiently and faithfully’.⁴⁸ In part two, an animal embryo model of equivalent complexity to the human model under assessment must develop into a foetus in an animal womb.⁴⁹ This two-part test corresponds to the case-law definitions of ‘embryo’, the first part being a proxy for indistinguishability, the second for development potential.⁵⁰ Figure 1 shows how different types of embryos will be legally categorised following application of this test. Although I do not propose writing the ‘Turing Test’ into law, it is important to ensure that means exist of determining when an embryo model will move from one definition to another.

	Legally ‘embryos’	Legally ‘embryo models’
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⁴⁷ Those seeking IVF treatment would be deterred by the notion that their non-viable embryos could be recategorised as ‘embryo models’, with fewer legal protections.

⁴⁸ Ibid

⁴⁹ Ibid

⁵⁰ With the caveat that the test’s stipulation about developing into a foetus should be replaced with an equivalent one about developing into an animal.

Capable of developing into a human	<ul style="list-style-type: none"> ✓ Viable (IVF) embryos ✓ CNR embryos ✓ Former embryo models which have passed the ✓ 'Turing Test' 	X
Not capable of developing into a human	✓ Non-viable (IVF) embryos	✓ Embryo models at a level of complexity which has not passed the 'Turing Test'

Figure 1: Relationship between legal status and developmental capability

6.3. Integrated and non-integrated

Regarding the distinction between integrated and non-integrated embryo models, Jackson notes that 'As more is understood about SCBEMs' complexity and their capacity to self-organize, enforcing and policing a bright line boundary between different types of SCBEM will not be straightforward'.⁵¹ Furthermore, Cave comments that 'new classifications will make better sense as the science develops.'⁵² I therefore follow Jackson's proposal that it be left to the regulator, the HFEA, to be more or less permissive of research projects depending on the level of integration of the embryo models used, and I do not propose writing the distinction into law.

6.4. Implantation

The current legality of implanting an embryo model into a human womb should be rectified, and s.3(2)(a) updated to: 'No person shall place in a woman (i) an embryo other than a permitted embryo; or (ii) an embryo model'. In addition, following Jackson, s.3(3)(b) should be updated to prohibit implantation of an embryo model into an animal womb.⁵³ Such human-animal experimentation is considered highly unethical, so is likely to undermine trust in science if permitted.

6.5. Duration of culture

The HFE Act makes it a criminal offence punishable by ten years' imprisonment to cultivate an embryo *in vitro* beyond 14 days.⁵⁴ The fourteenth day is the last day

⁵¹ Above, note 36

⁵² Emma Cave, 'How can we regulate embryo model research without stifling it?' (30.08.2024) Nuffield Council on Bioethics Blog <<https://www.nuffieldbioethics.org/blog/how-can-we-regulate-embryo-model-research-without-stifling-it>> Accessed 20.09.2024

⁵³ Above, note 36

⁵⁴ Human Fertilisation and Embryology Act 1990 (as amended), s.41(1)

before the 'primitive streak', a biological milestone which, according to the Warnock Report, 'marks the beginning of individual development of the embryo'.⁵⁵ It is also the last day before an embryo can split into twins, so marks the beginning of its status as an individual. These features provided grounds for treating the fourteenth day as an ethical 'bright line', and a means of addressing objections to embryos' use in research on the grounds that 'each one is a potential human being'.⁵⁶

The 14-day rule began to come under pressure in 2016, when scientists first succeeded in cultivating embryos for thirteen days before being legally obligated to destroy them.^{57,58} This led to increasing calls for the 14-day rule to be extended to 28 days, to cover the 'black box' in scientists' understanding of embryo development.⁵⁹ This 'black box' occurs because the earliest point at which embryos from miscarriages and abortions become available for research is 28 days after fertilisation. Those who support extending the rule have relied on utilitarian arguments about the benefits research could bring.⁶⁰ However, on a utilitarian basis, repeated and indefinite extensions of the limit could be justified as research applications using later embryos arise. For example, although aborted embryos are available to study after 28 days, research on living embryos which continue to develop after this point has obvious utility, providing grounds for extending the limit even further. Therefore, until there is a new, ethically-grounded limit justified on its own terms rather than through reference to its utility, the 14-day rule for embryos in s.41(1) of the Act should not be extended.

As noted, the 14-day rule derives from an embryo's potential to become an individual person. Because embryo models do not have this potential, the 14-day rule could be extended for embryo models without undermining the reasoning behind its application to embryos. Allowing research on embryo models for 28 days could partially address the 'black box' in our understanding of human development. However, the SCBEM Code of Practice was too permissive to impose no limit beyond this point. A public dialogue on the topic found that 'almost all participants believe that it is very important... [that there are] limits that make clear when

⁵⁵ The Warnock Report 11.22, 'The Inquiry's View'

⁵⁶ Ibid

⁵⁷ Marta N Shabazi et al. 'Self-organization of the human embryo in the absence of maternal tissues' (2016) *Nature Cell Biology* <<https://www.nature.com/articles/ncb3347>> Accessed 10.08.2024

⁵⁸ Alessia Deglincerti et al. 'Self-organization of the in vitro attached human embryo', *Nature* 533, 251-254 (2016) <<https://www.nature.com/articles/nature17948>> Accessed 10.08.2024

⁵⁹ John Appleby and Annelien Bredenoord, 'Should the 14-day rule for embryo research become the 28-day rule?' (2018) 10(9) *EMBO Molecular Medicine* <<https://www.embopress.org/doi/full/10.15252/emmm.201809437>> Accessed 01.10.2024

⁶⁰ Sophia McCully, 'The time has come to extend the 14-day limit' (2021) 47(12) *Journal of Medical Ethics* <<https://jme.bmj.com/content/47/12/e66>> Accessed 10.08.2024

research must stop'.⁶¹ Although embryo models do not merit the same protections as embryos, the lack of *any* limit on their *duration of culture* is likely to exacerbate public fears about a "Frankenstein' moment',⁶² as embryo models could theoretically be cultivated until resembling something closer to a foetus. Therefore, following France's approach,⁶³ I propose that s.3 of the HFE Act be amended to introduce a 28-day rule for embryo model research.

6.6. Governance

Following proposed updates to the HFE Act, research on embryo models would be regulated by the HFEA. Beyond the restrictions outlined above, I propose leaving other questions of regulation to the HFEA itself. As discussed, biotechnology is a fast-moving area in which scientists often feel hampered by outdated legislation. Once these ethical bright lines have been written into legislation, it is preferable to fall short of writing all best-practice rules into law.

7. Conclusion

Although scientists fear regulation of fast-moving areas, it is possible to reap the benefits of legislation without unduly stifling scientific progress. This may be done by granting the HFEA the powers of the Oversight Committee proposed by the SCBEM Code of Practice, giving the HFEA discretion to regulate integrated and non-integrated models, while also building ethical bright lines into law with a 28-day limit on *duration of culture* and a prohibition on implantation. The breadth of the proposed definition of 'embryo model' would ensure these protections apply to future advances in embryology, meaning further developments in the field would be regulated by the HFEA without requiring the Act to be re-opened. Governing embryo model research through a legal framework and a trusted regulator, rather than through a voluntarily adopted Code of Practice, can give the public confidence that no 'nameless horrors'⁶⁴ are going on in laboratories, allowing the public to enjoy the benefits of research without objecting to the manner in which it is conducted.

⁶¹ Hopkins Van Mill, 'A public dialogue on the governance of research involving stem cell-based embryo models' (April 2024) p.43

⁶² Above, note 42

⁶³ l'Agence de la biomédecine, 'The Conseil d'orientation of the Agence de la biomédecine publishes an opinion awaited by the international scientific community providing a framework for research on embryonic models' (19.10.2023) <<https://presse.agence-biomedecine.fr/publication-of-a-framework-for-research-on-embryonic-models-embryoids/>> Accessed 02.10.2024

⁶⁴Above, note 41