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Obstruction and obfuscation: Regulatory barriers to human embryo research in New Zealand

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Abstract

Over the last half-century, significant innovations have occurred in the fields of embryology and human assisted reproduction as a result of human embryo research. This dynamic and ethically complex field is generally subject to extensive regulatory oversight. This article examines New Zealand's legal framework governing such research. It argues that, despite the core legislative objective of establishing a robust and flexible framework, the current legal regime established under the Human Assisted Reproductive Technology Act 2004 is a classic example of regulatory failure. While not a necessary outcome of the devolved, principles-based regulatory scheme, this failure is primarily due to the perceived lack of authority and independence of the statutory policymaking body established under the Act, as well as the broader regulatory environment in which it operates. It argues that a confluence of problems, including Ministerial overreach as well as a lack of transparency and accountability on the part of decision makers, undermine the legitimacy of the current embryo research policy. This regime not only unjustifiably prevents the conduct of valuable embryo research, but also hinders simple quality improvement practices undertaken in the course of ordinary IVF service provision. This article concludes that, given the significance of embryo research as well as the associated ethical and legal challenges, the issue of embryo research should be remitted back to Parliament to legislate directly as a matter of urgency.

Keywords

Embryo research, HART Act, disallowable instrument, subordinate legislation, embryo ethics

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Introduction

In 2004, New Zealand (NZ) enacted a specific legislative regime governing the conduct of human assisted reproductive technology and reproductive research in the form of the Human Assisted Reproductive Technology Act 2004 (HART Act). Two laudable objectives of the Act are securing the 'benefits' of assisted reproductive technology and research for individuals and society while ensuring a protective framework (particularly for women and children),[1] as well as providing a 'robust and flexible' framework for guiding human assisted reproductive technology and reproductive research.[2] However, the extent to which either objective is being met in the context of human embryo research is debatable.

When introducing the HART Act, NZ's parliament opted for an amalgam of rules-based and principles-based regulation. The Act introduces certain prohibitions and establishes a statutory Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research (ACART).[3] ACART is tasked with issuing guidelines and providing advice in regard to human assisted reproductive procedures and human reproductive research.[4] Any advice or guidelines promulgated under the Act must be guided by prescribed statutory principles[5] and comply with statutory consultation requirements.[6] This regulatory approach of enshrining some rules in primary law, but otherwise devolving governance and policymaking authority, seeks to enable a flexible and responsive regulatory framework, ostensibly better suited to meeting the challenges of rapidly evolving biomedical technologies than traditional legislative mechanisms.[7]

This article is solely concerned with the regulation of human reproductive research. It is set out in three parts. First, it locates this discussion in the broader debate regarding the moral status of embryos and the evolution of the '14-day rule' widely applied in the context of embryo research. It then outlines the significance and spectrum of embryo research, before briefly sketching the regulatory approaches adopted by two comparator jurisdictions, the United Kingdom and Australia. The second part describes the regulatory framework established by the HART Act, before critiquing the policy contained in the *Guidelines for Research on Gametes and Non-viable Embryos (Research Guidelines)*.[8] The third part considers the respective roles of the Minister of Health and ACART, highlighting a troubling pattern of obstruction and obfuscation by officials performing statutory functions under the Act. It concludes that as a result of extensive

1. HART Act, section 3(a).
2. Section 3(d).
3. Section 32.
4. Section 35(1)(a).
5. Section (4).
6. Sections 36(1), (39), (41).
7. S. Devaney, 'Regulate to Innovate: Principles-Based Regulation of Stem Cell Research', *Medical Law International* 11 (2011), p. 53, 57.
8. NECAHR, *Guidelines for Research on Gametes and Non-viable Embryos* (*Research Guidelines*) (1 January 2005). Available at: www.acart.health.govt.nz (accessed 23 December 2020).

regulatory failures, a rigorous, principles-based, and transparent review of human embryo research is essential.

Part I: Embryo research debates and the '14-day rule'

Although Louise Brown's birth occurred over four decades ago, the permissible scope of embryo research continues to be widely debated due to competing, and largely irreconcilable, views regarding the moral status of human embryos. Extracorporeal embryos challenge neat ethical and legal categorisation, falling into a metaphorical 'gray zone, between life and not-yet-life'.[9] Ultimately, views regarding the permissibility of human embryo research depend upon the way in which the moral status of such entities are construed, which varies greatly in a pluralistic society.

There are several accounts as to what accords moral status to an entity. One approach draws on Joel Feinberg's analysis of rights whereby an entity has moral status if it possesses rights; an entity is a rights-bearer if it possesses interests that society is required to take seriously.[10] On this account, as non-sentient, entities without capacity for further human development via implantation, extracorporeal embryos cannot be said to possess interests of their own, nor will they acquire interests in the future. If this approach is adopted, extracorporeal embryos that are not destined for implantation in a woman cannot be attributed with significant moral status.[11]

Another approach is the view that what confers *full* moral status and moral rights on an entity is membership in the human community.[12] On this account, all *human beings* possess full moral status and moral rights.[13] The question that logically follows is when does a *human being* come into existence? For those who consider that a human being comes into existence at the point of fertilisation, an extracorporeal embryo has full moral status, and therefore destructive embryo research is morally wrong.[14] A necessary implication of this view is that if IVF was to be morally acceptable, it would require that *every* embryo created is implanted for the purpose of gestation to confer a chance of life on all

9. S. Jasanoff and I. Metzler, 'Borderlands of Life: IVF Embryos and the Law in the United States, United Kingdom, and Germany', *Science, Technology & Human Values* (2018), p. 3.
10. B. Steinbock, 'Moral Status, Moral Value and Human Embryos: Implications for Stem Cell Research', in B. Steinbock, ed., *The Oxford Handbook of Bioethics* (Oxford: Oxford University Press, 2007), p. 428, citing J. Feinberg, 'The Rights of Animals and Unborn Generations', in W. Blackstone, ed., *Philosophy & Environmental Crisis* (Athens: University of Georgia Press, 1974).
11. Op. cit., p. 430.
12. Op. cit.
13. Op. cit.
14. R. George and C. Tollefsen, *Embryo: A Defense of Human Life* (New York: Doubleday, 2008); George and Toleffson argue that an embryo is a human individual in the earliest stage of natural development because an early embryo is a human being on a developmental continuum that will, if all goes well, result in a born human being. This constitutes an argument of 'biological continuity', a human embryo *is* (not *potentially* is) an individual human being.

embryos.[15] Such a mandatory transfer rule was initially adopted in Italian legislation,[16] but did not withstand constitutional challenge.[17] In contemporary times, any proposed law that prioritised an ex vivo embryo's chance of life over a woman's right to make medical decisions would not be considered a serious proposition. Rather, the reality that IVF may result in the creation and subsequent destruction of surplus embryos has generally been considered an acceptable trade-off in assisted reproduction. However, for a minority who hold the full moral status view, IVF itself is morally wrong because it necessarily involves the creation, manipulation and destruction of human embryos.[18]

While some scholars, particularly those writing in the natural law tradition, might argue that at the point of fertilisation an embryo is the equivalent of a born human being, it is not a widely shared view. Even some commentators who consider embryos to be part of the human community do not consider that embryos should be attributed with the *same* moral status as a born human being, particularly in the very early stages postfertilisation when the embryo constitutes a cluster of 'undifferentiated cells'.[19] On this so-called gradualist account, moral status is perceived as something that gradually develops and compounds over time.[20] Hence, research on early-stage embryos may be morally permissible if it is offset by benefits accrued from conducting such research. In contrast to this intermediate or gradualist position, those at the very liberal end of the research spectrum consider that embryos are neither persons nor potential persons, hence they should not be afforded protected status. On this account, if research may yield beneficial results, it should be permitted.[21] What may ultimately be concluded is that there is a spectrum of views, reasonably held, regarding the moral status of extracorporeal embryos. Negotiating this ethical pluralism is particularly challenging for regulators tasked with determining the permissibility of embryo research.

The evolution and codification of the '14-day rule' internationally

One of the first jurisdictions to address the permissibility of embryo research was the United Kingdom. Following Louise Brown's birth, the UK Government appointed a Committee of Inquiry into Human Fertilisation and Embryology in 1982, chaired by

15. Warnock Committee, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (United Kingdom: Her Majesty's Stationery Office, 1984), para 11.9.
16. Law. 40/2004, Article 14(2).
17. Decision n. 151/2009 of the Constitutional Court. See L. Benagiano and L. Gianaroli, 'The Italian Constitutional Court Modifies Italian Legislation on Assisted Reproduction Technology', *Reproductive BioMedicine Online* 20 (2010), p. 398.
18. Congregation for the Doctrine of Faith Instruction on Respect for Human Life at its Origins and on the Dignity of Procreation: Replies to Certain Questions of the Day (Donum Vitae) (Rome: Vatican, 1987); Congregation of the Doctrine of Faith Instruction on Certain Bioethical Questions (Dignitas Personae) (Vatican, Rome, 2008).
19. D. De Grazia, *Creation Ethics, Reproduction, Genetics and Quality of Life* (Oxford-New York: Oxford University Press, 2012), p. 22.
20. Warnock, para 11.17.
21. Warnock, para 11.15.

Dame (now Baroness) Mary Warnock.[22] Although a philosopher, Warnock considered that philosophy had a limited role in determining law and policy; when it came to making law, the two relevant questions were 'when does life begin to matter morally' and 'should we permit research upon human embryos?'[23] In this way, instead of acting as 'moral' experts, the Committee perceived its role as seeking a 'middle way' between competing interests.[24]

When making its final recommendations the Warnock Committee drew on the expertise of developmental biologists.[25] The Committee heard evidence that it is generally 14 days after fertilisation that the so-called primitive streak begins to appear, which forms the antecedents of the spinal cord and nervous system. The formation of the primitive streak marks the beginning of *individual* development and was claimed to constitute an appropriate boundary-marker for permissible and non-permissible research.[26] Ultimately, the Warnock Committee recommended that embryo research should be permitted, but only on embryos less than 14-days postfertilisation. In this way, the rule was pragmatic; it would retain many benefits of embryo research, while offending as few people as possible.[27] However, the Committee concluded that the human embryo had a 'special' status, respect for which justified some degree of legal protection and oversight.[28]

For some, the view that the embryo does not have full moral status, but yet should be accorded 'special status', is incoherent.[29] However, the view that embryos do not have (full) moral status should not be conflated with the idea that embryos lack moral value. Bonnie Steinbock argues that an entity has 'moral value if there are moral reasons to treat it in certain ways and not in others'.[30] For example, even though a dead human body no longer has moral status, certain moral standards must be observed in the handling of dead bodies. Specifically, the criminal law prohibits the disrespect of human remains.[31] Arguably, dead bodies demand respect because they are symbolic of human life and the prior individual it represents. Similarly, human embryos may be thought to deserve

22. Warnock, para 1.2.
23. D. Wilson, *The Making of British Bioethics* (Manchester, Manchester University Press, 2014), pp. 141 and 160–171.
24. Op. cit., p. 141.
25. D. Wilson, 'Where to Draw the Line: Mary Warnock, Embryos and Moral Expertise' in D. Wilson, ed., *The Making of British Bioethics* ((Manchester: Manchester University Press, 2014).
26. A. Alichniewicz, 'The Ontological and Moral Status of the Human Embryo', in A. Alichniewicz and M. Michalowska, eds., *Medicine of the Beginning of Life* (Warsaw: Oficyna Naukawa, 2019).
27. Wilson, *Bioethics*, pp. 140–186.
28. Warnock, para 11.7.
29. E. Jackson, 'Fraudulent Stem Cell Research and Respect for the Embryo', *BioSocieties* 1(3) (2006), pp. 349–356.
30. Steinbock, 'Moral Status', p. 433.
31. Section 150(b) of the Crimes Act 1961 makes it an offence to 'improperly or indecently interfere[] with or offer[] any indignity to any dead human body or human remains'.

respect because they are 'a symbol of human existence'.[32] While embryos may not be rights bearers or moral subjects nor are they nothing.[33]

The '14-day rule' was subsequently codified by the United Kingdom's Human Fertilisation and Embryology Act 1990 (HFE Act). It constitutes a pragmatic compromise that enables beneficial research to be conducted, while imposing limits on the *use* of extracorporeal embryos.[34] This 14-day rule has since been adopted in at least 12 countries, including New Zealand's HART Act.[35] Despite recent challenges that the rule is too conservative,[36] it is viewed by many as the 'linchpin of an effective policy compromise between what remain deeply divided moral positions on the human embryo's status'.[37] For those jurisdictions that have adopted the 14-day rule, the nature of research that may be conducted on embryos less than 14-days postfertilisation varies.

The significance and spectrum of human embryo research

There is a wide spectrum of embryo research, as well as a range of embryos that could, theoretically, be used in such research. Embryo research may be performed to improve knowledge about infertility and to develop more effective ART techniques.[38] Alternatively, embryo research may focus on understanding early developmental biology,[39] or on identifying causes for, and treatment of, serious diseases and other serious medical conditions,[40] or to develop methods for detecting gene, chromosome or mitochondrial abnormalities in embryos prior to implantation.[41] Embryos may also be used to derive stem cells for research into disease and the development of regenerative therapies.[42] More recent developments, although still subject to considerable debate, include

32. Steinbock, 'Moral Status', p. 436.
33. J. Robertson, 'In the Beginning: The Legal Status of Early Embryos', *Virginia Law Review* 76(3) (1990), p. 447.
34. M. Brazier, 'Regulating the Reproduction Business?' *Medical Law Review* 7 (1999), pp. 166, 174.
35. I. Hyun, A. Wilkerson and J. Johnston, 'Embryology Policy: Revisit the 14-day Rule', *Nature* 533 (2016), pp. 169–171.
36. J. Appleby and A. Bredenoord, 'Should the 14-day Rule for Embryo Research Become the 28-day Rule?', *EMBO Molecular Medicine* 10(9) (2018), p. e9437; Nuffield Council on Bioethics, *Human Embryo Culture* (London, 2017).
37. S. Chan, 'How to Rethink the Fourteen-day Rule', *Hastings Center Report* 47(3) (2017), p. 5.
38. M. Shahbazi et al., 'Self-organization of the Human Embryo in the Absence of Maternal Tissues', *Nature Cell Biology* 18 (2016), pp. 700–708.
39. K. Niakan et al., 'Human Pre-implantation Embryo Development', *Development* 139 (2012), pp. 829–841.
40. I. Ben-Nun and N. Benvenisty, 'Human Embryonic Stem Cells as Cellular Models for Human Disorders', *Molecular and Cellular Endocrinology* 252 (2006), pp. 154-159
41. S. Kahrarnan et al., 'Recent Advances in Preimplantation Genetic Diagnosis', *Advances in Genomics and Genetics* 5 (2015), p. 189. See HFE Act, sch. 2 para 3A(2).
42. L. da Cruz et al., 'Phase 1 Clinical Study of an Embryonic Stem Cell-Derived Retinal Pigment Epithelium Patch in Age-related Macular Degeneration', *Nature Biotechnology* 36 (2018), pp. 328.

research into mitochondrial replacement therapy[43] as well as embryonic gene editing.[44] Predicted research developments include stem cell-derived gametes and embryos.[45]

As well as the wide range of possible research, various kinds of embryos may, at least theoretically, be used for research. Research may be performed on 'non-viable' embryos that will otherwise be discarded as unsuitable for implantation, as well as 'surplus' embryos that are no longer required by an individual/couple following IVF. Additional sources of embryos include those specifically created for research purposes, created using ordinary IVF procedures or by using cloning techniques such as somatic cell nuclear transfer (SCNT). Another source of embryos involves hybrid embryos (embryos containing both human and non-human DNA).

Before considering New Zealand's ostensibly decentred regulatory framework,[46] the following briefly outlines the regulatory positions adopted in the United Kingdom and in Australian federal law.

Embryo research: United Kingdom and Australia

The UK's Human Fertilisation and Embryology Act 1990 (HFE Act) as amended in 2008 expressly prohibits certain activities and establishes an independent arm's length regulatory authority, the Human Fertilisation & Embryology Authority (HFEA), to operationalise the law.[47] While the HFEA is responsible for licensing treatment and research,[48] the HFE Act specifies the purposes for which embryo research may be licenced[49] and identifies permissible sources of embryos for research.[50] The HFEA is responsible for formulating a Code of Practice governing the conduct of assisted conception treatment and research.[51] It is also tasked with advising the public and Government regarding scientific advances, evaluating such developments, and associated decision-making.[52]

The HFE Act permits research on embryos less than 14 days old, subject to licensing by the HFEA.[53] It facilitates a wide scope of research, including the creation of embryos for research purposes, but distinguishes between 'permitted' embryos that may be used to establish a pregnancy, and embryos that may only be used for research purposes and

43. I. Cohen et al., 'The Regulation of Mitochondrial Replacement Techniques around the World', *Annual Review of Genomics and Human Genetics* 21 (2020), p. 565.
44. National Academy of Sciences, *Heritable Human Genome Editing* (Washington, DC: The National Academies Press, 2020).
45. I. Moreno, J. Miguez-Forhan and C. Simon, 'Artificial Gametes from Stem Cells', *Clinical and Experimental Reproductive Medicine* 42 (2015), p. 33.
46. J. Black, 'Regulation as Facilitation: Negotiating the Genetic Revolution', *The Modern Law Review* 61(5) (1998), pp. 621–660.
47. HFE Act, section 5, schedule 1.
48. Section 11.
49. HFE Act, sch. 2 paras 3–3A.
50. HFE Act, sch. 2 para 3(1)(a) and sch. 2 para 3(3)(a).
51. Section 25.
52. HFE Act, s 8.
53. Sections 3(1), 3(3)(a).

not implanted.[54] The Act outlines the principal purposes for which embryo research may be licenced by the HFEA, provided it is satisfied that the research is *necessary and desirable* for those purposes,[55] or for such other purposes as may be specified in regulations.[56] Specified purposes include increasing knowledge about, and treatments for, serious disease or medical conditions; promoting advances in the treatment of infertility; increasing knowledge of the causes of congenital disease and miscarriage; developing methods for detection of gene or chromosomal abnormalities in pre-implantation embryos; and increasing knowledge about the development of embryos.[57]

Embryo research in Australia is regulated at the federal level by the Research Involving Human Embryos Act 2002 (RIHE Act) and the Prohibition of Human Cloning for Reproduction Act 2002 (PHCR Act). The RIHE Act adopts a licensing system in conjunction with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018).*[58] As in the United Kingdom, the RIHE Act precludes licences being given for any use that would result in embryo development beyond 14 days.[59]

The RIHE Act permits the use of donated excess IVF embryos in research, provided consent is obtained from the donors, and the research is authorised by a licence issued by the Embryo Research Licensing Committee of the NHMRC,[60] but does not permit the creation of IVF embryos for research purposes.[61] However, following the Government-appointed Lockhart review in 2005, the permissible scope of embryo research in Australia was expanded to include use of human embryos created other than by other than by fertilisation (such as by SCNT) or the use of hybrid embryos for research purposes.[62] Such research is permissible provided a licence authorising the creation or development,[63] and subsequent research use,[64] of those embryos is obtained. The NHMRC *Ethical*

54. Sections 3(2), 3ZA.
55. HFE Act 1990, schedule 2, para 3, 3A(1) and 3A(2). For a discussion, see E. Jackson, *Medical Law: Text, Cases, and Materials*. 3rd ed. (Oxford: Oxford University Press, 2013), p. 648.
56. HFE Act, Sched 2, 3A(1)(c).
57. HFE Act, Sched 2, para 3A.
58. RIHE Act, pt. 2; NHMRC, *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)* (Canberra, 2018).
59. RIHE Act, section 20(1A).
60. RIHE Act, section 10(1)(b), (2). The Licensing Committee must be satisfied that the research proposed has been assessed and approved by a Human Research Ethics Committee (HREC) acting consistently with the NHMRC *National Statement on Ethical Conduct in Human Research* (2018) and the NHMRC, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (Canberra: NHMRC, 2017).
61. RIHE, section 11.
62. Australian Government, *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002* (Canberra, 2005).
63. The PHRC Act permits the creation of a human embryo other than by fertilisation subject to authorisation by licence (section 22); section 23B of the PHRC Act prohibits the creation of a hybrid embryo unless a licence has been issued under section 21 of the RIHE Act.
64. RIHE Act, section 10A.

Guidelines provide criteria that proposed research must satisfy, including: 'sufficient evidence that the likely benefits of the proposed research cannot be achieved without using human embryos'; there is proof of concept; and the research is 'justifiable by its potential benefit in improving technologies for treatment of, or knowledge about, human diseases'.[65]

A feature of both the UK and Australian regimes is that they proscribe certain activities in statute, but otherwise facilitate embryo research, subject to extensive licensing systems. In both jurisdictions, approval for embryo research requires justification that conducting the research is necessary or desirable to achieve potential health benefits. Also notable is the significant attention that embryo research has received in both the United Kingdom and Australia from legislators, policymakers and academics. In Australia, the federal Government has undertaken several reviews of embryo research.[66] In the United Kingdom, multiple actors have engaged with issues in embryo research, in addition to the Government.[67] For example, prior to the recent introduction of regulations permitting mitochondrial replacement therapy,[68] the HFEA commissioned an expert panel to undertake scientific review of its safety and efficacy, which was updated over several years,[69] as well as conducting a public consultation.[70] In addition, the issue was subjected to independent ethical scrutiny by the Nuffield Council on Bioethics.[71]

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65. NHMRC, *Ethical Guidelines*, para 13.3.
66. Legislation Review Committee, Parliament of Australia, *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002* (2005); Legislation Review Committee, Parliament of Australia, *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002* (Canberra, 2011); Australian Senate Community Affairs References Committee, *Science of Mitochondrial Donation and Related Matters* (Australia: Commonwealth of Australia, 2018).
67. House of Commons Science and Technology Committee, *Inquiry into Human Reproductive Technologies and the Law* (Fifth Report of session 2004-2005, HC 7-1) (London: HMSO); House of Commons Science and Technology Committee Government, *Proposals for the Regulation of Hybrid and Chimera Embryo's* (Fifth Report of session 2006-2007, HC 272-1) (London: HMSO).
68. Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.
69. Review Panel, *Scientific Review of the Safety and Efficacy of Methods to Avoid Mitochondrial Disease through Assisted Conception* (London: Report to the HFEA, 2011); Review Panel, *Third Scientific Review of the Safety and Efficacy of methods to Avoid Mitochondrial Disease through Assisted Conception: 2014 update* (London: Report to the HFEA, 2013); Review Panel, *Review of the Safety and Efficacy of Polar Body Transfer to avoid Mitochondrial Disease: Addendum to 'Third Scientific Review of the Safety and Efficacy of methods to Avoid Mitochondrial Disease through Assisted Conception: 2014 Update*. (London: Report to the HFEA, 2014); Review Panel, *Scientific Review of the Safety and Efficacy of Methods to avoid Mitochondrial Disease through Assisted Conception: 2016 Update* (London: Report to the HFEA, 2016).
70. See HFEA (2013), *Mitochondria Replacement Consultation: Advice to Government*. Available at: www.hfea.gov.uk (accessed 23 December 2020).
71. Nuffield Council on Bioethics, *Novel Techniques for the Prevention of Mitochondrial DNA Disorders* (London: Nuffield Council, 2012).

Having established these two jurisdictions as relevant comparators, the following outlines the regulatory framework established by NZ's HART Act, before examining the regulatory regime governing embryo research

Part II: NZ's regulatory framework

When the NZ Parliament introduced the HART Act it opted for a hybrid – rules-based and principles-based – legal regime. Apart from creating a set of prohibited offences, it delegates authority to the statutory Advisory Committee on Assisted Reproductive Technology and Reproductive Research (ACART) to issue guidelines and provide advice in regard to human 'assisted reproductive procedures' (ARPs),[72] 'established procedures'[73] and 'human reproductive research' (HRR).[74] When formulating advice and guidelines, ACART must be guided by specific statutory principles and provisions, including mandatory consultation obligations.[75]

The HART Act establishes a two-tier system, distinguishing policymaking processes from approval processes. The Act confers authority on ACART to issue guidelines and give advice to both the Minister and the Ethics Committee on Assisted Reproductive Technology (ECART).[76] ECART is authorised to consider actual applications to perform 'ARPs' and 'HRR'.[77]

The purpose and principles contained in the Act signal Parliament's intentions when introducing the HART Act, and the values that underpin it. At first glance, these suggest a relatively liberal framework was intended.

A 'robust and flexible framework', and principles for policymaking

The first purpose declared in the Act is to 'secure the benefits' of ART and 'HRR' for individuals and society by taking 'appropriate measures' to protect and promote the 'health, safety, dignity, and rights of all individuals, but particularly those of women and children, in the use of these procedures and research'.[78] An additional purpose is to prohibit 'unacceptable assisted reproductive procedures and . . . research'.[79] Of greatest

72. 'ARP' is defined in section 5(a) as 'a procedure performed for the purpose of assisting human reproduction that involves— (i) the creation of an *in vitro* human embryo; or (ii) the storage, manipulation, or use of an *in vitro* human gamete or an *in vitro* human embryo; or (iii) the use of cells derived from an *in vitro* human embryo; or (iv) the implantation into a human being of human gametes or human embryos; but (b) does not include an established procedure'.
73. 'Established procedure' is defined in section 5 as 'any procedure, treatment, or application declared to be an established procedure under section 6'. An 'established procedure' does not need ethical approval—it is a routine clinical procedure. See section 3(e).
74. 'HRR' is defined in section 5 as 'research that uses or creates a human gamete, a human embryo, or a hybrid embryo'.
75. Sections 36 and 39–41.
76. Section 35(1).
77. Section 28(1)(a).
78. Section 3.
79. Section 3(b).

significance to this discussion are the following two purposes: the first is to 'provide a robust and flexible framework for regulating and guiding . . . assisted reproductive procedures and . . . human reproductive research' and to prohibit the performance of non-established 'ARPs' and 'HRR' without ethics committee approval.[80] Hence in addition to ACART, the Act establishes a statutory ethics committee (ECART). By expressly prohibiting some aspects of ART and 'HRR' in legislation, while also conferring policy-making authority on a statutory body, Parliament sought to ensure a flexible framework that could be responsive to the technical and fast-paced field of reproductive technology and medicine.

As noted above, the HART Act expressly adopts the '14-day rule' in regard to 'HRR'.[81] Thus, it is an offence to intentionally do anything to cause the further development of an embryo beyond 14 days; or to possess it with a view to using it in research; or to use it for research or reproductive purposes.[82] In addition, schedule 1 of the Act also provides a list of prohibited research activities. However, schedule 1 only includes *clinical* research, meaning research involving an attempt to achieve an actual pregnancy. While the schedule addresses controversial activities such as cloning and genetic modification of embryos, it is *only* the *implantation* of gametes or embryos in a human being or an animal following such procedures that is prohibited. These prohibitions do not extend to lab-based or 'non-clinical' research not involving *implantation* in a human being or animal. In this way, Parliament deliberately chose not to foreclose the possibility of allowing such 'non-clinical' research to be undertaken should ACART choose to permit it. In this respect, it is significant that NZ departed from the more restrictive approach taken in the equivalent Canadian Act, on which some provisions of the HART Act were modelled.[83]

Although the HART Act does not impose express restrictions on pure (i.e. 'non-clinical') research involving human embryos *less* than 14 days postfertilisation, such research is not simply left unregulated. Rather, it may *only* be conducted if written approval has been obtained from the statutory ethics committee – ECART.[84]

Significantly, ECART may only approve applications to conduct proposed 'HRR' if satisfied that an application is consistent with the relevant guidelines, or advice, made by ACART.[85] If there are no guidelines governing the particular procedure proposed, ECART cannot approve applications.[86] Further, it is an offence to conduct human embryo research without prior written approval from ECART, with a fine imposed for breach.[87] In addition, every provider and person who is responsible for embryo research

80. Sections 3(d)–3(e).
81. Section 9.
82. Section 9(2). Any person who breaches this provision is liable, on conviction, to imprisonment for up to 2 years and/or to a fine of up to NZD$100,000. HART Act, section 9(5).
83. Compare Assisted Human Reproduction Act SC 2004 c. 2, section 5.
84. Section 16(1).
85. Section 19(2).
86. Section 18(2).
87. Section 5 of the HART Act defines 'HRR' as 'research that uses or creates a human gamete, a human embryo, or a hybrid embryo'. Section 16(1) provides that 'HRR' may only proceed

that has been approved by ECART is required to take 'all practicable steps' to ensure that the statutory 14-day prohibition is not contravened.[88] Although ECART is responsible for vetting applications to perform 'HRR', it is not responsible for creating policies governing 'HRR', a responsibility which lies solely with ACART.

In summary, while the '14-day rule' serves as the legal demarcation for when human embryo research is *absolutely* prohibited under the Act, what constitutes permissible research involving embryos *less* than 14 days postfertilisation *and* which does not involve the specifically prohibited procedures is delegated to ACART to determine in accordance with the relevant statutory provisions. Given the wide scope of delegated decision-making authority, the Act also provides a set of principles to guide persons exercising powers, or performing functions, under the Act.[89]

The HART Act's guiding principles

The first principle is that 'the health and well-being of children born as a result of the performance of an assisted reproductive procedure . . . should be an important consideration in all decisions about that procedure'.[90] The following principle states that 'the human health, safety, and dignity of [both] present and future generations should be preserved and promoted'.[91] The next principle, drawn directly from the comparative Canadian Act,[92] provides that

> while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the use of these procedures.[93]

The subsequent principles provide that 'no assisted reproductive procedure . . . [or] research should be conducted on an individual unless . . . informed consent [has been obtained]'.[94] An additional principle acknowledges the importance of respecting Māori cultural practices, providing that 'the needs, values, and beliefs of Māori should be considered and treated with respect'.[95] The last principle states that 'the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect'.[96] These principles are relevant to ACART when performing functions under

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with prior written approval of the ethics committee. Breach of this provision attracts a fine of up to NZD$50,000. Section 16(2).

88. Section 9(3). Section 9(6) provides that breaching subsection (3) may result in a fine of up to NZD$50,000.
89. Section 4.
90. Section 4(a).
91. Section 4(b).
92. Assisted Human Reproduction Act SC c. 2, section 2(c).
93. HART Act, section 4(c).
94. Section 4(d).
95. Section 4(f).
96. Section 4(g).

the Act, such as issuing guidelines and providing advice. The following outlines the origins of the currently applied guidelines governing 'HRR' in NZ.

Provenance of the research guidelines

Prior to the introduction of the HART Act, the ministerial National Ethics Committee on Assisted Human Reproduction (NECAHR), first established in 1995,[97] was responsible for assessing applications to perform new assisted reproductive procedures and research, provided advice to the Minister of Health, and developed guidelines for fertility providers on ethical issues relating to assisted reproduction. Fertility services were not legally required to bring proposals before NECAHR, although it was required by their professional body.[98]

In its 2002 Annual Report to the Minister, NECAHR noted that it had received applications relating to the use of 'viable' embryos in research.[99] Although it had previously approved the use of 'non-viable' embryos (referred to as 'those unsuitable for implanting'), it considered the research use of 'potentially healthy' embryos attracted significant policy and ethical issues and was likely to be of public interest.[100] NECAHR deferred the applications until it could consider these wider issues and consult with the Minister of Health. Given the pending legislation, it did not wish to 'pre-empt government policy in this area by approving applications that would be inconsistent with the direction of the legislation'.[101]

Given this reticence, it is curious that, with the approval of the Minister of Health, NECAHR published guidelines on embryo research in January 2005, *after* the introduction of the HART Act. The NECAHR *Guidelines for Research on Gametes and Non-viable Embryos Research Guidelines* (*Research Guidelines)* are notable in that they make no reference to the HART Act, its purposes or its principles.[102] The NECAHR *Research Guidelines* were subsequently elevated from their ethical status to a legal status under transitional provisions contained in the HART Act.[103]

NECAHR research guidelines: Designated 'interim' ACART research guidelines

Under transitional provisions provided in the Act, the Minister of Health may require an ethics committee to treat specified provisions of any document as interim guidelines

97. NECAHR, initially established by the Minister of Health under section 46 of the Health and Disability Services Act 1993, was subsequently established as a ministerial committee under section 11 of the New Zealand Public Health and Disability Act 2000.
98. Their professional body, the Fertility Society of Australia and New Zealand, required fertility clinics to gain ethical approval as part of the accreditation requirements imposed by the Reproductive Technology Accreditation Committee.
99. NECAHR, *Annual Report to the Minister of Health for the Year Ending 31 December 2002* (Wellington, Ministry of Health, June 2003), p. i.
100. Op. cit.
101. Op. cit.
102. NECAHR, *Guidelines for Research on Gametes and Non-viable Embryos Research Guidelines* (Wellington, Ministry of Health, 2005).
103. Section 83.

issued by ACART for the purposes of the Act at any time during the 3 years after the date on which the Act gained Royal assent.[104] In August 2005, the Minister of Health approved a tranche of guidelines promulgated by NECAHR, including NECAHR's *Research Guidelines*, as interim ACART guidelines, under the Act.[105]

In accordance with the HART Act, the notice published in the *New Zealand Gazette* states that the *Research Guidelines* are effective until 21 November 2007 (3 years after the Act received Royal assent), unless revoked sooner.[106] This indicates an expectation that the interim guidelines would be revised once ACART was established. As this has not occurred, the *Research Guidelines* have not been effective legally since 2007. If NZ has no legally *effective* guidelines governing embryo research, ECART does not have legal authority to approve any applications to conduct any embryo research whatsoever. Despite this, the *Research Guidelines* continue to be treated as legally effective by both ACART and ECART. Given this, the following section considers the substantive content of the *Research Guidelines*.

A critique of the Guidelines for Research on Gametes and Non-viable Embryos

The *Research Guidelines* simply contain a selective 'cut and paste' from the 2004 version of the Australian National Health and Medical Research Council's *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (NHMRC *Guidelines*).[107] Because these guidelines originated from NECAHR, a Ministerial ethics committee, they were not professionally drafted or subject to the oversight that delegated legislation may receive.[108]

Significantly, even though the full title of the *Guidelines for Research on Gametes and Non-viable Embryos Research Guidelines* refers to 'non-viable' embryos, no definition is provided as to what constitutes 'non-viable'. However, given its prior exchange with the Minister, it is likely that NECAHR intended to narrowly restrict the scope of permissible research to research involving embryos 'unsuitable for implanting'.[109]

The first sentence acknowledges that all of the clauses contained in the *Research Guidelines* are derived from the Australian NHMRC *Guidelines*. However, these clauses are selectively extracted from a broader section in the NHMRC document, with no commentary or explanatory notes provided. This 'cut and paste' is problematic. The Australian NHMRC *Guidelines* specify requirements for research using not only human

104. Section 83(2). The Act also specifies that requirements which are issued, amended or revoked under subsection (2) should be published in the *New Zealand Gazette*. Section 83(6).
105. 'Approval of Interim Guidelines Under the Human Assisted Reproductive Technology Act 2004' (11 August 2005) 123 *New Zealand Gazette* 2965, p. 3010.
106. 'Approval of Interim Guidelines', p. 3010.
107. NHMRC, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2004), cls. 15.4-15.6, 15.8, 15.10–15.12 and 16.3–16.6.
108. D. McGee, *Parliamentary Practice in New Zealand*. M. Harris and D. Wilson, eds. 4th ed. (Auckland: Oratia Books, 2017), p. 459.
109. NECAHR, *Annual Report*, p. i.

gametes and 'non-viable' embryos but also encompasses two further categories of embryo research: research involving 'viable' embryos (embryos that are intended to be transferred to a woman)[110] and research involving 'excess' IVF embryos (embryos no longer needed by a couple/individual in an IVF programme and subsequently donated to research).[111]

Clause 15 of the NHMRC *Guidelines* provides generic ethical principles for research, expressly including both clinical and 'non-clinical' research. Clause 16 provides specific principles for research involving gametes, while clause 17 pertains to research involving embryos ('viable', 'non-viable' and 'excess' embryos).

The NZ *Research Guidelines* consist of specific provisions extracted from clauses 15 and 16 of the Australian NHMRC's guidelines. However, the NZ *Research Guidelines* clauses do not distinguish between research involving gametes and research involving embryos. Somewhat problematically, the NZ *Research Guidelines* refer to clinical research that results in a pregnancy, despite the fact that 'non-viable' embryos, by their very nature, would never be used in clinical care. These generic provisions refer to researchers' obligations to minimise risks in research involving clinical care, including that they must 'ensure that any risks of adverse effects to any subsequently created embryo (or to the long-term health of any person born as a result of use of the embryo to achieve a pregnancy) are minimal'.[112] This clause is confusing – given that the title of the guidelines restricts research to use of 'non-viable' embryos.

Additional clauses require researchers to keep records, including records of all 'gametes and embryos in their care' and to 'assess, evaluate and monitor outcomes for all participants (including any persons conceived using reproductive procedures, their siblings, where relevant, and the gamete or embryo donors)'.[113] Neither of these provisions are restricted solely to gametes and arguably presuppose the use of 'viable' embryos in research. Finally, the *Research Guidelines* contain a clause enabling conscientious objection.[114] This latter clause is strange – given that it would seem to be most applicable to the use of 'viable' embryos in research rather than gametes and 'non-viable' embryos. In this way, the guidelines lack clarity and coherence.

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110. The NHMRC's *Ethical Guidelines* state at cl. 17 that '[r]esearch on embryos intended for transfer to a woman to achieve a pregnancy may be undertaken either to trial a new procedure that is expected to bring benefits to the embryo concerned (such as a trial to compare two culture media) or to advance knowledge without direct benefit to the embryo (such as microscopic observation of the embryo during its development before transfer to the woman)'.
111. The NHMRC's *Ethical* Guidelines provide at cl. 17.12 that '[r]esearchers must not approach persons responsible for the embryos for consent to use their embryo in a specified research project until after a decision has been made, and confirmed in writing, by all persons responsible for the embryo that it is no longer needed for reproductive treatment and that it is therefore an excess ART embryo (as defined by the RIHE Act . . .)'.
112. NECAHR, *Research Guidelines,* cl. 16.4.
113. NECAHR, *Research Guidelines,* cls. 15.8 and 15.10.
114. Clause 15.12.

Implications of the 'interim' Research Guidelines

As noted above, before a researcher may lawfully conduct 'HRR', they must obtain written ethical approval from ECART.[115] ECART may only approve an application if it is consistent with ACART's guidelines.[116] Therefore, ECART may *only* approve embryo research applications involving 'non-viable' embryos.

Distinct problems arise from restricting research solely to 'non-viable' embryos. The first is definitional. Although not defined, it is likely that 'non-viable' is meant to denote embryos that are not likely to implant due to poor morphological qualities or that have been diagnosed by pre-implantation genetic diagnosis as carrying serious genetic mutations and therefore deemed 'unsuitable for implantation'. Yet, it may also be argued that *any* embryo that is not destined for implantation, whether due to poor morphology or because of a choice made by its progenitors not to implant it, may be considered to be 'non-viable' because it is not on a trajectory of implantation and potential foetal development.

A different issue arising from restricting research to 'non-viable' embryos is that it may limit the generalisability of any research results. Although it is not suggested that 'non-viable' embryos are of no value to research, the majority of embryo research requires the study of healthy embryos.[117] An additional issue is that limiting research to 'non-viable' embryos narrows the options available for individuals, in particular women, who must make decisions regarding disposition of their 'surplus' embryos.

It is not uncommon for couples to be left with embryos that are 'surplus' to their reproductive requirements, for various reasons, following IVF. They may have completed their family or may no longer want to pursue IVF. 'Excess' embryos cannot be cryopreserved indefinitely; the HART Act imposes a 10-year limit on storage, at which point a decision must be made regarding embryo disposition.[118] For some, donating their 'excess' embryos to research, rather than having them destroyed or donated to another couple, may be preferable.[119] While in Australia and the United Kingdom, couples or individuals may donate their 'surplus' or 'excess' embryos to research this is not an option in NZ. Under the *Research Guidelines*, ECART is unable to consider any proposed research involving 'surplus' donated embryos. By default, such research is impermissible under the HART Act. Consequently, the choice of embryo disposition is denied to the very individuals who have expended significant emotional, physical and financial labour in their creation.

Although no justification was provided for this, scholars elsewhere have argued that limiting research to 'non-viable' embryos may allay the concerns of those individuals

115. HART Act, section 16(1).
116. HART Act, section 18(2).
117. Compare F. Baylis, 'Embryological Viability', *American Journal of Bioethics* 5(6) (2005), pp. 17–18.
118. Section 10.
119. S. Goedeke et al., 'The Fate of Unused Embryos: Discourses, Action Possibilities, and Subject Positions', *Qualitative Health Research* 27(10) (2017), p. 1533.

who would ascribe full moral status to the embryo.[120] However, this approach is problematic. First, by preventing the use of 'surplus' 'viable' embryos, it implies that policy makers endorse the full moral status argument. Yet, if this were the case, *IVF* should be prohibited, as it routinely involves the creation and destruction of (surplus) embryos. However, the embryo loss involved in *IVF* is generally accepted as justifiable in the circumstances, an acceptable trade off given the benefits of assisted reproduction. Further, it is questionable whether requiring the destruction of a 'surplus' embryo is less morally problematic than allowing it to be donated for use in beneficial research. Significantly, the current policy position does not prevent the loss of any 'surplus' embryos, it merely prevents their use in research. It precludes research that may benefit other individuals undergoing IVF and/or may prevent broader research, potentially undermining one of the purposes of the HART Act – to secure the benefits of 'HRR' for individuals and society.[121]

Another highly problematic outcome of restricting research to 'non-viable' embryos is that ECART has no capacity to approve research involving 'viable' embryos conducted in the course of providing IVF,[122] such as research into the effects of using different embryo culture media on embryo development, implantation rates and pregnancy outcomes.[123] In the context of a well-designed study, this kind of clinical research is an important aspect of quality improvement. The implications of this are exemplified by the recent attempt of local researchers to conduct a study into embryo transfer practices.[124]

A case of regulatory failure: The day of transfer study

Embryo transfer, which involves the transfer of an IVF embryo to a woman's uterus, is an 'established procedure' under the Act, consequently it does not require ECART approval but can be performed as a routine clinical procedure.[125] In practice, fertility providers may choose whether to transfer an embryo to a woman's uterus on day three or day five. In the proposed 'Day of Transfer' (DOT) study, researchers wished to compare pregnancy and birth outcomes following different transfer times to obtain evidence as to which had the better outcome in terms of improving pregnancy rates and neonatal outcomes.[126] The study, which excluded any women with fewer than four embryos who might be disadvantaged if included, involved all women receiving standard care, *but*

120. F. Baylis, 'The Ethics of *Ex Utero* Research on Spare "Non-viable" IVF Human Embryos', *Bioethics* 4(4) (1990), pp. 311–329.
121. Section 3(a).
122. NHMRC, *Ethical Guidelines,* cls. 17–17.9.
123. A. Sunde et al., 'Time to Take Human Embryo Culture Seriously', *Human Reproduction* 31(10) (2016), pp. 2174–2182.
124. L. Goodman et al., 'The Futility of Fertility Research? Barriers to Embryo Research in New Zealand', *New Zealand Medical Journal* 131(1477) (2018), pp. 63–70.
125. HART Act, sections 3(e), 5 and 6; Human Assisted Reproductive Technology Order 2005, cls. 4–5 and sch. 1 pt. 1.
126. Goodman et al., 'Fertility Research', p. 64.

randomised whether they had a day three or day five transfer.[127] To be clear, the study intervention did not depart from standard practice but sought to better inform standard practice.

'HRR' is defined in the HART Act as 'research that *uses* . . . a human embryo'.[128] On the basis of legal advice obtained first from Health Legal (the legal arm of the Ministry of Health) and then Crown Law, ECART declined the study, essentially because the *Research Guidelines* only confers authority to approve research involving the *use* of 'non-viable' embryos. While this interpretation of 'use' may be reasonable given that the DOT study was an interventional study, the implications of the restriction of research to 'non-viable' embryos is perverse. It prevents two procedures, where there is genuine uncertainty as to which has the better outcome, from being compared, and thus prevents the derivation of valuable clinical data.

In the event, the researcher questioned the interpretation adopted, requesting copies of the legal opinion relied upon by ECART under the Official Information Act 1982 (OIA).[129] The Ministry declined the request on the basis that the legal opinions obtained were subject to legal privilege,[130] following which the researcher complained to the Ombudsman.[131] After investigation, Ombudsman Judge Peter Boshier concluded that the research proposed:[132]

> is a matter of considerable public importance and interest. It seems to me that it is incumbent on the Ministry to do everything it can to assist researchers adopt correct procedures and to ensure that the best first hand information is made available. I can think of no plausible reason why the Ministry would seek to withhold from a senior health researcher advice, whether privileged legal advice or not, about the interpretation of a crucial term in the governing legislation.

The Ombudsman noted that disclosing the legal opinions would

> promote the accountability of the statutory decision maker, enable more effective participation by concerned or affected citizens in the administration of the HART Act and the making of policies by ACART and thereby enhance respect for the law and to promote the good government of New Zealand.[133]

The Ombudsman's strong emphasis on ACART's accountability to those subject to regulatory restraint as a result of its embryo research policy is significant, but certainly

127. Op. cit.
128. Section 5 (emphasis added).
129. Section 12.
130. OIA, section 9(2)(h).
131. See Ombudsmen Act 1975, section 13.
132. Chief Judge P. Boshier, *Opinion of Chief Ombudsman (Abridged) – Request for Legal Opinions about a Key Term in Human Assisted Reproductive Technology Act 2004 – Public Interest in Access by a Senior Health Researcher Outweighs Legal Professional Privilege* (Office of the Ombudsman, Case No. 378663, 16 February 2016), para 47.
133. Boshier, *Legal Opinions*, paras 47 and 51.

unsurprising. More surprising was the Ministry's reluctance to release the legal advice in the first place. There was little of note in the legal opinions, except a passing comment made by Crown Law regarding ACART's powers under the Act.

Crown Law noted that if ECART is unable to approve an activity because it is not covered by a guideline, it must not only decline the application, it must also refer the matter to ACART.[134] However, what is most significant is the following, and manifestly reasonable observation by Crown Law that after referring the matter to ACART '*presumably the advisory committee may then give relevant advice or issue applicable guidance*'.[135] As the following section explains, despite statutory provisions appearing to delegate policymaking authority to ACART, there are significant barriers to ACART discharging its obligations to provide advice, guidance and issue guidelines under the Act.

Part III: 'Interim' Guidelines? A troubled regulatory relationship

A specific function of ACART is to provide the Minister with advice on issues arising out of 'ARPs' and 'HRR' and, without limitation, advice as to whether a moratorium should be imposed in relation to these activities.[136] In addition, section 37(1) provides that ACART *must*, within agreed time frames, provide information, advice and, if it thinks fit, recommendations in relation to the use of embryos in 'HRR'.[137] Soon after it was established, in 2005, ACART prioritised reviewing the *Research Guidelines* in its work programme. In doing so, it partnered with the National Bioethics Council: Toi te Taiao, a Government-appointed body which has since been disestablished.[138]

Given that Parliament empowers ACART with policymaking authority, extensive consultation requirements are imposed to facilitate deliberative democracy.[139] This

134. HART Act, section 18(2).
135. Letter from Crown Law to Health Legal regarding an application to perform 'HRR' under the HART Act (HEA007/820, 18 February 2014) (obtained under OIA request to the Ministry of Health).
136. Section 35(1)(b) (emphasis added).
137. This includes information, advice or recommendations pertaining to cloned embryos, donations of human embryos, genetic modification of embryos, and hybrid embryos. HART Act, section 37(1).
138. The Council was established by the government in 2002 and disestablished in 2009. Available at: https://www.mfe.govt.nz/about-us/other-websites/closed-websites Closed Websites (accessed 20 May 2020); The Council's role, as declared on its website, was to '[p]rovide independent advice to Government on biotechnological issues involving significant cultural, ethical and spiritual dimensions', '[p]romote and participate in public dialogue on cultural, ethical and spiritual aspects of biotechnology, and enable public participation in the Council's activities' and '[p]rovide information on the cultural, ethical and spiritual aspects of biotechnology'. Available at: http://ndhadeliver.natlib.govt.nz/webarchive/wayback/20080422070746/http://www.bioethics.org.nz/about-us/terms-of-ref-english.html Our Terms of Reference (accessed 20 May 2020).
139. 'Deliberative democracy' has been defined as '*mutual communication that involves weighing and reflecting on preferences, values, and interests regarding matters of*

reflects the view that in the case of controversial biotechnologies, regulators are required to engage directly with the public, ensuring respect for the status of citizens as stakeholders.[140] Before giving significant advice under section 37 of the Act, ACART must give interested parties and members of the public a reasonable opportunity to make submissions and are required to take such submissions into account.[141] When ACART considers giving significant advice, it must undertake active public engagement and enable public meetings to facilitate oral submissions if ACART believes a considerable number of people would wish to do so.[142] In addition, section 41 of the Act requires that, before ACART gives advice to the Minister or issues guidelines to ECART, ACART must 'consult' with any members of the public, government departments and agencies, or any other person ACART considers appropriate. Further, before ACART issues guidelines, it must 'consult on the proposed guidelines with the Minister'.[143]

ACART commenced its review of the *Research Guidelines* in 2006, in partnership with the Bioethics Council. In July 2006, the Bioethics Council published a booklet to facilitate public dialogue about the use of human embryos in research: focusing on cultural, ethical and spiritual aspects. In that same year, ACART released a public consultation document inviting written submissions from the public.[144] ACART also conducted eight public meetings to receive oral submissions, including hui (to obtain the views of Māori) and fono (to obtain the views of Pacifica peoples). This was supplemented by independent research commissioned by ACART, which utilised focus groups to canvass the views of five particular groups: young people; women; people with experience of infertility; people with experience of genetic disorders and Chinese and Indian ethnic groups.[145]

ACART sought public views regarding the moral status of the embryo and what kind of embryo research, if any, should be permitted in NZ including research involving basic science, research into fertility and infertility, research into the prevention of hereditary disease and research concerned with treating disease. For those participants who were not opposed to embryo research, ACART sought views regarding what sources of

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common concern'. See A. Bächtiger et al., eds., *The Oxford Handbook of Deliberative Democracy* (Oxford: Oxford University Press, 2018), p. 2.

140. R. Ankeny and S. Dodds, 'Hearing Community Voices: Public Engagement in Australian Human Embryo Research Policy, 2005–2007', *New Genetics and Society* 27(3) (2008), p. 219. 'Public engagement, stakeholder involvement, and the testing of competing arguments for policy recommendations are each characteristic of an approach to democratic political legitimacy that seeks to move beyond the purely formal processes characteristic of aggregative democracy'.
141. HART Act, section 39(2).
142. Section 40.
143. Section 41(2).
144. ACART, *Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New Zealand: A Discussion Paper* (December 2006).
145. Phoenix Research, *Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New Zealand: Research to Supplement Public Consultation on ACART's Discussion Document* (April 2007).

embryos were considered acceptable, with the options being 'non-viable' embryos;[146] 'surplus' embryos; and embryos created specifically for research, including hybrid embryos and embryos created using IVF or therapeutic cloning via SCNT. ACART also sought views about how Tikanga Māori (Māori cultural values) might apply to human embryo research, as well as different ethical, spiritual and cultural perspectives held by the public.

ACART received 345 written submissions. A further nine oral submissions were heard at public meetings. Approximately 160 people attended the public consultation meetings, including hui with Māori and fono with Pacific communities.[147] Two broad positions in relation to the use of embryos in research were identified in the submissions: (a) complete opposition on the grounds that embryos are human life and any intervention (including IVF) is akin to murder; and (b) support for some research 'on the grounds that they have a lesser moral status than persons who have been born, provided that such research has scientific merit and potential to benefit human health'.[148] In respect to Māori views, the submissions reflected a wide range of attitudes to the use of embryos in research. Overall, there was a sense that more time and a greater degree of engagement at an iwi level (the wider kinship group) was needed to discuss the issues. Similar views have been expressed in more recent discussions.[149]

In its analysis of submissions, ACART stated that it had 'considered not only the strength of public opinion, but also the strength of the arguments made'.[150] ACART subsequently provided the Minister with recommendations regarding reform and advice regarding further work and consultation. However, there is no public record of ACART's recommendations to the Minister, nor has ACART commenced any further work in this area. The destination of ACART's advice can only be pieced together from snippets of redacted information obtained under the OIA.

Ministerial mandate, or obstruction and obfuscation?

According to documents accessed under the OIA, ACART provided advice to the Minister of Health in June 2007,[151] proposing only modest immediate

146. 'Non-viable' embryos are defined as embryos that 'do not have the potential to develop into a foetus because of arrested growth, defects within the blastomeres, or poor morphology. Analysis of their genetic component often reveals abnormalities in the chromosomes, which are sometimes limited to only a small number of cells in an embryo'. ACART, *Determining Policy*, para 55.
147. ACART, *Use of Gametes and Embryos in Human Reproductive Research: Summary of Submissions* (September 2007).
148. ACART, *Submissions*, p. 2 (footnotes omitted).
149. M. Hudson et al., 'Dialogue as a Method for Evolving Matauranga Maori Perspectives on the Use of Embryos in Research', *AlterNative: An International Journal for Indigenous Peoples* 6(1) (2010), pp. 54–65.
150. ACART, *Submissions*, p. 1.
151. Specific advice from ACART to Pete Hodgson (Minister of Health) regarding 'HRR' (File Ref.: AD20-86-6, 29 June 2007) (obtained under OIA request to the Ministry of Health).

reform.[152] It recommended the development of guidelines enabling the use of both 'non-viable' embryos and donated 'surplus' IVF embryos for research.[153] It also advised the Minister that guidelines should *not* permit the creation of embryos specifically for research or the genetic modification of embryos in research – but that these activities should be subject to an 18-month moratorium.[154] Under the Act, the Minister may recommend to the Governor General that an Order in Council be passed declaring an activity to be subject to a moratorium, for up to 18 months, 'for the purpose of allowing time for the development of advice or guidelines, or both'.[155] After a moratorium is imposed, ACART must agree on a date with the Minister as to when it will provide the Minister with 'information, advice, and, if the committee thinks fit, recommendations'.[156]

ACART subsequently met with then Minister of Health, David Cunliffe and his Associate Minister to discuss ACART's recommendations in May 2008. The Minister was clearly not receptive to ACART's advice. Nevertheless in subsequent written correspondence, ACART reiterated that it wanted to proceed with guideline development, stating:[157]

> . . . the [current] guidelines themselves do not reflect the values that New Zealanders have told us are important to see implemented in the conduct of human reproductive research. I would, therefore, like to begin work on new guidelines . . . Finally, ACART feels strongly that it owes members of the public a response to the input they had as part of our consultation on embryo research . . . We would, therefore, like your agreement to publishing our advice on embryo research on our website.

In a written response, Minister Cunliffe reinforced his complete rejection of ACART's advice, stating unequivocally that he 'wished to see *explicit* prohibitions on research using: donated surplus IVF embryos, hybrid embryos, genetically modified embryos, [and] embryos specifically created for research purposes'.[158] Further, he did not agree to ACART publishing its advice on its website.[159] The letter culminated with

152. Specific advice from ACART to Pete Hodgson (obtained under OIA request to the Ministry of Health).
153. Op. cit.
154. Op. cit.
155. Section 24(1).
156. Section 24(3).
157. Letter from Sylvia Rumball (ACART Chair) to Steve Chadwick (Associate Minister of Health) regarding ACART's work programme (3 June 2008) (obtained under OIA request to the Ministry of Health).
158. Letter from David Cunliffe (Minister of Health) to Sylvia Rumball (ACART Chair) regarding ACART's advice to the Minister of Health (10 November 2008) (emphasis added) (obtained under OIA request to the Ministry of Health).
159. Letter from David Cunliffe to Sylvia Rumball (obtained under OIA request to the Ministry of Health).

the Minister advising that after the imminent election he would be 'seeking an urgent meeting' to discuss ACART's 'future advisory activities'.[160]

This exchange is concerning in several respects, primarily because it reflects a seeming disregard for the statutory framework and the respective roles of ACART and the Minister. While ACART has statutory obligations to 'consult' the Minister, its primary statutory obligations are in regard to developing policy advice and guidelines in accordance with the purposes and principles of the Act. In developing its advice and recommendations, ACART clearly discharged its obligations to consider the HART Act principles and undertake public consultation. While the Minister may not have liked ACART's advice, it was made in accordance with the statutory provisions.

Although the Minister may not agree, there is arguably no statutory mandate for the Minister to simply reject ACART advice, certainly not without explanation or justification. More importantly, the Act does not confer a Ministerial power to unilaterally demand ACART introduce certain prohibitions, particularly when such a prohibition is inconsistent with what, after undertaking substantial consultation, ACART considers appropriate. While the Minister's demand that ACART introduces explicit prohibitions on the use of certain types of embryos was simply *ultra vires* it was, in any event, it was unnecessary. The effect of the *Research Guidelines* is that they prevent the very activities that the Minister wished to see explicitly prohibited. If a particular type of 'HRR' is not permitted by the *Research Guidelines*, ECART cannot approve it, and by default it cannot be lawfully performed.

That said, the Act clearly requires ACART to 'consult' with the Minister prior to issuing significant advice, or guidelines to ECART.[161] Although the Act does not define 'consult', the common law approach adopted by the High Court in *Air New Zealand Limited v Wellington International Airport Ltd* is applicable.[162] When considering the nuances of a statutory duty to 'consult', McGechan J observed that the essence of 'consult' is 'not merely to tell or present. Nor, at the other extreme, is it to agree. Consultation does not necessarily involve negotiation toward an agreement, although the latter not uncommonly can follow'.[163] In other words, consulting is the 'statement of a proposal not yet finally decided upon, listening to what others have to say, considering their responses and then deciding what will be done'.[164]

Although the purpose of the statutory consultation requirements is to impose constraint on ACART, this arguably does not equate to providing the Minister with a power of veto. On the face of the Act, ACART has authority to give advice *and* to issue guidelines, provided it has discharged its statutory obligations. This approach is

160. Op. cit.
161. Section 41(2).
162. *Air New Zealand Ltd v Wellington International Airport Ltd* HC Wellington CP403/91, 6 January 1992 per McGechan J.
163. *Air New Zealand Ltd v Wellington International Airport Ltd,* at 8 per McGechan J.
164. *Air New Zealand Ltd v Wellington International Airport Ltd,* at 8 per McGechan J citing *West Coast United Council v Prebble* (1988) 12 NZTPA 399 (HC) at 405.

strengthened by the purpose of the Act, which is to provide a 'robust and flexible framework',[165] and to delegate policymaking authority and ethical review to two statutory bodies.[166]

Not only is it arguable that the Minister exceeded his statutory power in vetoing ACART's recommendations and demanding express prohibitions, also troubling is the Minister's obfuscation of ACART's advice by refusing to agree to ACART publishing its advice on its website. This lack of transparency undermines the objectives of the Act, specifically establishing a robust, flexible framework, and fails to ensure transparency and accountability of regulators to the public.

Options for ACART

As a result of the current impasse, NZ's embryo research policy which has not been legally effective since 2007 continues to prevent potentially valuable embryo research, despite ACART's efforts to review it. It is arguable that ACART could, despite ministerial opposition, publish its advice on its website and proceed with developing and consulting on new embryo research guidelines. As noted above, apart from the consultation obligations, the Act does not require that the Minister agree with advice or approve ACART's guidelines. The Act simply requires that, following the mandatory consultation, when issuing guidelines ACART must give copies to the Minister, the Director-General of Health, ECART and providers and publish the guidelines on the Internet.[167] The Act states that as 'soon as practicable' after receiving a copy of the guidelines, the Minister must present a copy to the House of Representatives.[168]

This statutory power does not mean, however, that guidelines issued by ACART under the HART Act should not be subject to external oversight and scrutiny. It is a core democratic principle that any delegation of Parliament's lawmaking power should be subject to review. However, this requires determining how the *Research Guidelines* should be characterised in the legislative and regulatory landscape.

External scrutiny: Constraints on ACARTs power to issue guidelines

A variety of terms may be used in relation to the products of lawmaking powers that are delegated under an empowering Act, for example, a 'regulation', a 'code', a by-law or an 'order in council', all of which fall under the umbrella concept of 'delegated' or 'subordinate' or 'secondary' legislation.[169] While not specified on the face of the HART Act, it is arguable that the *Research Guidelines* fall within the category of subordinate legislation referred to in the Legislation Act 2012 (LA) as a 'disallowable instrument'.[170]

165. Section 3(d).
166. Sections 3(e), 27–28, 32 and 35.
167. Section 36(2).
168. Section 36(3).
169. McGee, *Parliamentary Practice*, p. 461.
170. LA, section 38(1)(c).

A 'disallowable instrument' is subject to the House of Representatives power to disallow (or amend, revoke or replace),[171] enabling the House of Representatives to supervise Parliament's delegations of lawmaking power.[172] The LA deems an instrument made under an enactment to be 'disallowable' if it fulfils one or more of three criteria.[173] One criterion is that the instrument has a 'significant legislative effect'.[174] The LA specifies that an instrument has a 'significant legislative effect' if the effect of the instrument is to both 'create, alter, or remove rights or obligations' *and* 'determine or alter the content of the law applying to the public or a class of the public'.[175] The *Research Guidelines* clearly satisfy this definition: they create legal obligations for researchers and providers, which are statutorily enforced by a penalty if a person breaches the guidelines.[176] Further, by establishing the lawful scope of embryo research, the guidelines determine the law applying to fertility service providers, patients and researchers.[177] There is undoubtedly a strong case for finding the Research Guidelines fall within the category of secondary legislation referred to as disallowable instruments in the LA. However, proposed new legislation that seeks to simplify and remove uncertainty regarding the boundaries of secondary legislation by clearly identifying secondary legislation does not (as yet) expressly include the HART Act Guidelines.[178] While this is likely an oversight, it creates residual uncertainty as to whether the Research Guidelines constitute delegated legislation.

If ACART were to issue new guidelines, the Minister is required to present them in the House, even if he does not endorse them.[179] However, if there are concerns regarding the guidelines, and if it is accepted that they constitute a disallowable instrument, they may be referred to the Regulations Review Committee. The Regulations Review Committee may review 'disallowable instruments', but it focuses on procedural issues rather than the substantive content/policy of subordinate legislation.[180] Alternatively, Parliament's Standing Orders give subject select committees, including the Health Select Committee, power to initiate an inquiry into subject matter that falls within their terms of reference.[181] Hence, it would be open to the Health Select Committee to undertake a

171. LA, sections 42–46.
172. R. Carter, 'Disallowable Instruments', *New Zealand Law Journal* 6 (2014), p. 236.
173. Section 38(1).
174. LA, section 38(1)(c).
175. Sections 39(1)–39(2).
176. HART Act, Sections 16–17, 23, 26, 45–50, 52–57 and 60–61.
177. Section 39(3) of the LA Act provides that the description, form and maker of the instrument must be disregarded when determining if an instrument is an 'ISLE': hence the core issue in determining whether the guidelines constitute an ISLE is whether they alter rights and obligations.
178. See the Secondary Legislation Bill which applies in tandem with the Legislation Act 2019. Although it has received Royal Assent, the Legislation Act 2019 will only come into force when the Secondary Legislation Bill is enacted.
179. HART Act, section 36.
180. The Regulations Review Committee may review 'disallowable instruments', but it focuses on procedural issues rather than the substantive content/policy of subordinate legislation. See McGee, *Parliamentary Practice* p. 461.
181. Standing Orders of the House of Representatives 2017, SO 189(2).

review of any tabled guidelines. Following review, it may recommend to the House of Representatives that a resolution be passed to disallow any provision(s).[182] This would provide a formal oversight mechanism for any guidelines issued by ACART that do not have the support of the Minister.

While this option, which depends upon the *Research Guidelines* being deemed to be a 'disallowable instrument'/secondary legislation is potentially available to ACART, forcing the issue in this way may not be a particularly attractive or feasible option. The Minister appoints, and has the power to terminate, ACART members.[183] In addition, ACART is not well resourced. It is dependent upon limited secretariat support and funding from the Ministry of Health. Consequently, ACART has sought agreement from the Minister when formulating its work programme. Given this relationship, it would be understandable if ACART wished to avoid antagonising the Minister. However, it remains that ACART's primary obligations under the Act are to patients, providers and the public in general.[184] Clearly, this would be an easier task for ACART if it were established as an arm's length body similar to the UK's HFEA, with independent resources. While this analysis has suggested that the HART Act does not empower the Minister to dictate ACART policy, it must also be acknowledged that there are features of the regulatory environment that affect ACART's ability to act independently, including resource issues and a lack of will across the political spectrum to prioritise the issue of embryo research.

The impasse between the Minister and ACART has never been resolved. Since its early efforts, ACART has unsuccessfully sought approval from consecutive Ministers to revisit the issue of embryo research. After a National-led coalition government was formed in 2008, Tony Ryall replaced David Cunliffe as Minister of Health. ACART, once again, sought agreement to commence a review of embryo research, but it was never obtained.[185] In 2014, ACART noted in its briefing to Jonathan Coleman, the incoming Minister, that reviewing the *Research Guidelines* was a 'priority item' in regard to its work programme, subject to ministerial agreement, which again did not eventuate.[186] In 2017, a Labour-led coalition government was formed, with a majority Labour government following elections in 2020 . As yet no announcements have been made regarding review of the *Research Guidelines*.

182. The LA authorises the House of Representatives, by resolution, to disallow any provision of a 'disallowable instrument', sections 42(1),(2). The LA Act 2019, s 116 similarly allows the House to disallow, by resolution, any secondary legislation or provision therein.
183. HART Act, sections 34(1)–34(3).
184. See HART Act, sections 3–4, 34–36 and 39–41.
185. Letter from Tony Ryall (Minister of Health) to Sylvia Rumball (ACART Chair) regarding consent to review the *Research Guidelines* (10 September 2009) (obtained under OIA request to the Ministry of Health).
186. ACART, *Briefing to the Incoming Minister of Health* (10 November 2014), pp. 7 and 9–10.

Conclusion

This article makes two distinct claims. First, that the policy contained in the *Research Guidelines* is insufficiently justified and substantively flawed, with adverse consequences for research and the provision of fertility services. Second, that while the HART Act's principles-based framework may be superficially appealing, the current regulatory environment fails to enable the core regulatory values of procedural legitimacy, effectiveness, transparency and accountability of regulators.[187] Despite the deficiencies of the *Research Guidelines* and repeated attempts by ACART to engage with this issue, successive Ministers have actively prevented policy review in this area.

On the face of it, NZ's HART Act establishes a flexible, but protective, regulatory framework, introducing specific prohibitions in regard to embryo research,[188] but otherwise delegates policy development, in the form of advice and guidelines, to ACART.[189] By permitting IVF to be performed routinely, and by endorsing the '14-day rule' in primary legislation, NZ has implicitly adopted a nuanced or gradualist approach to the embryo. Despite the fact that the HART Act seeks to facilitate flexible, principles-based regulation, outdated *Research Guidelines* made prior to the introduction of the Act remain in use. Yet is is trite that when regulating modern technologies, regulators may be called to account if the regulatory objectives being pursued are not perceived to be ethically legitimate; if regulatory interventions are ineffective in practice; or if regulation fails to appropriately connect to a regulatory target.[190] This analysis suggests that while the regulatory objectives set out in the HART Act are defensible, they are not being achieved in practice, and regulators are failing to meet required standards.

The current policy that narrowly restricts embryo research adopts an extremely conservative position on the ethical spectrum that is difficult to reconcile with the purposes and principles of the HART Act. Arguably, demonstrating respect for human embryos as a form of human life does not require treating them as inviolable, prohibiting all embryo research. Demonstrating respect for human life does not preclude their use in significant and beneficial research. Rather, it requires careful regulation regarding their use. Further, restricting research to 'non-viable' embryos does not prevent the destruction of any embryos, and it comes at significant cost to beneficial research. A recent survey provides evidence that New Zealand researchers would, if legally permitted, conduct research into improving fertility rates and/or increasing understanding of embryo biology.[191] Ultimately, fertility service patients, and society in general, are denied the benefits that may be derived from embryo research.

187. Legislation Design and Advisory Committee, *Legislation Guidelines* (Wellington, NZ, LDAC, 2018), ch 14.
188. HART Act, sections 8–10, 11–16, 25–26, 51 and 62.
189. HART Act, sections 35 and 37–38.
190. R. Brownsword and M. Goodwin, *Law and the Technologies of the Twenty-First Century* (Cambridge: Cambridge University Press, 2012), p. 46.
191. Goodman et al., 'Fertility Research', p. 67.

In a pluralist and largely secular society, individual views may differ as to what kind of research should be permissible. However, at a minimum, fertility service providers should be able to conduct well-designed clinical research into fertility treatment. To prevent such research is to prevent the development of good quality services. This predominantly disadvantages the women who undergo, and children born as a result of, IVF procedures, contrary to the purposes and principles of the HART Act. Significantly, couples/individuals who have completed their reproductive treatment are denied a choice as to how their embryos will be disposed of when embryo storage limits expire. It is reasonable to suggest that couples who must decide the fate of their stored 'surplus' embryos should be able to decide whether they are simply destroyed or used for research purposes. To require a disposition decision to be made, but to limit it to destruction, simply cannot be justified when alternatives exist.

It is certainly true that embryo research exists on a spectrum in terms of the type of research that may be performed and the type of embryos that may be used. These are the very questions that ACART is mandated to explore under the HART Act. However, despite appearing to have considerable authority under the Act, it is clear that ACART is subject to ministerial control. This article has identified a concerning pattern of obstruction and obfuscation, preventing ACART from discharging it statutory duties, and ultimately undermining the effectiveness, transparency and accountability of ACART as regulators.

In practice, ACART lacks independence, and the issue of embryo research remains politicised. ACART, by seeking agreement from consecutive Ministers to proceed with the review of the guidelines governing embryo research, appears to have ceded control to the Minister. These problems are compounded by the fact that, due to the expiry of the interim period, the current *Research Guidelines* are no longer legally effective. This results in two things: ACART failing to discharge its statutory obligations by not reviewing guidelines that it considers are inadequate[192] and wrongly suggesting that the Minister has statutory authority over ACART.

Ultimately, it is apparent that the HART Act is not functioning as intended, a problem that extends beyond the regulation of human embryo research. Given this it is arguable that, in the interests of transparency, accountability and regulatory legitimacy in general, the HART Act should be reformed and Parliament should assume direct responsibility for determining these matters.

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192. ACART, *Briefing,* p. 9; ACART, *Human Reproductive Research – Associated Paper 6* (10 November 2014). Available at: https://acart.health.govt.nz/briefing-incoming-minister-health-2014 Briefing to the Incoming Minister of Health 2014 (accessed 22 May 2020).

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