Embryo Research in Legal Limbo:

A Critique of the Legal Framework for Embryo Research in New Zealand

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I. INTRODUCTION

People who require the aid of assisted reproductive technologies (ARTs) to have children may go to many lengths to produce embryos; they are required to take burdensome medications, undergo invasive procedures, and may also have to make significant financial contributions. The aim of this endeavour, in which they invest so much, is a child. Sometimes, at the end of the process, embryos have been created which are not implanted. These 'surplus embryos' may be stored for possible future use or donated to others for reproductive purposes. In many jurisdictions these surplus embryos may also be donated for research. Embryos not used by those who created them and not donated for another purpose are eventually required to be destroyed. One of the aims of embryo research is to improve the efficacy and safety of assisted reproductive technology, potentially improving the health of those born through ARTs and decreasing the cost and medical risk to those seeking ARTs. New Zealand (NZ) is currently in a position where we have vague, outdated and arguably inappropriate guidelines governing embryo research. Due to a combination of factors which will be outlined, the current situation in NZ is that research using "viable" embryos is not permitted.

This dissertation will outline the current legal framework in NZ concerning embryo research and assisted reproductive technologies. The current guidelines are examined and critiqued, I will argue that the guidelines are not inconsistent with the way NZ currently carries out ARTs. I will also argue that the guidelines are incompatible with current practices and views in NZ and have created unfavourable circumstances which are disadvantaging ART consumers as well as researchers.

The Advisory Committee on Assisted Reproductive Technology (ACART), who is tasked with producing advice regulating assisted reproductive procedures and human reproductive technology, attempted to issue new guidelines in 2007 by issuing advice to the Minister. However, ACART was stopped by the Minister of Health (the Minister) from taking the guidelines further. I will consider whether ACART's 2007 advice to the Minister, that was never publically released is commensurate with the principles of the Human Assisted Reproductive Technology Act 2004 (HART Act). Having reviewed the current impasse I will make suggestions as to what the guidelines surrounding embryo research should cover and I will outline the relevant authority's ability to issue these guidelines in light of the current legal framework.

II. THE CURRENT LEGAL FRAMEWORK

A. The HART Act 2004

The HART Act governs the performance of assisted reproductive procedures and human reproductive research. It prohibits certain activities and creates a system to provide governance and ethical oversight of "assisted reproductive procedures" and "human reproductive research".

An "assisted reproductive procedure" is a procedure performed for the purpose of assisting human reproduction, involving: the creation of a human embryo in vitro; or the storage, manipulation, or use of an in vitro human embryo or gamete.[1] It also includes the use of cells derived from an in vitro human embryo, or the implantation into a human of human embryos or gametes.[2] An assisted reproductive procedure does not include an "established procedure".[3] These are procedures that, unlike "assisted reproductive procedures", have been deemed to be routine in nature; they do not require ethical oversight.[4] Human reproductive research is **"**research that uses or creates a human gamete, a human embryo, or a hybrid embryo".[5]

B. Legislative History

The HART Act came about following a protracted, difficult process. In 1996 Labour MP Dianne Yates submitted a Private Member's Bill called the Human Assisted Reproductive Technology Bill (the HART Bill).[6] The HART Bill proposed a framework similar to that in the United Kingdom (UK), where licences are issued by a licencing authority for the conduct

[1] Human Assisted Reproductive Technology Act 2004, s 5.

[2] HART Act, s 5.

[3] HART Act, s 3

[4] Human Assisted Reproductive Technology Order 2005, cl 4.

[5] A Hybrid embryo is made by fusing a human gamete with a non-human gamete; or by fusing or compacting a cell of a human embryo with a cell of a non-human embryo; or by fusing or compacting a cell or cells of a human embryo with the cell or cells of another human embryo; or by transferring the nucleus of a human cell into a non-human egg or a non-human embryo; or by transferring the nucleus of a non-human cell into a human egg or a human embryo - HART Act, s 5

[6] Jeanne Snelling "Cartwright calamities, Frankenstein monsters and the regulation of PGD in NZ" in Sheila A.M. McLean, Sarah Elliston (ed) *Regulating Pre-implantation Genetic Diagnosis: A Comparative and Theoretical Analysis* (Routledge, London and New York, 2013) 171 at 171

of assisted reproductive procedures and human reproductive research.[7] The HART Bill was unanimously sent to the Health Committee in 1997, where it remained.[8] In 1998 a government bill called the Assisted Human Reproduction Bill was introduced.[9] The government bill proposed a scheme which would give the existing National Ethics Committee on Assisted Human Reproduction (NECAHR) ethical oversight of assisted reproductive procedures and human reproductive research.[10] NECAHR was established in 1995 to review applications from fertility clinics wanting to perform assisted reproductive procedures.[11] It also created guidelines covering areas of assisted reproductive technology and human reproductive research.[12] In 1998 Attorney General Doug Graham claimed that a licencing system was not appropriate for NZ.[13] He stated that a licensing regime would be costly for tax payers and, as NZ had fewer fertility providers than the UK, a licencing regime would not be appropriate.[14]

In April 2003, the HART Bill was the subject of Supplementary Order Paper No.80. (SOP).[15] The SOP effectively redrafted the HART Bill, leaving only its name.[16] The SOP removed the licencing regime, providing for an Advisory Committee that would issue advice, create guidelines and monitor established procedures.[17] The SOP did not specify reasons for removal of the licencing regime. It was likely that it was removed for the reasons given by the Attorney General in 1998. The Health Committee recommended the HART Bill be

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[7] The Human Fertilisation and Embryology Act 1990 (UK), s 5 establishes the licencing authority, the Human Fertilisation and Embryology Authority which issues licences for activities listed in schedule 2 of the Human Fertilisation and Embryology Authority 1990 (UK).

[8] Snelling "Cartwright calamities, Frankenstein monsters and the regulation of PGD in NZ", above n 6, at 181

[9] Jeanne Snelling, "Law and Regulation" in *Choosing genes for future children: regulating preimplantation genetic diagnosis/ Human Genome Research Project* (Human Genome Research Project, Dunedin, 2006) 229 at 246.

[10] Snelling "Law and Regulation", above n 9, at 246.

[11] Jeanne Snelling "Embryonic HLA Tissue-Typing and Made-to-match Siblings: The NZ Position" (2008) 9 Med.L.Int.13, at 15.

[12] Snelling "Embryonic HLA Tissue-Typing and Made-to-match Siblings: The NZ Position", above n 11, at 15 .

[13] Doug Graham, Attorney General of NZ "Current Medico-legal Issues" (Address To 7th Annual NZ Medico-Legal Conference, Wellington, 23 February 1999).

[14] Graham, above n 13; This view was in line with the The Ministerial Committee on Assisted Reprodcutvie Technologies (MCART) report: Ministerial Committee on Assisted Reproductive Technologies, *Assisted Human Reproduction: Navigating Our Future* (Wellington, Department of Justice, 1994. MCART was establisehd in 1993 by the Minister of Justice to report on options for the development of a scheme to regulate asisted reproductive procedures and research: Snelling "Cartwright calamities, Frankenstein monsters and the regulation of PGD in NZ", above n 6, at 178.

[15] Supplementary Paper 2003 (80) Human Assisted Reproductive Technology Bill 1996 (195–1).

[16] Peter Martin, *HART Failure: The Power of the Advisory Committee under the Human Assisted Reproductive Technology Act 2007* (LLB(Hons) dissertation, University of Otago, 2005), at 18

[17] Supplementary Paper 2003 (80) Human Assisted Reproductive Technology Bill 1996 (195–1) (explanatory note), at 35-36.

passed with amendments that largely reflected the changes made in the SOP.[18] On 21 November 2004 the Bill received royal assent.

C. Purposes

The HART Act aims to secure the benefits of assisted reproductive procedures by taking appropriate measures to protect and promote the health, safety, dignity and rights of all individuals, particularly of women and children, in the use of these procedures and in research.[19] The Act also aims to establish a "robust and flexible framework for regulating and guiding" the conduct of assisted reproductive procedures and human reproductive research while prohibiting 'unacceptable assisted reproductive procedures and…human reproductive research'.[20]

D. Principles

The Act sets out principles that must be considered by those exercising powers or performing functions under it.[21] Principles relevant to embryo research include: that 'the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure'; that the 'human health, safety, and dignity of present and future generations should be preserved and promoted'; 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'.[22]

The principles section also requires that 'the needs, values and beliefs of Māori', along with 'the different ethical, spiritual and cultural perspectives in society' should all be treated with respect.[23] Moreover, reproductive procedures and human reproductive research may only occur with informed consent.[24]

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[18] Human Assisted Reproductive Technology Bill (195-3) (Commentary) at 1.
[19] HART Act, 3(a).
[20] HART Act, s 3.
[21] Under the HART Act it is the Ethics Committee, the Advisory Committee and the Minister of Health who exercises powers and functions: HART Act, s 4.
[22] HART Act, s 4.
[23] HART Act, s 4.
[24] HART Act, s 4.

E. Statutory Bodies Established

The HART Act establishes two separate statutory bodies with their own distinctive roles. These are ACART and the Ethics Committee on Assisted Reproductive Technology (ECART).

1. ACART

ACART is authorised to determine policy on assisted reproductive procedures and human reproductive research rather than Parliament.[25] It is one of ACART's functions to advise the Minister on issues surrounding assisted reproductive procedures and human reproductive research.[26] In doing so, ACART must monitor the application and health outcomes of assisted reproductive procedures, established procedures and developments in human reproductive research.[27] ACART may also prepare guidelines and advice that are issued to the Minister and ECART .[28]

2. ECART

ECART implements the guidelines issued by ACART.[29] ECART will determine applications for the performance of assisted reproductive procedures and human reproductive research.[30] The guidelines effectively have force of law as ECART may only approve applications consistent with the guidelines.[31] It is an offence to perform an assisted reproductive procedure or conduct human reproductive research without ECARTs approval.[32] Because of this the guidelines are comparable to delegated legislation.[33]

F. Three Tiers Of Regulation

The HART Act establishes three categories of activities: established procedures that are unregulated, assisted reproductive procedures and human reproductive research that are regulated procedures, and prohibited activities.[34]

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[25] Nicola Peart "Legal Regulation of Assisted Human Reproduction" in Peter Skegg and Ron Paterson (ed) *Health Law in NZ* (Thompson Reuters, Wellington, 2015) 515, at 525.

[26] HART Act, s 35.

[27] HART Act, s 35.

[28] HART Act, s 35.

[29] HART Act, s 29.

[30] HART Act, s 29.

[31] Peart, above n 25, at 526; HART Act, s 29.

[32] Snelling "Law and Regulation", above n 9, at 242; HART Act, s 35.

[33] Snelling "Law and Regulation", above n 9, at 242.

[34] Snelling "Law and Regulation", above n 9, at 248.

1. Established Procedures

Established procedures are not considered to be an assisted reproductive procedure or human reproductive research.[35] The Governor General may, by Order in Council and upon the Minister's recommendation, declare a procedure or treatment to be an established procedure.[36] One of ACART's functions is to provide the Minister with advice on whether an established procedure should be created, modified or cease to be an established procedure.[37] The Human Assisted Reproductive Technology Order 2005, made under s 6 of the HART Act, declares procedures that are established procedures.[38] Procedures such as artificial insemination, egg cryopreservation, in vitro fertilisation (IVF) and pre-implantation genetic diagnosis (PGD) are all established procedures and therefore do not require prior approval from ECART.[39]

2. Prohibited Activities

The 1st schedule of the HART Act specifies certain prohibited actions which, if performed, constitute an offence.[40] Included among these are: artificially forming a cloned embryo for reproductive purposes, forming a hybrid embryo for reproductive purposes, implanting into a human an animal gamete or embryo, implanting into an animal a hybrid embryo, and implanting into a human a genetically modified gamete.[41] Notably, the Act does not prohibit research being conducted on cloned embryos or hybrid embryos.

3. Regulated Activities

Regulated activities require ECART approval before they can occur; these include assisted reproductive procedures and human reproductive research.[42] Embryo research falls into the ambit of regulated activities as it is neither an established procedure nor a prohibited activity. Regulated activities can only be approved if they are consistent with the guidelines issued by ACART.[43]

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[35] HART Act, s 5.
[36] HART Act, s 6.
[37] HART Act, s 35.
[38] HART Order 2005, cl 5.
[39] HART Order, cl 4, Schedule of Established Procedures.
[40] HART Act, s 6; HART Act, Sch 1.
[41] HART Act, Sch 1.
[42] HART Act, s 16.
[43] HART Act, ss 19, 29.

4. Limits on The Use and Storage of Embryos Under the HART Act

The HART Act imposes some limits on how embryos can be stored and treated. Embryos cannot be stored for more than 10 years unless an extension has been granted by ECART.[44] It is also an offence to knowingly allow an embryo to develop outside the body of a human for more than 14 days.[45] In the chapter that follows, it will be argued that these limits provide sufficient safeguards for embryo research and that the current restriction on embryo research to non-viable embryos is inconsistent with the Act's statutory objectives and principles.

[44] HART Act, ss 10, 10A.

[45] HART Act, s 9.

III. THE CURRENT GUIDELINES

A. The Current Guidelines – Introduction

NECAHR, a statutory body that preceded the introduction of the HART Act, were responsible for drafting the *Guidelines for Research on Gametes and Non-viable Embryos* (the NECAHR guidelines).[46] NECAHR was established to review applications from fertility clinics wanting to perform assisted reproductive procedures and human reproductive research.[47] It also created guidelines to ensure that procedures and research would be carried out in a safe and ethical manner.[48] The NECAHR guidelines were approved by the Minister in 2005.[49] These guidelines were only intended to be interim guidelines which would be subsequently reviewed by ACART.[50] Section 83 of the HART Act stipulates that the interim period lasts for three years.[51] In 2007 the NECAHR guidelines were issued to ECART.[52] They therefore have the same force as they would have had, had they been promulgated by ACART, and will not expire.[53] While intended to only be interim guidelines, the NECAHR guidelines are the only guidelines applicable to embryo research. Despite attempts to do so, ACART has not been successful in revising the guidelines.[54]

B. Origins Of The NECAHR Guidelines: The Australian NHMRC Guidelines

The NECAHR guidelines consist of a series of clauses taken from the 2004 Australian National Health and Medical Research Council's *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (the NHMRC guidelines).[55] Bizarrely, clauses of the NHMRC guidelines have been copied from a large document and

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[46] NECAHR "*Guidelines for Research on Gametes and Non-viable Embryos*" (1 January 2005) <www.acart.health.govt.nz> (the NECAHR guidelines).

[47] Snelling "Embryonic HLA Tissue-Typing and Made-to-match Siblings: The NZ Position", above n 11, at 15.

[48] Snelling "Embryonic HLA Tissue-Typing and Made-to-match Siblings: The NZ Position", above n 11, at 15.

[49] Approval of Interim Guidelines Under the Human Assisted Reproductive Technology Act 2004 (11 August 2005) 123 *New Zealand Gazette* 2965 at 3010; HART Act, s 83.

[50] HART Act, s 83.

[51] HART Act, s 83.

[52] Guidelines and Advice Issued to Ethics Committee on Assisted Reproductive Technology (29 November 2007) 130 *New Zealand Gazette* 3345 at 3375; HART Act, ss 35, 36.

[53] Snelling "Law and Regulation", above n 9, at 237.

[54] ACART was instructed by the Minister of Health in 2009 to not prepare guidelines on embryo research in a letter from Rt Hon Tony Ryall: "Letter by Hon Tony Ryall to ACART" (10 September 2009) (Obtained under Official Information Act 1982 Request to the Ministry of Health).

[55] The NECAHR guidelines stipulate that the clauses have been taken from the NHMRC ethical guidelines: NECAHR guidelines, above n 46; NHMRC "Ethical guidelines on the use of assisted reproductive technology in clinical practice and research" (Australia) (September 2004).

combined in an out-of-order fashion to form a photocopied document that lacks any context and is entirely ambiguous.[56]

The NHMRC guidelines are issued in accordance with the National Health and Medical Research Council Act 1992 (Australia).[57] The NHMRC issues guidelines and advices the community on matters relating to health care.[58] The NHMRC guidelines, along with the relevant Australian legislation guide practitioners and researchers performing assisted reproductive procedures and human reproductive research.[59]

1. NECAHR Guidelines: The Paradox Of The Non-Viable Distinction

The NECAHR guidelines (which guidelines can be read in full at Appendix 1) consist of clauses which provide for:[60]

- minimising risks of research to participants and ensuring they are balanced by possible benefits;
- ensuring separate decision-making processes for clinical care and research;
- ensuring that participants give free and informed consent and are not coerced into giving consent;
- ensuring that the participants understand what the research entails and any possible consequences;
- providing participants with information about the research;
- keeping detailed records of embryos in researchers care and the outcomes of research;
- assessing and monitoring present and future outcomes for all participants (present and future); and
- disclosing financial interests that a researcher or clinic may gain from research.

Significantly, apart from the title there is no mention of the terms ‘viable’, ‘non-viable’, or any terms of a similar meaning, in the NECAHR guidelines. The term ‘non-viable’ only

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[56] NHMRC Ethical guidelines , above n 55. See Appendix. Note that the guidelines are askew and the clauses are out of numerical order.

[57] National Health and Medical Research Council Act 1992 (Australia) (NHMRC Act), s 7(1)(a).

[58] NHMRC Act, 7(1)(a).

[59] NHMRC Ethical guidelines, above n 55, at 8.

[60] NECAHR guidelines, above n 46, at cls 15.4, 15.4.1, 15.4.2, 15.5, 15.6, 15.8, 15.10, 15.11, 15.12, 16.3, 16.4, 16.5 and 16.5.1. See Appendix 1 for the guidelines in full.

appears in the title: *Guidelines for Research on Gametes and Non-viable Embryos*, the only part written by NECAHR.[61]

This anomaly has occurred because the NHMRC guidelines, from which all clauses in the NECAHR guidelines have been directly taken, permit research using excess ART embryos. These are embryos no longer required for ART treatment (which may be 'viable').[62] In fact, despite the reference to 'non-viable' embryos in the title of the NECAHR guidelines there is absolutely no reference to or description of 'non-viable' embryos anywhere in the NHMRC guidelines. For this reason, the NECAHR guidelines are hard to make sense of. It is arguable that in an area as important as embryo research, guidelines which are so out of context and displaying such a lack of clarity are concerning. For this reason, it is all the more problematic that ACART has been unable to update the guidelines.

2. The NECAHR Guidelines Are Deficient

The Australian guidelines are extensive and have been carefully drafted. When contrasted to the haphazard, copy and paste NECAHR guidelines the legitimacy of the NECAHR guidelines is called into question. It is possible that NECAHR did not have the funding or resources to draft guidelines as comprehensive as the NHMRC guidelines. However, it arguably may have been more effective, and would have left the state of embryo research in a better place, had NECAHR used the entirety of the NHMRC guidelines. NZ has been left with guidelines that are out of context and lack coherence. This means that embryo research in NZ is highly restrictive. It is not known why NECAHR decided to pick the clauses they did, and why they chose to limit research to non-viable embryos, and why they did not define this term.[63] It should also be noted that no other jurisdiction has the same viability limit on embryo research.

3. The NECAHR Guidelines Are Out Of Date

The NECAHR guidelines are still in force 13 years after they were approved by the Minister and have not been replaced by ACART. While the NHMRC guidelines are more comprehensive and coherent than the NECAHR guidelines, they have been revised in 2007 and again in 2017.[64] Therefore, even the clauses which form the basis of the NECAHR guidelines are twice out of date. Embryo research is a serious matter, carrying important

[61] NECAHR guidelines, above n 46.

[62] NHMRC guidelines, above n 565, at 49.

[63] Lucy Goodman and Others "The futility of fertility research? Barriers to embryo research in New Zealand" (2018) 131 NZMJ 63 at 68.

[64] NHMRC "Ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research" (Australia) (June 2007) < www.nhmrc.gov.au>; NHMRC "Ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research" (Australia) (April 2017) < www.nhmrc.gov.au>.

implications for parents, researchers and future generations. Therefore, there are strong reasons for these out of date guidelines to be revisited.

C. The Viability Distinction: What Is The Underlying Ethical Reasoning?

The term "non-viable" in the title of the NECAHR guidelines has not been justified by NECAHR. However, Canadian bioethicist Françoise Baylis is one notable academic who advocated for limiting embryo research to non-viable embryos.[65] Baylis contends that using the 14-day limit as the cut off point for embryo research is invalid, as embryo development is continuous.[66] There is, therefore, no one point in an embryos development that is more important than another.[67] Baylis claims that the 14-day limit could be seen as arbitrary.[68] For this reason, she contends that there is a greater risk of embryo research descending down a 'slippery slope' of embryo experimentation.[69] For this reason, she advocates that the distinction between 'viable' and 'non-viable' embryos is a better limit to place on embryo research.[70] Baylis does not explain what she means by the 'slippery slope'. She may mean descent into controversial practices like late term abortion and reproductive cloning.

It is arguable a more pragmatic approach to embryo viability would be defining 'non-viable embryos' as all embryos not intended for reproductive purposes ('surplus' embryos).[71] All embryos not used for reproductive purposes must be destroyed.[72] Because of this certainty, defining viability on the basis of intrinsic developmental potential is flawed.[73] Without transfer, these embryos will not ever be able to develop into a human. If this definition of 'non-viable' was adopted all embryos not intended for transfer could be used in research if the progenitors wished to donate them to research.

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[65] Francoise E. Baylis "The ethics of ex utero research on spare 'non-viable' IVF human embryos" (1990) 4 Bioethics 311.

[66] Baylis, above n 65, at 311.

[67] Baylis, above n 65, at 311.

[68] Baylis, above n 65 at 312.

[69] Baylis, above n 65, at 312.

[70] Baylis, above n 65, at 312.

[71] Baylis noted that this was a possible interpretaiton for 'non-viable: Baylis, above n 65 at, 315.

[72] Embryos may only be stored for 10 years unless an extention is granted. Unless the embryos are used in this time for reproduction or are donated to another couple for reproductive purposes they must be destroyed: HART Act, s 10.

[73] The embryos intrinsic ability to develop is its genetic constitution, meaning if it were to be transferred it would have the ability to develop.

Baylis's paper was written in 1990.[74] In the 28 years since then Australia and the UK have been permitting research using viable surplus embryos.[75] To date, no negative effects have arisen from this kind of research. Arguably, NZ should similarly allow for research using viable surplus embryos. Moreover, as the following sections will argue, viability is not defined in the NECAHR guidelines and is difficult to determine. They will also show that the NECAHR guidelines are overly cautious, ethically unjustified, and impractical.

D. Defining And Determining Viability.

1. ACART's Definition

In 2014 ACART criticised the NECAHR Guidelines to the Minister for not defining the terms 'viable' or 'non-viable'.[76] Baylis defines a 'non-viable' embryo as:[77]

> An IVF embryo that is dying with no hope of reprieve. In a healthy and physiologically receptive uterus, it would either fail to implant or would implant then spontaneously abort. The non-viable IVF embryo…has no potential for ongoing development.

This is consistent with the definition of 'non-viable' adopted by ACART in its 2006 discussion paper, where it stated: "non-viable embryos have no potential to develop into a living individual and no potential to implant. They may be regarded by some merely as clusters of human cells".[78]

Baylis contends that limiting embryo research to 'non-viable' embryos is justified because the 'non-viable' embryo has no chance of survival.[79] Baylis remarks that because the 'non-viable' embryo lacks any ability to become a 'full-fledged member of the moral community'

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[74] Baylis, above n 65.

[75] In Australia a licence to use excess embryos in research can be obtained Research Involving Human Embryos Act 2002 (Australia), s 20(a); In the UK licences for using embryos in research and the creation of embryos for research can be granted : Human Fertilisation and Embryology Act 1990 (UK), Sch 2, cl 3.

[76] ACART "Briefing to the Incoming Minister of Health 2014: Human Reproductive Research: Associated Paper 6" (Associated Paper 6) (10 November 2014), at [4].

[77] Baylis, above n 65, at 318.

[78] ACART "Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for NZ: A Discussion Paper" (Discussion Paper) (December 2006, Wellington, Advisory Committee on Assisted Reproductive Technology), at [125].

[79] Baylis, above n 65, at 325.

it is no more valuable than human somatic cells.[80] Therefore, destruction of non-viable embryos does not cause any harm.[81]

2. Determining Viability

It is arguable that separating embryos into 'viable' and 'non-viable' as per Baylis' and ACART's definitions is not possible. ACART has stated: [82]

> …some of the embryos produced by IVF 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…. These embryos are considered '**non-viable**'.

It is not clear how poor morphology, defects in blastomeres or chromosomal abnormalities can determine conclusively that the embryo has absolutely no hope of developing if the embryo were transferred to a uterus. It is possible these methods could be used to determine which embryos have defects, or which embryos have a lesser chance of implantation, and therefore should not be selected for transfer. However, it is not possible to use these methods to determine whether the embryo has absolutely no potential to develop to full term. A morphological assessment involves an embryologist using visual methods and expert opinion to determine if the embryo is developing normally.[83] Assessing embryo health on a morphological basis is inherently unreliable.[84] Studies have shown embryos that were defined as 'non-viable' due to their early morphology have gone on to develop into a healthy baby upon transfer.[85]

When Baylis wrote her paper in 1990, she hoped that in the future there would be a non-invasive way to determine viability which was more accurate than determining viability on a morphological basis.[86] Currently the only available mechanisms to determine pre-implantation health of the embryo in NZ are PGD and a visual assessment of the embryo. PGD is only available where the child has at least a 1 in 4 chance of inheriting a condition, or

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[80] Baylis, above n 65, at 326.

[81] Baylis, above n 65, at 325.

[82] ACART "Discussion Paper", above n 78, at [55].

[83] David K. Gardner and Basak Balaban "Assessment of human embryo development using morphological criteria in an era of time-lapse, algorithms and 'OMICS': is looking good still important?" (2016) 22 Mol Hum Reprod 704 at 704.

[84] ACART Associated Paper 6, above, n 76, at [4].

[85] ACART Associated Paper 6, above, n 76, at [4].

[86] Baylis, above n 65, at 319.

for chromosomal abnormalities associated with recurrent miscarriage.[87] PGD is not routinely used to determine embryo viability, and is generally used to determine genetic disorders which may still be consistent with successful implantation and birth. Therefore, reliably identifying embryos which will have absolutely no hope of developing is currently an impossible task.

3. The Distinction May Only Be Justified If 'Non-Viable' Can Be Determined

Limiting embryo research to 'non-viable' embryos can only be justified if one can determine which embryos have no hope of development so are 'non-viable' and which embryos have developmental potential so are 'viable'. If embryos with developmental potential were destroyed because they were deemed to be 'non-viable' (due to the lack of technology being available to accurately determine which embryos lack all developmental potential), it would, according to Baylis, cause a harm.[88] Therefore, if 'non-viable', as defined by ACART and Baylis, cannot be determined, either no embryos should be used in research (as the destruction of any would cause harm under Baylis' logic). Alternatively, we could accept there is no real way of distinguishing between viable and non-viable and all embryos may be used in research.

In the absence of a bright line test to determine which embryos are viable and which are non-viable, distinguishing between the two for the purpose of research is misguided. The NECAHR guidelines are based on an artificial black and white background, when in reality, viability is more akin to many shades of grey. In this sense, the NECAHR guidelines rely on a distinction that has no realistic basis. However, there are additional reasons to question the current guidelines.

4. Wording Of The Guidelines

The wording of the NECAHR guidelines is inconsistent with the definition of 'non-viable' adopted by ACART. Clause 15.4.2 of the NECAHR guidelines reads: "any risks (particularly any long-term risks to *persons born*) should be minimal".[89] ACART noted the wording in clause 15.4.2 of the NECAHR guidelines contradicts their interpretation of 'non-viable.[90] The reference to "persons born" mean that the NECAHR guidelines could be seen as covering 'viable' embryos in research.[91] This highlights the inherent problem of the guidelines, which

[87] ACART "Advisory Committee on Assisted Reproductive Technology: Guidelines on Preimplantation Genetic Diagnosis with Human Leucocyte Antigen Tissue Typing" (18 August 2014) <www.acart.health.govt.nz>, at 2-3

[88] Baylis, above n 65, at 325.

[89] The NECAHR guidelines, above n 46.

[90] The NECAHR guidelines, above n 46, cl 15.4.2 cited in ACART Associated Paper 6, above n 76, at [10].

[91] ACART Associated Paper 6, above n 76, at [10].

is that although the NECAHR guidelines are entitled "*Guidelines on the use of Non-viable Embryos for Research*" , the title is not consistent with the actual clauses within the guidelines. This makes sense given that the origins of the clauses were in the NHMRC guidelines that permitted research on viable embryos. It is conceivable that clinical research could be conducted on embryos that are transferred into a woman using viable embryos. Therefore, on the face of the NECAHR guidelines 'non-viable' cannot mean that the embryo has no hope of development. As stated in the last section, the NECAHR guidelines cannot be justified as they appear to cover embryos with hope of development and, according to Baylis, this destruction of embryos with intrinsic developmental potential would cause a harm.[92]

5. Guidance From Australia

Given that the NECAHR guidelines refer to 'persons born', it seems 'non-viable' cannot mean that the embryo has no hope of development. Australian law and guidelines use distinct and clear terminology to provide guidance as to what 'non-viable' means. An "unsuitable embryo for transfer" is defined by the 2017 NHMRC guidelines as an embryo where there is a "low likelihood of implantation according to the clinic's established policies and procedures for grading embryos".[93] This is a purely clinical concept, used by the embryologist to decide which embryos to transfer.[94] Embryos 'unsuitable for transfer' are different from embryos 'unsuitable for implantation'.[95] Embryos 'unsuitable for implantation' can be used in circumstances described in s 24(8) of the Research Involving Human Embryos Act 2002 (RIHE Act).[96] Embryos 'unsuitable for implantation' have been diagnosed by PGD as carrying a serious genetic disorder or have been identified by an embryologist as being unsuitable for implantation according to the objective criteria.[97] These embryos may have the capacity to develop to term if they were transferred to a person's uterus. In Australia embryo suitability is used to determine whether an alternate form of consent can be given for research under a particular licence type, not to determine whether embryos can be used at all.

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[92] Baylis, above n 65, at 325.

[93] NHMRC 2017 guidelines, above n 64.

[94] NHMRC 2017 guidelines, above n 64, at 10.

[95] NHMRC 2017 guidelines, above n 64, at 10.

[96] NHMRC 2017 guidelines, above n 64, at 10; the definition of proper consent in the NHMRC guidelines to be applied in a modified form in relation to the use, under a licence, of excess ART embryos that are unsuitable for implantation. For example, the guidelines could apply to a particular licence in a modified form, to alter the cooling-off period required in relation to the use of excess ART embryos that are unsuitable for implantation: Research Involving Human Embryos Act 2002 (Australia), s 24(8).

[97] NHMRC "Objective criteria for embryos that are unsuitable for implantation" (Objective Criteria) (6 December 2007).

It is arguable 'non-viable' should be taken as meaning the same thing as embryos 'unsuitable for implantation', meaning PGD discarded embryos could be used in research. Embryos 'unsuitable for implantation' are treated in a different way to embryos suitable for implantation.[98] However, they can still be deemed to be excess embryos and used in research.[99] If this definition was adopted, embryos would meet the definition of unsuitable for implantation if they were identified by PGD as carrying a serious genetic condition or met the objective criteria and then could be used in research. This definition would be consistent with clause 15.4.2 of the NECAHR guidelines which referenced 'persons born', as these embryos may be able to develop to term if transferred. This definition would provide practitioners with a clear way to tell which embryos are non-viable.

E. Are PGD Discarded Embryos Deserving of Less Protection?

Under ACART's definition of viability PGD discarded embryos would be considered viable. ACART stated:[100]

> Preimplantation genetic diagnosis (PGD) identifies those embryos that carry genetic diseases passed down from their parents, and these embryos can also be considered surplus….

PGD can be used to identify embryos which have single gene disorders like Cystic Fibrosis, and Huntington's Disease or chromosomal abnormalities like trisomy 21 which causes Down's Syndrome.[101] These are conditions which have profound effects on those who suffer from them. However, they are not lethal. Embryos carrying conditions like this may still be able to develop to term.

As ACART sees it, PGD discarded embryos are viable because of their developmental potential, despite carrying deleterious gene mutations. However, this interpretation of 'non-viable' is inconsistent with clause 15.4.2. of the NECAHR guidelines.[102] If 'non-viable' is taken as meaning 'embryos unsuitable for implantation', as in the RIHE Act, which would provide practitioners with clarity, then PGD-discarded embryos would be considered non-viable and could then be used in embryo research.

If PGD discarded embryos can be used in research, limiting embryo research to non-viable embryos becomes arguably eugenic. Dangerous inferences can be drawn if research is

[98] NHMRC 2017 guidelines, above n 64, at 10;

[99] Research Involving Human Embryos Act 2002 (Australia), s 9.

[100] ACART "Discussion Paper", above n 78, at [61].

[101] Fertility Associates "Pathway To A Child Booklet" (August 2017) at 86

[102] NECAHR guidelines, above n 56, cl 15.4.2 cited in ACART Associated Paper 6, above n 76 at [10].

permitted on PGD discarded embryos and not 'healthy' embryos. Embryos that carry serious conditions like trisomy 21 or Cystic Fibrosis would be seen as deserving less protection than healthy embryos. The extension of this view would be that individuals who are affected by these disorders are less valuable than healthy individuals.

The NECAHR guidelines are ambiguous and vague. Viability is not defined, and the definition a of 'non-viable' adopted by ACART does not align with the wording of the NECAHR guidelines. Moreover, on a pragmatic level, there is no way to determine if an embryo has no hope of development. Even if an unambiguous definition of 'non-viable' was adopted, like 'embryos unsuitable for implantation', dangerous inferences arise. Moreover, the NECAHR guidelines cannot be justified if 'non-viable' includes embryos that are capable of development as their destruction would, according to Baylis's account, cause harm.[103] To avoid ambiguity, ethical inconsistences, and dangerous inferences, the NECAHR guidelines need to be updated.

F. A Major Flaw: The Guidelines Are Inconsistent With The Gradualist Approach

1. The Gradualist Approach

Even if it were possible to determine if an embryo had no developmental potential, limiting embryo research on the basis of viability is inconsistent with the gradualist approach taken towards the embryo and foetus in NZ. This means, in the eyes of the law, that the embryo is seen as:[104]

> more than a mere collection of cells, but less than a full person…. the embryo of the human species is worthy of respect at all stages, but that certain interventions/treatments may be permissible at certain stages, with the limits of permissibility narrowing as the embryo/foetus nears maturity.

Therefore, as the embryo or foetus develops its protected status increases. The gradualist approach towards the embryo and foetus is seen in our laws surrounding abortion where protection of the foetus is increased after 20 weeks.[105] The gradualist approach is also seen in the adoption of the 14-day limit on embryos being allowed to develop outside the human body.[106]The 14-day limit shows that as the embryo develops it is deserving of more

[103] Baylis, above n 65, at 325.
[104] Mark Henaghan and Sheila McLean "Main Findings" in *Choosing genes for future children: regulating preimplantation genetic diagnosis/ Human Genome Research Project* (Human Genome Research Project, Dunedin, 2006) 1 at 8.
[105] Crimes Act 1961, s 187A(3).
[106] HART Act, s 9.

protection. The reasoning behind the limit is based on the formation of the primitive streak which occurs around day 14.[107] This moment in development signifies when the embryo is an individual as it can no longer split in two.[108]

2. The Origins Of The 14-Day Limit

The Warnock Committee first introduced the concept of the 14-day limit on human embryos being allowed to develop outside the body.[109] The Warnock Committee was established in the UK in 1982 for the purposes of considering developments in human fertilisation and embryology, and to recommend what polices and safeguards should be put in place.[110] The Warnock Committee were faced with conflicting submissions from the public. Some saw the embryo as "a person from fertilisation/conception".[111] Others were "supportive of embryo research due to the potential to help infertility/prevent hereditary disease" with many others expressing views in between.[112] The committee noted that:[113]

> the more generally held positon, however, is that the human embryo is entitled to some added measure of respect beyond that accorded to other animal subjects, that respect cannot be absolute, and may be weighed against benefits arising from research.

In its recommendations, the Warnock Committee took a gradualist approach towards the human embryo. Their recommendations specified that the embryo had a protected status but that this could be overridden in certain circumstances. However, only up to 14-days after creation.[114] Thereby, the embryo would become more protected as it develops. The gradualist approach towards the embryo "can be viewed as a 'compromise'" between the desire for embryo research to occur and the fact that some limits are required.[115] This compromise resulted in the 14-day limit being imposed, which worked to "allay public anxiety" over embryo research becoming out of hand.[116]

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[107] Natasha Hammond-Browning "Ethics, Embryos, And Evidence: A look Back at Warnock*"* (2015) 23 Med. L. Rev. 588 at 604.

[108] Hammond-Browning, above n 102 at 604.

[109] Giulia Cavaliere "A 14-day limit for bioethics: the debate over human embryo research" (2017) 18 BMC Med Ethics at 3.

[110] Hammond-Browning, above n 107, at 590

[111] Hammond-Browning, above n 107, at 593.

[112] Hammond-Browning, above n 107, at 593.

[113] Department of Health and Social Security "Report of the Committee of Inquiry into Human Fertilisation and Embryology (cm 9314, 1984) (the Warnock Report) at [11.15] as in Hammond-Browning, above n 100, at 603.

[114] Hammond-Browning, above n 107, at 605.

[115] Hammond-Browning, above n 107, at 605.

[116] Hammond-Browning, above n 107, at 606.

3. The Viability Distinction Is Not Consistent With The Gradualist Approach

Baylis claimed that the viable/non-viable distinction recognizes that the value of the embryo is equal at every developmental stage.[117] This means that "the focus is not on some particular developmental feature of the human embryo, but rather on the embryos potential for development *tout court"*.[118]

However, limiting embryo research based on viability, as seen in NECAHR guidelines, is not commensurate with the gradualist approach. This approach has been adopted in NZ as the HART Act provides for the 14-day limit. The gradualist approach holds that as the embryo develops, it protected status increases. Whereas, the viability distinction holds that 'viable' embryos should never be used in research as their protected status is absolute from creation.

4. The 14-Day Limit Is Redundant

It is unusual that NZ has imposed both a viability limit on research in the NECAHR guidelines and has also statutorily imposed a 14-day limit to the embryo being permitted to develop outside the body. It begs the question of what the 14-day limit is actually protecting if research using viable embryos is not permitted. Furthermore, the fact that research is not permitted using viable human embryos flouts the very reason that the Warnock Committee first introduced the idea of the 14-day limit, which was to allow beneficial research to occur in specified circumstances, while protecting the embryo in law.[119]

5. The Gradualist Approach: Conclusion

The fact that the NECAHR guidelines are inconsistent with the gradualist approach in NZ suggests that they cannot be justified under a principle-based approach. The gradualist approach is something that has been clearly accepted in NZ. Therefore, the NECAHR guidelines which do not follow this gradualist approach are arguably illegitimate. This is because they do not align with how the embryo is treated in other areas of reproductive medicine.

G. The Distinction Does Not Align With How ART's Are Carried Out

It is arguable that distinguishing between 'viable' and 'non-viable' embryos for their use in research does not align with how IVF is carried out in NZ in general.

In the course of IVF, multiple eggs are retrieved and fertilized with sperm to form embryos.[120] One or two embryos are transferred with the hope that at least one will

[117] Baylis, above n 65, at 311.

[118] Baylis, above n 65, at 313.

[119] Hammond-Browning, above n 107 at 605.

[120] Fertility Associates, above n 101 at 65.

implant.[121] In most cases not all embryos will be transferred and the rest will be frozen.[122] In many cases the progenitors do not want to donate their embryos for reproductive purposes.[123] Therefore, surplus embryos are usually destroyed.[124]

As stated, the only justifiable reason for limiting embryo research to 'non-viable' embryos is because the destruction of human life is harmful. However, if this view is taken to its logical endpoint, no embryo with any intrinsic developmental potential should be destroyed under any circumstance. Therefore, the destruction of surplus embryos in IVF cannot be ethically consistent with the NECAHR guidelines limiting embryo research to non-viable embryos. Jones notes that no case has been made for prohibiting the destruction of viable embryos in research yet allowing their destruction routinely in IVF.[125] For IVF to be ethically consistent with the NECAHR guidelines embryos would need to be created and implanted as required so that surplus embryos were not produced. Creating embryos as required would add to the costs associated with IVF. If eggs had to be obtained multiple times to create embryos as required this would be harmful to the person undergoing IVF. To obtain eggs ovarian stimulation drugs are required, which can have significant effects on people.[126] It is clear that the viability distinction is not ethically consistent with how IVF is carried out in NZ. Therefore, if IVF is to continue to be carried out in its current fashion, the current policy contained in the NECAHR guidelines cannot be justified.

H. Embryos Going To Waste

Jones describes the destruction of surplus IVF embryos as "an unavoidable situation of loss, including potential benefits for human health from research on early embryological development".[127] Surplus embryos that are not going to be used for reproductive purposes will never have the ability to develop into a human. These embryos eventually must be destroyed. The progenitors have gone through considerable effort and possibly expense to form these surplus embryos. Therefore, even if some see the destruction of a viable embryo as causing a harm, it is arguable that an even greater harm is caused by requiring surplus embryos to be destroyed without anything being learnt from them. For this reason, it is arguable that the NECAHR guidelines cannot be justified.

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[121] Fertility Associates, above n 101 at 65.

[122] Fertility Associates, above n 101 at 71.

[123] Sheryl de Lacey "Death in the clinic: women's perceptions and experiences of discarding supernumerary IVF embryos" (2017) 49 Sociol Health Illn 397 at 398.

[124] Surplus embryos are usually destroyed as they can only be stored for up to 10 years: HART Act, s 10

[125] Gareth Jones "Where does New Zealand stand on permitting research on human embryos? (2014) 127 NZMJ 74, at 75.

[126] Fertility Associates "IVF problems, risks and solutions" <www.fertilityassociates.co.nz>.

[127] Jones, above n 125, at 79.

I. Viability Is Ever Changing

As technology advances it is possible that even if it could be determined whether or not an embryo had hope of development, the viability distinction cannot be justified. Despite being in the experimental phase, scientists have used CRISPR/CAS9 to edit the genomes of embryos in an attempt to correct genetic disorders.[128] As more is discovered about genetic editing, the possibility of editing embryos deemed to be non-viable to become mutation free and therefore viable, may become reality. If this sort of development occurs, the distinction between 'viable' and 'non-viable' embryos becomes murkier. It is arguable that the NECAHR guidelines, in limiting research to non-viable embryos are inappropriate in light of today's rapidly developing scientific climate.

J. Non-Viable Embryos And Their Usefulness In Research

It is arguable that non-viable embryos are not particularly useful for research. ACART defines 'non-viable' as embryos with no ability to develop.[129] It is foreseeable that only being able to use embryos which do not have the potential to develop would severely limit research aimed at studying embryo development. Moreover, there may be difficulties in generalising knowledge obtained from non-viable embryos and applying it to improve outcomes for viable embryos. Being able to study embryo development may provide knowledge about congenital diseases and the causes of miscarriage.[130] Therefore, research in this area could improve the outcomes for those undergoing ARTs and for the children born from ARTs. Studies have shown human embryonic stem cells (HSECs) can be obtained from non-viable embryos.[131] However, this is only a subset of embryo research. A valid purpose of research is improving success rates of ARTs. Therefore, the NECAHR guidelines are severely limiting what kind of embryo research can be done.

K. A Duty To Improve Fertility Treatment?

Studies have been conducted which show that the rate of birth defects in children born from IVF procedures is higher than children conceived naturally.[132] While the IVF process itself

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[128] See Lichun Tang and others "CRISPR/Cas9-mediated gene editing in human zygotes using Cas9 protein" (2017) 292 MGG 525.

[129] ACART "Discussion Paper",, above n 78, at [125].

[130] Thomas Douglas and Julian Savulescu "Destroying unwanted embryos in research. Talking Point on morality and human embryo research" (2009) 10 EMBO Rep 307 at 307.

[131] Svetlana Gavrilov "Non-viable human embryos as a source of viable cells for embryonic stem cell derivation" (2009) 18 Reprod Biomed Online 301 at 301.

[132] Sheree L. Boulet and others "Assisted Reproductive Technology and Birth Defects Among Liveborn Infants in Florida, Massachusetts, and Michigan, 2000-2010" (2016) 170 JAMA Pediatr 1 at 1.

may not be the cause of these defects, other confounding factors which may have caused the infertility.[133] It is a risk that research could serve to minimise. Only 18.1% of ARTs in NZ and Australia result in live births.[134] Embryo research could work to improve this statistic. Research into embryo development and the causes of miscarriages could help improve the efficacy and safety of IVF procedures. This may, in turn, increase the rates of successful pregnancy through ARTs.

The NECAHR guidelines, by limiting embryo research to using non-viable embryos, mean that practitioners are unable to conduct studies to improve IVF. This is inconsistent with the fact that the government promotes and funds IVF for couples and individuals who may struggle to conceive naturally.[135] Jones expressed the view that a country which promotes this kind of treatment also has a duty to promote research into it in order to "increase the efficacy and the safety of the procedures being used".[136] Jones suggests that there may be a "moral imperative to protect children and families who use IVF".[137] He reiterates that "we have a duty to minimise the health risks to which we expose future children".[138] This is consistent with the first principle of the HART Act which is that the health and well-being of children born as a result of ARTs should be an important consideration.[139] This means research into IVF to improve its efficacy and to minimise its potentially harmful effects to children born from IVF should be a priority. The lack of research using viable embryos in NZ fails to protect the rights of children born from ARTs and couples who use ARTs.[140] Therefore, it is arguable that the NECAHR guidelines are inconsistent with the strong moral imperative to improve ARTs through research.

L. Professional Duty

Health care policy in NZ is aimed at ensuring practitioners are offering the best treatment available to patients, and that procedures are conducted in the safest way possible. It could be contended that there is a professional duty on practitioners to keep up to date with the latest procedures and to improve procedures already offered. By restricting embryo research to non-viable embryos achieving this outcome is severely limited.

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[133] Sheree L. Boulet and others, above n 132, at 1.

[134] Goodman and Others, above n 63, at 63.

[135] If an individual or couple meets the eligibility criteria they may receive publically funded fertility treatment: Fertility Associates "Public funding and eligibility" < www.fertilityassociates.co.nz>.

[136] Jones, above n 125, at 75.

[137] Jones, above 125, at 80.

[138] Ronald Green *The Human Embryo Research Debates: Bioethics in the Vortex of Controversy* (Oxford University Press, 2001) at 152 cited in Jones, above n 125, at 80.

[139] HART Act, s 4.

[140] Goodman and Others, above n 63, at 67.

The Health Quality and Safety Commission of NZ states that the definition of clinical governance in Australia has been adopted in NZ, which is:[141]

> the system by which the governing body, managers, clinicians and staff share responsibility and accountability for the quality of care, continuously improving, minimising risks, and fostering an environment of excellence in the care for consumers/patients/residents.

From this definition it is clear that in order to practice good clinical governance in the context of ARTs, practitioners offering ARTs need to continuously improve the procedures offered and minimise the risks to children born from ARTs and individuals undergoing treatment. Research using viable embryos would be required to do this.

In 2003 the Ministry of Health released a publication aimed at improving quality.[142] Safety was deemed to be one of the key dimensions of quality.[143] The Ministry stated that "safety is the extent to which harm is kept to a minimum".[144] Efficiency is also an aspect of quality, described as: "the extent to which a service gives the greatest possible benefit for resources used".[145] Therefore, in order to promote safety and efficiency by minimising harm and maximising benefits from ARTs, research using viable embryos is required.

Section 80 of the HART Act states that fertility services are included in the definition of 'specified health or disability services' under the Health and Disability Services (safety) Act 2001 (the HDS(S) Act).[146] Among the purposes of the HDS(S) Act is to 'promote the safe provision of health and disability services to the public' and to 'encourage providers of health and disability services to the public to continuously improve the quality of those services'.[147] Therefore, in order for fertility services to meet the purposes of the HDS(S) Act, ARTs need to be continuously improved. Research allowing the improvement of ARTs would be in line with the purposes of the HDS(S) Act. It is clear that it is part of NZ health policy to continually improve services so that practitioners are offering the best possible service to patients. Therefore, it is arguable that the NECAHR guidelines establish inappropriate barriers to quality improvement.

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[141] Health Quality & Safety Commission "Clinical Governance – guidance for health and disability providers" (22 March 2017) at 6.

[142] Minister of Health "Improving Quality (IQ): A Systems Approach for the NZ Health and Disability Sector" (September 2003, Ministry of Health, Wellington) at 10.

[143] Minister of Health, above n 142 at vii.

[144] Minister of Health, above n 142 at 10.

[145] Minister of Health, above n 142 at vii,10.

[146] HART Act, s 80.

[147] Health and Disability Services (safety) Act 2001, s 3.

M. NZ Health Research and Development Is Falling Behind Other Countries

Due to the NECAHR guidelines, research using surplus embryos cannot occur, yet this is permitted in other secular liberal democracies.[148] ACART notes that Australia and the UK "are the most similar to NZ with respect to the principles on which assisted reproductive technology legislation is based".[149] The fact that NZ is likely no more religious than either Australia or the UK makes it all the more perplexing that NZ does not yet allow this research to occur. These limits may be more acceptable if we had robust and clearly stated reasons for limiting embryo research to non-viable embryos. However, there does not appear to be any justification for the limits being imposed. The fact that the NECAHR guidelines have not been updated means "NZ is missing out on opportunities in reproductive science and medicine".[150] The guidelines are restrictive, meaning research into improving fertility treatments, allowing for the development of stem cell technology, and genetic editing of embryos to repair disease causing genes cannot occur.[151] This type of research can only occur in countries like the UK and Australia where research using surplus embryos is permitted.[152] The NECAHR guidelines prohibit the use of viable human embryos in research. This means NZ is dependent on overseas research to ensure that the ARTs offered are up to date.[153] While NZ does see benefits from overseas research "current polices on embryo research pass the burden to researchers overseas by preventing scientists in NZ from contributing to our future healthcare".[154] Significantly ACART expressed the view that being able to conduct this sort of embryo research in NZ would be of a "reputational" and "economic benefit".[155]

Jones highlights that there is an ethical inconsistency in permitting IVF in NZ yet prohibiting embryo research using viable embryos. By permitting IVF, embryo research occurring overseas is accepted.[156] Jones notes "doing research on human embryos is required to support IVF". Moreover, embryo research underpins IVF, as research was required in order for the procedure to be developed.[157] This means in NZ, by allowing for IVF we are accepting the benefits of embryo research from overseas, thereby condoning research conducted on overseas embryos but not NZ embryos.

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[148] In Australia excess embryos can be used in research: Research Involving Human Embryos Act 2002 (Australia), s 20; In the UK embryos can be used in research: Human Fertilisationa and Embryology Authority, Sch 2, cl 3.

[149] ACART Associated Paper 6, above n 76, at [6].

[150] Goodman and Others, above n 63, at 68.

[151] Goodman and Others, above n 63, at 68.

[152] Goodman and Others, above n 63, at 68.

[153] Jones, above n 125, at 80.

[154] Goodman and Others, above n 63, at 68.

[155] ACART Associated Paper 6, above n 76, at [18].

[156] Jones, above n 125, at 78.

[157] Jones, above n 125, at 78.

In order for the practice of IVF to be ethically justified, embryo research using viable embryos should be permitted in NZ. Moreover, in order for NZ practitioners to contribute to the improvement of ARTs, both on a national and world-wide level, being on an even playing field with other secular countries is important. Therefore, the NECAHR guidelines need to be updated to allow for research using viable embryos.

N. Effects On Practitioners

The legitimacy of the current framework in which research can be conducted has been challenged by those who work in fertility services. Jones articulated that limiting embryo research to non-viable embryos "precludes practitioners in this country from improving the safety and protocols of their practice, with its input into the health of resulting children".[158]

1. Perceived Barriers

In a recently study, *The futility of fertility research? Barriers to embryo research in New Zealand,* 20 researchers were interviewed, and some identified that they are currently faced with barriers to embryo research.[159] Fifteen respondents of the survey identified barriers to embryo research that they or their institution had experienced.[160] Nine of those surveyed perceived that the HART Act was part of the barrier to research.[161] Six perceived that it was the lack of suitable guidelines surrounding the use of human embryos in research that were creating a barrier.[162] It is clear that the current guidelines and legislative framework are limiting practitioners from conducting embryo research.

2. Limiting Research Which Can Be Undertaken

The study identified that over half of the respondents had potential research projects that the they would undertake in the future, but that they could not do under the NECAHR guidelines.[163] Five respondents described their potential projects in more detail, stating they "would use surplus embryos *in vitro* to improve fertility success rates and/or increase understanding of embryo biology".[164] The study stated that "strong support for improved guidelines was apparent".[165] It was concluded that the results of the study indicate that "researchers are not committing themselves to research projects using human embryos, since

[158] Jones, above n 102, at 80.
[159] Goodman and Others, above n 63.
[160] Goodman and Others, above n 63 at 65.
[161] Goodman and Others, above n 63 at 65.
[162] Goodman and Others, above n 63 at 65.
[163] Goodman and Others, above n 63 at 67.
[164] Goodman and Others, above n 63 at 67.
[165] Goodman and Others, above n 63 at 67.

they are aware that they will not be able to undertake them in NZ's present legislative climate".[166] This study provides empirical evidence that practitioners are being limited by the current guidelines, therefore restricting their contribution to health care.

3. Wide Reaching Limits

The limitations caused by the NECAHR guidelines are wide reaching. An example of these wide reaching limits is encapsulated by Cindy Farquhar's rejected application for the 'Day of Transfer Study' (the DOT study).[167] In this study it was proposed that day 3 transfer (of a fertilized embryo) would be compared with day 5 transfer.[168] The transfer of embryos created by IVF is an established procedure.[169] Moreover, the transfer of embryos usually occurs on either day 3 of 5.[170] Therefore, the transfer of embryos on day 3 or 5 would not require approval from ECART.[171] However, the fact that the days of transfer were being compared meant that they were being 'used'. Therefore, the study came into the definition of human reproductive research.[172] Because the embryos were being 'used' in research, approval from ECART was required.[173] ECART was unable to approve the application because the embryos being used were viable.[174] Research that involved an established procedure and did not involve the destruction of embryos was prevented. This shows that the NECAHR guidelines in limiting research to non-viable embryos has far reaching effects. This means that rather than conducting studies on IVF and gathering evidence to see which day is best to transfer embryos, possibly increasing the success rates of IVF, practitioners are required to take an educated guess as to when embryo transfer should occur.

O. Limiting The Progenitors Wishes

Studies from overseas have concluded that donation of surplus embryos to other couples or individuals for reproductive purposes is not a popular option.[175] Sheryl de Lacey's numerous studies on this topic provide strong empirical evidence that couples would prefer to donate

[166] Goodman and Others, above n 63 at 68.
[167] Goodman and Others, above n 63 at 64.
[168] Goodman and Others, above n 63 at 64.
[169] HART Order 2005, cl 5.
[170] Fertility Associates, above n 101, at 65.
[171] HART Order 2005, cl 4.
[172] Crown Law Legal Opinion "Research covered by Human Assisted Reproductive Technology Act" (18 February 2014) (Obtained under Official Information Act 1982 Request to the Ministry of Health), at [4.9].
[173] Crown Law Legal Opinion, above n 162, at [4.9].
[174] ECART can only approve applications which are consistent with guidelines - HART Act, ss 19,29.
[175] Sheryl de Lacey "Parent identity and 'virtual' children: why patients discard rather than donate unused embryos" (2005) 20 Human Reproduction 1661 at 1661.

their embryos to research or have their embryos discarded, rather than donate them to another couple for reproductive purposes.[176]

De Lacey notes that after the emotional, financial and physical investment that the progenitors have put into their embryos, they often feel that the effort and commitment should not go to waste.[177] In 2003 an Australian study stated that 89.5% of patients chose to discard their surplus embryos rather than donate them for reproductive purposes. However, a 2013 Swedish study indicated that there was a shift towards donating surplus embryos to research.[178] Moreover, In 2007, In Denmark 60% of couples whose embryos had been destroyed "were receptive to the concept of donating embryos for research, while only 29% would consider donation to another couple".[179] In Australia 10% of couples with embryos frozen for more than 2 years indicated a probability of donating their embryos to research, and 34% of couples believed it was possible.[180] This data suggests that internationally, progenitors would be willing to donate their surplus embryos to research.

De Lacey found that while the majority of Australians surveyed saw the embryo as human or potentially human, it did not affect the majority view that embryos should be used for research purposes rather than discarded.[181] 75.5% of Australians thought spare embryos should be used rather than discarded.[182] Half thought they should be used in research.[183] Half of this group thought the research should focus on infertility.[184] The other half thought the surplus embryos should be used for human embryonic stem cell (HSEC) research.[185] Additionally, the majority of Australians surveyed thought the decision about the fate of

[176] De Lacey "Parent identity and 'virtual' children: why patients discard rather than donate unused embryos", above n 175, at 1661.
[177] De Lacey "Parent identity and 'virtual' children: why patients discard rather than donate unused embryos", above n 175, at 1664.
[178] De Lacey "Death in the clinic: women's perceptions and experiences of discarding supernumerary IVF embryos", above n 123, at 398.
[179] Sheryl de Lacey "Patients' attitudes to their embryos and their destiny: social conditioning?" (2007) 21 Best Pract Res Clin Obstet Gynaecol 101 at 105.
[180] De Lacey "Patients' attitudes to their embryos and their destiny: social conditioning?", above n 179 at 105.
[181] De Lacey and others "Perceptions of embryo status and embryo use in an Australian community" (2012) 24 Reprod Biomed Online 727 at 727.
[182] De Lacey and others "Perceptions of embryo status and embryo use in an Australian community", above n 181, at 732.
[183] De Lacey and others "Perceptions of embryo status and embryo use in an Australian community", above n 181, at 732.
[184] De Lacey and others "Perceptions of embryo status and embryo use in an Australian community", above n 181, at 732.
[185] De Lacey and others "Perceptions of embryo status and embryo use in an Australian community", above n 181, at 732.

spare embryos should be left to the progenitors.[186] This is compelling empirical evidence that not only are the progenitors supportive of embryo research, but that many Australians support embryo research in some shape or form. Studies of this kind have not been conducted in NZ. However, it is quite possible that the progenitors of embryos in NZ would have similar feelings.

Jones and Whitaker in the *Ethical Framework for ACART* stated that autonomy is an additional ethical principle to be considered in addition to those stipulated in s 4 of the HART Act.[187] Jones and Whitaker state: "to respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others".[188] To reflect this ethical principle, progenitors should have the choice to donate their embryos to research. This is an option which is clearly not detrimental to others, even if some of the community may be offended by it as it is only the progenitors who have the right to use the embryos.[189] The progenitors have a real interest in the embryo; they have put in time, finances, and physical effort into producing the embryo. Therefore, it is arguable that in order to give effect to the progenitor's autonomy they should be able to choose what to do with their embryos.

P. Property Rights And The Embryo

If a property interest can be found in embryos, it is arguable that this provides an additional reason for the progenitors having more control over what happens to their embryo when it is no longer needed for reproductive purposes. In *Yearworth v North Bristol NHS Trust* it was found that men had property rights in their stored sperm.[190] If property rights can be found in gamete it is possible this could extend to embryos being considered as property.

Moreover, how embryos are treated at law would indicate that they have qualities which could mean that an embryo could be considered the progenitors property. It has been noted that property law "concerns itself, not with things *per se*, but with various *rights* to operate in respect of things".[191] A critical feature of property rights is that they entitle the owner to

[186] De Lacey and others "Perceptions of embryo status and embryo use in an Australian community", above n 181, at 732.

[187] Gareth Jones and Maja Whitaker "Ethical Framework for ACART" (17 November 2008) <www.ACART.health.govt.nz> at 4.

[188] Jones and Whitaker "Ethical framework for ACART", above n 187, at 11.

[189] Informed consent is required before anything can be done using the embryos.

[190] *Yearworth and others v North Bristol NHS Trust* [2009] EWCA Civ 37.

[191] Lance Green "Does The Definition Of "Property" In The Crimes Act 1961 Include Electronically Stored Data? The Computer Says "No"" (LLB (Hons) Dissertation, University of Otago, 2015) at 10.

exclude third parties from interfering with that right.[192] The fourth principle of the HART Act requires that no assisted reproductive procedure or human reproductive research occur without informed consent.[193] Peart notes:[194]

> Consent must therefore be obtained for the collection of gametes, their cryopreservation and storage, their treatment or modification, their fertilisation, implantation, or use in treatment or research….

Another feature of property rights is the ability to transfer them.[195] The progenitors have the power to give informed consent to have their embryo donated to another couple or individual. If the embryo is non-viable, progenitors have the right to donate it to research.[196] Moreover, it is the progenitors that have the exclusive ability to apply to ECART for an extension to store the embryos.[197] Therefore, only the progenitors have the right to use the embryos and they must give informed consent before any such use. The progenitors can exclude others from using their embryos and can transfer the right to use the embryos to another couple or individual. These factors would tend to indicate that the embryo is the property of the progenitors.

The HART Act places a limit on the progenitor's ability to control their embryo as they can only be stored for a maximum of 10 years.[198] However, as it was noted in *Yearworth*:[199]

> there are numerous statutes which limit a person's ability to use his property – for example a land owner's ability to build on his land…or a pharmacist's ability to sell his medicines – without eliminating his ownership of it.

Therefore, despite limits being imposed on what one can do with one's property it does not diminish property interests or claimed rights.

If the progenitors can have property right in their embryos, being able to control what is done to their embryos (when they are no longer required for their own reproductive purposes) would be commensurate with the purpose of the HART Act. The HART Act aims to protect and promote the rights of all individuals. Moreover, an embryo is not an individual, whereas

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[192] Sarah Worthington *Equity and Property: Fact, Fantasy and Morals* (University of Queensland Press, Queensland, 2009) at 35 cited in Lance Green, above n 193 at 11.
[193] HART Act, s 4(d).
[194] Nicola Peart, above n 25, at 543.
[195] Lance Green, above n 191, at 12.
[196] Nicola Peart, above n 25, at 543.
[197] HART Act, s 10A.
[198] HART Act, s 10.
[199] *Yearworth*, above n 190, at 45(f)(ii).

the progenitor's rights are protected and promoted by the Act. Therefore, it is arguable that in limiting embryo research to non-viable embryos the NECAHR guidelines are not justifiable as they unnecessarily impinge on the progenitor's claimed rights.

Q. Moral Responsibility

Even if property rights are not found in the embryo the progenitors have causal and moral responsibility for the embryo's existence. Therefore, they arguably have a moral responsibility to determine how the embryo is disposed of. Progenitors have gone through risk and potentially expense to create their embryos so have a legitimate interest in their disposition. There are strong reasons for their views holding more weight than just any person who submits to the law-making process.

Moreover, de Lacey has demonstrated that many progenitors have feelings of parentage towards the embryo.[200] Feelings of parentage towards the embryo influenced the progenitor's decisions. Many felt that donating embryos to another couple was "relinquishment of a child".[201] This meant couples opted to discard their embryos. Feelings of parentage towards embryos may provide moral reasons for why progenitors should be able to choose to donate their embryos to research. If the progenitors already feel they are causally responsible for bringing about the embryo they are morally responsible for how it is treated. In some senses this is akin to ordinary parental responsibility. There is evidence that choosing what to do with spare embryos is distressing and challenging for some individuals.[202] Having feelings of responsibility towards the embryo(s) may make it more difficult. It may even harm the mental health of the progenitors if there are barriers to their preferred disposition choice. One of the purposes of the Act is the "protection and promotion of the health, safety, dignity, and rights of all individuals, but particularly those of women and children, in the use of these procedures and research".[203] Therefore, by giving progenitors the additional option of donating embryos to research, something that would cause no harm to others, it is arguably promoting their heath, but also their moral obligations that may exist towards the embryo.

For these reasons it is arguable that even if there are no property rights found in embryos, there is a moral duty for progenitors to have the ability to decide whether they will donate their embryos to research. The option to donate embryos to research is available in other

[200] De Lacey "Parent identity and 'virtual' children: why patients discard rather than donate unused embryos", above n 175, at 1667.
[201] De Lacey "Parent identity and 'virtual' children: why patients discard rather than donate unused embryos", above n 175, at 1667.
[202] De Lacey "Parent identity and 'virtual' children: why patients discard rather than donate unused embryos", above n 175, at 1664.
[203] HART Act, s 3

countries such as the UK and Australia. There is no evidence to suggest that this has had adverse effects on other areas of law. By allowing the option of donating viable embryos to research it would offer couples another option; it would not force couples to donate their embryos to research, nor would it inhibit couples from donating their embryos to others for reproductive purposes. These are all strong reasons supporting the fact that the NECAHR guidelines are illegitimate. The NECAHR guidelines limit the progenitor's choice, when having the choice to donate their viable embryos to research would cause no harm and may likely be beneficial.

IV. Is The 2007 Advice Commensurate With The Principles Of The HART Act?

In ACART's work programme it identified that s 37 of the HART Act meant that ACART was required to provide the Minister with information, advice, and, if it thought fit, recommendations about the use of embryos in human reproductive research.[204] ACART noted that the interim guidelines (the NECAHR guidelines) would expire in November 2007 so would have to have advised the Minister on human reproductive research by this time.[205] In 2005 and 2006 ACART prepared a discussion paper titled *Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New Zealand*.[206] After receiving submissions from the public following ACART's 2006 discussion paper, ACART drafted advice to be issued that was formally issued to the Minister in 2007.[207] In this advice ACART stated that they considered:[208]

> the strength of public submissions but also the strength of the arguments made…potential scientific and medical benefits, international literature on the ethics of embryo research, NZ policy and practice in related areas, and policy and practice in other jurisdictions. Finally, in forming its advice ACART has been guided by the principles of the HART Act.

The HART Act requires that all persons exercising powers or performing functions under the Act should be guided by the principles of the Act. It is one of ACART's functions to issue advice to the Minister.[209] Therefore, when ACART was issuing advice to the Minister they should have acted in accordance with the principles of the HART Act.[210] The rest of this chapter will consider whether ACART's advice to the Minister was commensurate with the principles of the HART Act.

A. Health and Well-Being Of Children

The first principle of the HART Act states:[211]

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[204] ACART "Annual Report 2005–2006" (January 2007, Wellington, Advisory Committee on Assisted Reproductive Technology), at 4.

[205] ACART Annual Report 2005–2006, above n 204, at 4.

[206] ACART Annual Report 2005–2006, above n 204, at 5.

[207] ACART "Specific Advice to the Minister of Health in Respect of Human Reproductive Research" ("the 2007 advice") (29 June 2007) (Obtained under Official Information Act 1982 Request to the Ministry of Health)

[208] ACART "the 2007 advice", above n 207, at 3.

[209] HART Act, s 35.

[210] HART Act, s 4.

[211] HART Act, s 4(a).

> the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure.

It should be noted that the health and well-being of the child is not a 'paramount' consideration.[212] This can be contrasted with the Care of Children Act 2004.[213] Children born from ARTs are at an increased risk of being born with foetal abnormalities or health problems compared to children conceived naturally.[214] To allow ARTs to occur despite risks, the paramountcy of this principle was removed.[215] Otherwise, even if there were small risks, ARTs may not be approved despite all the benefits which may come of them.[216]

1. Research Using Viable Surplus Embryos

The 2007 advice recommended that research using surplus IVF embryos should be permitted.[217] There is "growing evidence that fertility treatment may have subtle effects on offspring phenotype".[218] For example, whether the embryo was transferred fresh or thawed has been correlated with birth weight.[219] Additionally, the risk of imprinting disorders and birth defects are higher in children born through IVF than children conceived naturally.[220] While the number of children who may be affected by a disorder may be small, their health and well-being should be an important consideration as per the first principle of the Act. Embryo research in this area could work to reduce the number of children who are affected by disorders associated with IVF. Therefore, in recommending that surplus embryos be used for research ACART was acting in accordance with the first principle of the Act.

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[212] Snelling, "Law and Regulation", above n 9, at 246.

[213] Care of Children Act 2004, s 4 As In Casandra May Kenworthy "Three's a Crowd? The Legal and Ethical Considerations of Mitochondrial Replacement Therapy" (LB (Hons) Dissertation, University of Otago, 2014)

[214] Peart, above n 25, at 521.

[215] Snelling "Law and Regulation", above n 9, at 246.

[216] Snelling "Law and Regulation", above n 9, at 246.

[217] ACART "the 2007 advice", above n 206, at 5.

[218] M.P. Green and others "The phenotype of an IVF child is associated with peri-conception measures of follicular characteristics and embryo quality" (2014) 29 Human Reproduction 2583 at 2584.

[219] M.P. Green and others, above n 218, at 2584.

[220] M.P. Green and others, above n 218, at 2584.

B. Human health, safety, and dignity of present and future generations should be preserved and promoted

1. Research Using Surplus Embryos

The second principle of the HART Act states that "the human health, safety, and dignity of present and future generations should be preserved and promoted".[221] This principle takes into account the lives of future and present children.[222] Research involving surplus embryos which may improve the health, safety and dignity of future and current generations would be consistent with this principle, particularly in the area of HSEC research. HSECs can be derived from the inner cell mass of an embryo and can be obtained from surplus IVF embryos.[223] HSECs are particularly useful as they are pluripotent, meaning they can differentiate into any cell type.[224] The applications HSECs are vast and if more research is done they may be able to have important therapeutic effects for the ill or injured. HSECs can be used to treat cancers, heal damaged tissues or organs, and they may even be used to repair spinal cord injuries.[225] If more research is done, scientists may be able to use HSECs to grow whole organs or tissues in the laboratory. [226] HSECs can also be used so that researchers can learn about cell growth, migration and differentiation. Understanding these processes may help researchers to better understand human development. This could mean that birth defects and the cause of miscarriage may be better understood.[227] It is clear that there is a wide range of potential benefits which could come from using HSECs. Therefore, using surplus embryos as recommended by ACART would be commensurate with the second principle of the HART Act.

2. Creating Embryos By SCNT For Research

In its 2007 advice ACART recommended a moratorium be placed on the creation of embryos thorough somatic cell nuclear transfer (SCNT) for their use in research. [228] A moratorium is able to be imposed by an Order in Council for a maximum of 18 months, allowing time for the development of advice and or guidelines.[229] This can be extended for one further 18-

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[221] HART Act, s 4(b)

[222] Jones and Whitaker "Ethical framework for ACART", above n 187, at 6.

[223] ACART ""Discussion Paper", above n 78 at [42]

[224] Katrien Devolder "Introduction" in *The Ethics of Embryonic Stem Cell Research.'* (Oxford University Press, Oxford, 2015) at 10

[225] Devolder "Introduction", above n 224, at 6.

[226] Devolder "Introduction", above n 224, at 7.

[227] Devolder "Introduction", above n 224, at 8.

[228] ACART, "the 2007 advice", above n 207, at 5.

[229] HART Act, s 24.

month period.[230] SCNT involves the transfer of DNA from the nucleus of a somatic cell, to a de-nucleated egg .[231] The egg is then stimulated with an electric current which causes cell division, forming an embryo.[232] The embryo is a clone of the donor of the somatic cell DNA.[233] HSECs may then be derived from the inner cell mass of this embryo. It is possible this was imposed due to the controversy surrounding cloned embryos. ACART did not provide reasons for imposing the moratorium. Moreover, creating embryos for research purposes is a controversial subject and will be addressed later in this chapter.

The main benefit of obtaining HSECs from SCNT embryos is that they are genetically identical to the donor/patient.[234] Therefore, HSECs would better match the patient's immune system.[235] Often in transplant medicine immunosuppressive drugs are required to avoid rejection of the transplanted material.[236] This can have negative or even life threatening side effects for patients.[237] HSECs from SCNT created embryos would reduce the need for using immunosuppressant's.[238] In order for this sort of treatment to become reality more research is required.[239] Creating embryos by SCNT and obtaining HSECs would mean that HSECs could be generated from patients with rare genetic diseases or patients with common diseases that are complex.[240] These HSEC lines could be used to study pre-symptomatic phases of the disease, genetic predispositions, and other contributing factors such as environmental, epigenetic and genetic factors.[241] They could also be used for testing potential drug therapies, meaning drug toxicity could be tested using HSECs rather than people.[242] It is clear that research into this area could have positive effects for patients suffering from diseases today and in the future. Therefore, there is compelling evidence that allowing for research to occur on embryos created by SCNT would be in line with the second principle of the HART Act.

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[230] HART Act, s 24.

[231] Katrien Devolder "The Discarded–Created Distinction" in *The Ethics of Embryonic Stem Cell Research* (Oxford University Press, Oxford, 2015) at 4.

[232] Devolder "The Discarded–Created Distinction", above n 231, at 4.

[233] Devolder "The Discarded–Created Distinction", above n 231, at 4.

[234] Devolder "The Discarded–Created Distinction", above n 231, at 4.

[235] Devolder "The Discarded–Created Distinction", above n 231, at 4.

[236] Devolder "The Discarded–Created Distinction", above n 231, at 4-5.

[237] Devolder "The Discarded–Created Distinction", above n 231, at 5.

[238] Devolder "The Discarded–Created Distinction", above n 231, at 5.

[239] Devolder "The Discarded–Created Distinction", above n 231, at 5.

[240] Kristina Hug "Sources of human embryos for stem cell research: ethical problems and their possible solutions" (2005) 41 Medicina 1002 at 1005.

[241] Devolder "The Discarded–Created Distinction", above n 231, at 5.

[242] Devolder "The Discarded–Created Distinction", above n 231, at 5.

I Induced Pluripotent Stem Cells

Some claim that obtaining HSECs from embryos created through SCNT is unnecessary due to the discovery of induced pluripotent stem cells (iPSCs).[243] In 2007 adult fibroblasts (skin cells) were reprogrammed to an "embryonic stem cell-like state…without using cloning".[244] This was done by inserting four transcription factors into the genome of the skin cells, this caused the resulting cells to show characteristics of HSECs.[245] Like HSECs obtained from SCNT, iPSCs are genetically identical to the patient.[246] iPSCs were hailed as a solution to the ethical problems caused by SCNT as no embryos are created or destroyed and no oocytes are required.[247]

However, Devolder cogently argues iPSCs cannot replace HSECs in research in the short term. iPSC research is still developing and HSEC research is considered the gold standard.[248] To learn more about iPSCs they must to be compared against HSECs. Therefore, further work using HSECs is required.[249] Moreover, iPSC's and HSECs "seem to be different in important ways". [250] For this reason, each type of stem cell research may be useful for different things. HSECs are more useful for studying the genetic basis of the disease, while iPSCs are better for studying expression of the disease.[251] Furthermore, HSECs from SCNT created embryos allow for the study of early human development.[252] Therefore, the two cell types do not need to compete but rather can "complement each other".[253]

There is still a need for HESCs and SCNT is a useful way to obtain these, along with having many additional benefits which may not be realised if HSECs can only be obtained from surplus embryos. Therefore, allowing the creation of embryos by SCNT would be consistent with the second principle of the Act. Thus, in ACART recommending a moratorium be placed on creating embryos by SCNT for research, it was not acting in accordance with this second principle.

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[243] Devolder "The Discarded–Created Distinction", above n 231, at 6.

[244] Katrien Devolder "Technical Solutions" in *The Ethics of Embryonic Stem Cell Research* (Oxford University Press, Oxford, 2015) at 17.

[245] Devolder "Technical Solutions" above n 244, at 18.

[246] Devolder "Technical Solutions" above n 244, at 18.

[247] Devolder "Technical Solutions" above n 244, at 18.

[248] Devolder "Technical Solutions" above n 244, at 19.

[249] Devolder "Technical Solutions" above n 244, at 19.

[250] Devolder "Technical Solutions" above n 244, at 20.

[251] Devolder "Technical Solutions" above n 244, at 20.

[252] Devolder "Technical Solutions" above n 244, at 20.

[253] Daisy A. Robinton and George Q. Daley "The Promise of Induced Pluripotent Stem Cells in Research and Therapy" (2012) 481 Nature 295 at 301 cited in Devolder "Technical Solutions" above n 243, at 20.

3. Gene Editing

The 2007 advice to the Minister recommended that a moratorium be imposed on the genetic modification of embryos.[254] Research involving gene editing of embryos may contribute to being able to repair disease causing genes.[255] This may mean that in the future genetic disorders are a thing of the past. While this is not ready for clinical use or currently legal, it is possible that in the future these treatments will be available. These treatments may improve the health and well-being of future generations as children may be able to be born without debilitating genetic conditions like Cystic Fibrosis.[256] For this reason it is arguable that genetic editing of embryos in research would be commensurate with the second principle of the HART Act. Therefore, in recommending that a moratorium be imposed on the genetic modification of embryos ACART was not acting in accordance with the second principle of the Act as they did not take into account the effects on future generations that could be realised from genetic modification.

4. Hybrid Embryos

In its 2007 advice to the Minister ACART recommended a moratorium be imposed on forming hybrid embryos for research.[257] Hybrid embryos are formed in a process similar to SCNT and are a useful source of human-like embryonic stem cells.[258] The implantation of a hybrid embryo is prohibited in either an animal or a human, therefore they can only be used for research purposes.[259] In the UK the Human Fertilisation and Embryology Authority approved research on human-animal hybrids based on the fact that research would help scientists understand how drive pluripotent cells into particular cell types.[260] Research using hybrid embryos could eventually lead to human organs being grown inside animals for transplant patients.[261] Hybrid embryos could have positive effects on the health of future generations. It is arguable that by imposing a moratorium on the creation of hybrid embryos for research ACART was not exercising its functions in accordance with the principles of the HART Act.

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[254] ACART, "the 2007 advice", above n 207, at 5.

[255] Hong Ma and others "Correction of a pathogenic gene mutation in human embryos" (2017) 548 Nature 413 at 414.

[256] Michele Marangi and Giuseppa Pistritto "Innovative Therapeutic Strategies for Cystic Fibrosis: Moving Forward to CRISPR Technique" (2018) 9 Front. Pharmacol at 1.

[257] ACART, "the 2007 advice", above n 207, at 5.

[258] ACART "Discussion Paper", above n 78, at [41].

[259] HART Act, Sch 1, cl 5.

[260] Susan Mayor "UK regulatory body approves research using human-animal hybrid embryos" (2008) 336 BMJ at 177.

[261] Insoo Hyun "What's Wrong with Human/Nonhuman Chimera Research?" (2016) 14 PLoS Biology at 1.

C. Effects On Women

The third principle of the HART Act states: [262]

> 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.

It is often difficult physically and mentally to go through assisted reproductive procedures. For example, the drugs required for ovarian stimulation to retrieve enough oocytes for IVF can have serious physical and psychological effects.[263]

1. Surplus Embryos Used For Research Into Fertility.

Using surplus embryos in research was recommended by ACART in the 2007 advice to the Minister.[264] By studying embryo development information could be gained about how miscarriages occur and congenital diseases.[265] Miscarriage can cause emotional distress for many peopele and has been shown to increase the chances of having mental health problems during subsequent pregnancies.[266] Research aimed at increasing the chances of successful pregnancy for women so that the chance of experiencing a miscarriage is decreased, would be commensurate with the third principle of the HART Act, as this kind of research aims to protect the health, safety and well-being of women in assisted reproductive procedures.

2. Creating Embryos For Research Into Fertility

In the 2007 advice that was issued to the Minister, ACART recommended a moratorium be placed on creating embryos specifically for research.[267] ACART did not provide reasons for this positon in their advice. However, it is arguable that creating embryos for the purpose of research would be in line with the third principle of the HART Act. Surplus embryos are already formed, therefore they prevent research into the process of fertilisation itself.[268] Moreover, the effects of fertility drugs on gametes and the resulting embryo cannot be

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[262] HART Act, s 4(c).

[263] Fertility Associates, above n 101 at 68.

[264] ACART "the 2007 advice", above n 207, at 5

[265] Douglas and Suvulescu, above n 130, at 307.

[266] Catherine Chojenta and others "History of Pregnancy Loss Increases the Risk of Mental Health Problems in Subsequent Pregnancies but Not in the Postpartum" (2014) 9 PLoS ONE at 5.

[267] ACART "the 2007 advice", above n 207, at 5

[268] Ronald M. Green "At the Vortex of Controversy: Developing Guidelines for Human Embryo Research" (1994) 4 KIEJ 345 at 351.

studied using already fertilised embryos.[269] Surplus embryos may also have abnormalities, which may be the cause of the patient's infertility. Therefore, surplus embryos may be less suitable for research on normal embryo development.[270] Research focused on decreasing miscarriages works to promote the health and well-being of women. Therefore, it is in line with the third principle of the Act to create embryos for research. Creating embryos for the purpose of research is controversial; while it is permitted in the UK,[271] in Australia it is an offence to create embryos specifically for research through IVF.[272] Some argue creating embryos for research is morally impermissible.[273] Devolder contends that arguments for allowing the destruction of surplus embryos yet prohibiting creation of embryos created for research purposes are weak.[274]

I The Discarded-Created Debate

ACART was opposed to the creation of embryos for research, recommending a moratorium be placed on creating embryos for research, and creating embryos by SCNT for research.[275] Some argue it is permissible to obtain HSECs from surplus/discarded embryos but impermissible to obtain HSECs from embryos created for research.[276] However, it can be argued that the moral distinction between destroying embryos created for research and surplus embryos is illegitimate. Currently IVF is carried out in what Devolder calls a 'woman-friendly' way.[277] This is where many oocytes are retrieved from the woman and fertilised to form embryos.[278] One or two are transferred, the rest are frozen and can then be thawed and used if needed.[279] This is 'woman-friendly' because it means women do not have to go through multiple rounds of egg retrieval, which can have harmful effects.[280] This form of IVF is not practiced in every country. In Italy embryos cannot be cryopreserved and must be created and used as needed.[281] Devolder claims that if we see the benefits of 'woman-friendly' IVF as outweighing the harms of destroying surplus embryos in IVF, which is an inevitable part of 'woman-friendly' IVF; then the moral status of the embryo must be low

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[269] Green, above n 267, at 351.
[270] Green, above n 267, at 351-52.
[271] Human Fertilisation and Embryology Act 1990, Schedule 2 cl 3(a).
[272] Research Involving Human Embryos Act 2002, s 11.
[273] Devolder *The Discarded–Created Distinction*, above n 231, at 2.
[274] Devolder *The Discarded–Created Distinction*, above n 231.
[275] ACART "the 2007 advice", above n 206, at 5
[276] Devolder *The Discarded–Created Distinction*, above n 231, at 2.
[277] Devolder *The Discarded–Created Distinction*, above n 231, at 39. It is acknowledged that although this quote only refers to women, it is acknowledged that transgender men may also carry a child.
[278] Devolder *The Discarded–Created Distinction*, above n 231, at 38.
[279] Devolder *The Discarded–Created Distinction*, above n 231, at 38.
[280] Devolder *The Discarded–Created Distinction*, above n 231, at 40.
[281] Devolder *The Discarded–Created Distinction*, above n 231, at 39.

enough so that the benefits flowing from creating embryos specifically for research must outweigh the destruction of those embryos in research.[282]

Devolder notes that some may see the creation of embryos for research as not treating the embryo with respect, instead, treating it as a means to an end, and failing to acknowledge its potential for life.[283] However, again she notes:[284]

> the form of moral respect that is required to be consistent with women friendly IVF and the destruction of discarded [surplus] embryos is so diluted that it is hard not to see why it cannot be outweighed by the strong moral reasons we have to conduct research using stem cells from research embryos [embryos created for research].

If we were to hold embryos in such high moral regard so that their destruction cannot be outweighed by the benefits of helping the ill and injured through the creation of embryos to obtain HSECs, then the destruction of embryos in IVF cannot be outweighed by the benefits of women friendly practices.[285] Instead, like in Italy, embryos would be created and used as required. However, in NZ the health of women is a priority, so we do engage in 'woman-friendly' IVF. Moreover, 'woman-friendly' IVF is in line with the third principle of the HART Act.[286] Therefore, in order for IVF to be carried out in a way which is consistent with the third principle of the HART Act, embryos must have a low enough moral status that their destruction can be outweighed by the benefits of creating embryos specifically for research. Therefore, the distinction between embryos created for research and surplus IVF embryos cannot be justified. For this reason, it can be contented that the advice issued to the Minister in 2007 is ethically inconsistent with the way that IVF is carried out in NZ.

3. Genetic Editing

In the UK genetic editing has been conducted on embryos in order to discover the function of a gene involved in development.[287] Understanding what genes are involved in embryo development could allow for improvement of IVF treatments and could help researchers learn about the causes of miscarriage. Research which may improve the chances of successful pregnancy promotes the health and well-being of women. Therefore, genetic editing of embryos would be in line with the third principle of the HART Act.

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[282] Devolder *The Discarded–Created Distinction*, above n 231, at 42.

[283] Devolder *The Discarded–Created Distinction*, above n 231, at 44.

[284] Devolder *The Discarded–Created Distinction*, above n 231, at 49-50.

[285] Devolder *The Discarded–Created Distinction*, above n 231, at 49-50.

[286] HART Act, s 4(c)

[287] Norah M. E. Fogarty "Genome editing reveals a role for OCT4 in human embryogenesis" (2017) 550 Nature 67 at 67.

D. Māori And Other Cultural Perspectives

The sixth and seventh principles of the HART Act require that the needs, values, and beliefs of Māori, and the different ethical and cultural perspectives in society should be considered and treated with respect.[288] This can be done through ACART's duty of consultation.[289] ACART must give members of the public the opportunity to make submissions on proposed guidelines and take the submissions into account.[290] However, taking submissions into account does not mean that the guidelines produced need to reflect the submissions.[291] ACART must only 'turn its mind' to public submissions.[292] Since ACART is tasked with drafting guidelines it is in effect ACART that decides what kinds of ARTs are permitted and the rules surrounding them. Therefore, ACART will be acting in accordance with these principles so long as they that they have considered the views of Māori and others in society.

Jones and Whitaker stated that "it should be noted...there is rarely one single viewpoint representative of Māori concerns, any more than that there is a single religious viewpoint".[293] There is not one viewpoint which represents all of society. Therefore, these final principles are more concerned with showing respect and acknowledging "the considerable diversity of opinion that exists in relation to assisted reproduction".[294] While the last two principles of the HART Act are important, especially in recognising that NZ is a pluralistic society, they are unlikely to have the same force as the earlier principles.

When ACART called for submissions on PGD becoming an established procedure, they were met with criticism from some members of the public.[295] It was found that there was also no single Māori view nor was there a single Christian view[296] Due to the differing views in society, and the fact that these views often cannot be reconciled meant: [297]

> The question of whether PGD should or should not be permitted is ultimately not usefully addressed by seeking to answer to the question of the status of the human embryo or foetus.

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[288] HART Act, s 4(f)

[289] HART Act, s 41.

[290] HART Act, s 36

[291] Martin, above n 16, at 45.

[292] *Te Runanaga o Raukawa Inv v Treaty of Waitangi Fisheries Commission,* (14 October 1997) unreported, Court of Appeal, CA 178/97, 4 cited in Peter Martin, above n 16, at 45

[293] Jones and Whitaker "Ethical framework for ACART", above n 187, at 8.

[294] Jones and Whitaker "Ethical framework for ACART", above n 187, at 9.

[295] Henaghan and McLean, above n 104, at 8.

[296] Henaghan and McLean, above n 104, at 7-8.

[297] Henaghan and McLean, above n 104, at 8.

ACART took into account the different views of Māori and other cultural and spiritual beliefs when drafting advice on PGD. However, ultimately the advice did not align with the conservative views of some members of society.

The different views of Māori and other spiritual and cultural beliefs should be taken into account and respected when producing advice or guidelines covering embryo research. However, these principles should not hold more weight in the context of embryo research than they did for PGD. Matters like SCNT, creating embryos for research, gene editing and using surplus embryos in research may be controversial to many, and against their views and beliefs. Whilst ACART must take these views into account, the guidelines produced do not have to be commensurate with these views if they are not consistent with the objectives and principles of the HART Act.

E. Proposed Guidelines

It is submitted that if ACART were to produce guidelines that were commensurate with the principles of the HART Act that the guidelines should permit:

1. The use of surplus IVF embryos in research;
2. the creation of embryos via IVF specifically for research purposes;
3. the creation of embryos via SCNT for research purposes;
4. the genetic modification of embryos for research purposes; and
5. the creation of hybrid embryos for research purposes.

Guidelines which permit these actions to occur would allow the benefits of embryo research to be realised. They would also be consistent with the principles of the HART Act. Furthermore, they are ethically consistent with how ARTs are carried out in NZ.

V. Operationalizing

A. Lack Of Ministerial Controls

When Parliament debated the HART Bill, the regulatory framework was criticised for being far too permissive.[298] The Act delegated considerable power to ACART, and is virtually devoid of any ministerial or parliamentary checks on the guidelines produced by ACART.[299] Critics were concerned about an unelected committee having so much power over an area as important as assisted reproduction and human reproductive research.[300] Martin notes that when it came to PGD, apart from the statutory prohibition on non-medical sex selection, there were no prohibitions on what kinds of PGD could be permitted in guidelines and that in theory ACART could prepare guidelines permitting PGD to select for IQ.[301]

B. Ministerial Powers Of Veto

However, it is arguable that the concern that ACART would have unfettered discretion to issue guidelines has been unnecessary. ACART's expected free reign has been curtailed by the Minister. In November 2008, in response to the advice issued to the Minister in 2007, ACART received a letter from Hon David Cunliffe stating he wanted to see prohibitions on research using donated surplus IVF embryos, hybrid embryos, genetically modified embryos, and embryos created specifically for research purposes.[302] In his letter to ACART he seemed to assert control over how ACART was conducting its functions by threatening ACART, sating: "Following the election, I will be seeking an urgent meeting with you to discuss ACART's future activities".[303] After the change of government, ACART wrote to Hon Tony Ryall to see whether he would proceed with the prohibitions suggested by Cunliffe or if he intended to revisit the matter.[304] Seven months later Hon Tony Ryall responded, stating that he did not want ACART to do further work on guidelines covering embryo research.[305]

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[298] (6 Oct 2004) 620 NZPD 15909

[299] No where in the Act does it state that the minister needs to approve of the guidelines: Martin, above n 16 at 48.

[300] Martin, above n 16 at 62.

[301] Martin, above n 16 at 46.

[302] Letter from Hon David Cunliffe Minister of Health to ACART (10 November 2008) (Obtained under Official Information Act 1982 Request to ACART).

[303] Letter from Hon David Cunliffe, above n 302.

[304] Briefing to the Minister "Meeting with chair of the advisory committee on assisted reproductive technology" (25 February 2009) (Obtained under Official Information Act 1982 Request to ACART).

[305] Letter by Hon Tony Ryall to ACART (10 September 2009) (Obtained under Official Information Act 1982 Request to ACART).

ACART at all points has listened to the Minister's directions, effectively giving the Minister the power of veto over any advice or guidelines issued by ACART. However, the following sections will explain that this ministerial power of veto is not legislated for.

C. Consultation

The Act states that before issuing guidelines ACART must "consult" the Minister.[306] However, consultation does not mean that the guidelines produced need to be supported by the Minister before they can be issued.[307] Consultation is not defined in the Act. However, the consultation obligation has been considered by courts. In the Court of Appeal in *Wellington International Airport Limited v Air NZ* it was held that consultation is not the same as negotiation and therefore agreement is not required.[308] Therefore, in consulting the Minister, the Minister does not have to agree with the advice or guidelines that ACART presents. However, ACART must listen to the Minister and consider the Ministers response.[309] It could be argued that it is the consultation process which provides the Minister with the de facto veto power. As it would be unusual for the Minister to table guidelines in parliament that he did not support.[310] However, there is no legal requirement that the Minister must approve of ACART's guidelines. Therefore, ACART arguably has the ability to create guidelines and issue them, no matter their content. If the Minister did not agree with the guidelines only remedial action could be taken.[311]

D. Remedial Action Could Be Taken By The Minister

Martin notes that if the Minister was not happy with the content of the guidelines he could remove members of ACART.[312] It is the Minister who has the powers of appointment and termination of committee members, therefore, the committee could be replaced with people that would draft guidelines in line with the Minister's desires.[313] Reasons are not required for removal of members.[314]

Another option for the Minister would be making regulations providing for:[315]

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[306] HART Act, s 41.
[307] Martin, above n 16 at 48.
[308] *Wellington International Airport Ltd v Air NZ* [1991] 1 NZLR 671 CA at 675.
[309] *Wellington International Airport Ltd,* above n 308, at 676.
[310] Martin, above 16, at 48.
[311] Martin, above 16, at 48.
[312] Martin, above 16, at 48.
[313] HART Act, s 34.
[314] Martin, above 16, at 49.
[315] HART Act, s 76 cited in Martin, above 16, at 49.

> …the circumstances and the manner in which, and the conditions subject to which, any kind of assisted reproductive procedure may be performed, or any kind of human reproductive research may be conducted.

Through these regulations the Minister would be able to change how human reproductive research is conducted. While these actions are available in a remedial sense, there is nothing stopping ACART from issuing guidelines that the Minister does not approve of. The Minister would be obliged to table the guidelines in parliament regardless of whether the Minister agreed with them or not. Moreover, Parliament does not have to approve of the guidelines. The guidelines would be legitimate so long as ACART obliged by their statutory duties of consultation, both with the public and the Minister.[316]

This freedom on the part of ACART to draft guidelines that have force of law stands in contrasted to committees created by other legislation in NZ. For example, under the Animal Welfare Act the National Animal Welfare Advisory Committee may recommend that regulations be made.[317] However it is ultimately the Minister of Agriculture who approves the regulations.[318]

E. Parliaments Intent

It does not seem that the Minister having a power of veto was intended for. The Rt Hon Bill English noted that when he was the Minister of Health the former advisory committee (NECAHR) had power to make decisions that he may have disagreed with, stating: [319]

> As the minister who appointed the advisory committee, I was greatly anxious about what would happen if the committee made decisions I believed were wrong – were against the public interest and outside the scope of what parliament would accept.

He also noted: [320]

> Any ministerial interference with that process will be regarded as a breach of good faith, because that was what I was threatened with when I sought advice about what role I might take as Minister of Health in those decisions.

[316] HART Act, s 76
[317] Animal Welfare Act 1999, s 73.
[318] Animal Welfare Act, s 183A
[319] (6 Oct 2004) 620 NZPD 15908.
[320] (6 Oct 2004) 620 NZPD 15908

Rt Hon Bill English saw that the advisory committee proposed for in the HART Bill would have the power to issue guidelines on whatever they liked without Parliament being able to challenge them.[321] MP Sue Kedgely echoed this sentiment, stating: "It then essentially hands the entire thing, lock, stock and barrel, to this unelected and unaccountable committee".[322] Therefore, it is clear that while some MPs were against it, it was Parliaments intention for ACART to be able to produce guidelines without Ministerial approval or Parliamentary scrutiny .

F. Going Against The Act's Purpose

It is arguable that because the Act does not prohibit the Minister from directing ACART as to the content of the guidelines or whether guidelines should be produced at all, that the Minister can do it. However, it could be argued that in directing ACART to not produce guidelines or recommending the content of the guidelines, that the Minister is going against the purpose of the Act.

In *Quake Outcasts & Fowler Developments Ltd v Canterbury Earthquake Recovery Authority* the Supreme Court held that the Minister for Canterbury Earthquake Recovery (Minister for CER) needed to act in accordance with the purposes of the Act.[323] However, in this case s 10 of the Canterbury Earthquake Recovery Act 2011 stated that any powers exercised under the Act needed to be necessary for that purpose.[324] Therefore, there was an additional element ensuring the Minister for CER acted in accordance with the purpose of the Act. It could be argued that the Minister in directing ACART to not produce guidelines and directing the content of guidelines that the Minister has acted ultra vires as he is directing ACART in a way which is not in accordance with the purposes of the Act. By directing ACART to not produce guidelines, the benefits of human assisted reproductive research are not being secured.[325] Moreover, another purpose of the Act is to provide a robust and flexible framework for regulating and guiding the performance of assisted reproductive procedures and the conduct of human reproductive research.[326] By curtailing ACART's capacity to formulate guidelines, the Minister is preventing the framework from operating in a flexible way as envisioned by parliament. Not only is the framework not flexible, the interim guidelines which were introduced by NECAHR in 2005 remain in force simply as a result of unilateral Ministerial dictate. As the *Fowler* case demonstrates, it is arguable that the Minister

[321] (6 Oct 2004) 620 NZPD 15908
[322] (6 Oct 2004) 620 NZPD 15909
[323] *Quake Outcasts & Fowler Developments Ltd v Canterbury Earthquake Recovery Authority* [2015] NZSC 27 at [118]
[324] *Fowler*, above n 323, at [19].
[325] HART Act, s 3(a).
[326] HART Act, s 3(d).

is not at liberty to issue instructions to ACART that override the statutory scheme. Therefore, the Minister may be liable for judicial review.

G. Is ACART Abdicating Its Statutory Function?

It could be argued that ACART is unlawfully abdicating its statutory function by failing to issue guidelines on human reproductive research and to keep such guidelines and advice under review. This would mean that ACART could be liable for judicial review. It will be an unlawful abdication of power even if ACART's inaction was not deliberate or if they felt they could not proceed.[327] In *Padfield v Minister of Agriculture*, the Minister of Agriculture was found to have unlawfully abdicated his function through purposeful inaction.[328] In that case the Minister of Agriculture declined to exercise his discretionary power to refer a complaint to a committee of investigation because he feared political repercussions.[329] It is arguable that ACART is failing to exercise its statutory function in failing to keep guidelines and advice under review because of fear of what the Minister may do. Therefore, it is possible that ACART could face judicial review under the ground of illegality.

H. Operationalising: Conclusion

The framework provided by the HART Act gives ACART the power to issue whatever guidelines it likes. So long as ACART properly engages in its duties of consultation and takes into account the principles of the Act when exercising its statutory function of producing guidelines, any guidelines that ACART does produce could be issued to the Minister, tabled in parliament, and then issued to ECART without Ministerial or Parliamentary approval. The Ministers only option would be to then issue regulations to counter the guidelines, or to replace the members of ACART so that new guidelines could be made. However, it is arguable that it would be ultra vires to direct ACART to not act so that the purpose of the Act is not fulfilled. Moreover, if ACART continues to not prepare guidelines or issue advice on embryo research, it could be argued that ACART is abdicating their statutory function. ACART has the ability to issue guidelines and in order to act in accordance with the principles of the HART Act, guidelines covering what has been suggested in this dissertation should be issued. Moreover, the Minister should endeavour to not interfere with ACART's process.

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[327] Philip Joseph *Constitutional & Administrative Law in NZ* (4th ed, Brookers, Wellington, 2014) at [23.3.5].
[328] *Padfield v Minister of Agriculture, Fisheries and Food* [1968] AC 997 (HL) Cited in Joseph, above n 326, at [23.3.5]
[329] *Padfield*, above n 328.

IV. Conclusion

The fact that the NECAHR guidelines are poorly prepared, lack coherence and context, and out of date is only the start of why they need to be replaced. The NECAHR guidelines are vague and do not define viability. Due to technological constraints viability cannot be accurately determined. The viability distinction cannot, therefore, be ethically justified. Moreover, the viability distinction created by the NECAHR guidelines does not reflect how ART's are carried out in NZ nor how the embryo is treated at law. They have also caused NZ to lag behind other nations, limiting our practitioners from improving ARTs, which is against health policy in NZ.

Scientific advancement is unavoidable, the rest of the world is shifting forwards and embracing these changes. As science and technology develop it is clear that the NECAHR guidelines are becoming even more inappropriate. The current guidelines are severely limiting scientific development where it may benefit many.

It is submitted that guidelines in line with those suggested in this dissertation should be drafted. These guidelines would adequately take into account the principles of the HART Act. Therefore, in exercising their statutory function ACART would be acting in accordance with the principles of the Act. While research in these areas may seem controversial it may have positive effects on the health and well-being of all people — whether that be people undergoing assisted reproductive procedures, children born as a result of those procedures, or people in society who may one day benefit from treatments which are able to be realised due to embryo research.

It is understandable that many are concerned about embryo research one day extending into the genetic modification of humans for reasons not related to disease or the prospect of cloning. However, these practices are prohibited and so long as every nation takes a strong stance against reproductive cloning and genetic editing for non-medical reasons, extending research into these areas should not cause issues.

The fact that ACART has been unable to issue new guidelines covering embryo research shows that how the regulatory mechanism provided by the HART Act is not functioning as it was intended, and the lack of new guidelines on embryo research is an instance of regulatory failure. The way that ACART is being controlled by the Minister means that the HART Act is not able to operate in the flexible way it was intended to. This is an area in which the Minister or ACART could be liable for judicial review. As it is clear that arguable that the Act us not being applied as intended. The Minister may be acting outside of the Act's purpose while ACART could be seen as abdicating their statutory function.

It is submitted that the current framework does not preclude ACART from preparing guidelines on embryo research and issuing them to ECART. Therefore, if ACART chose to do so, the guidelines suggested in this dissertation could be implemented without Ministerial approval. Whether judicial review is the answer, legislative reform, or ACART issuing guidelines without the support of the Minister, it is clear that something needs to shift as the current position that NZ is in is wholly inadequate.

Through their inaction ACART and the Minister have been neglectful, only prolonging the suffering of potential families and the ill. They must engage with their moral and legislative duty to update the NECAHR guidelines, so that they finally fulfil their duty of securing the benefits of assisted reproductive technologies and human reproductive research for all New Zealanders.

Appendix

1. The next three pages contain the entirety of the NECAHR *Guidelines for Research on Gametes and Non-viable Embryos.*

Guidelines for Research on Gametes and Non-viable Embryos

The following clauses are taken from the National Health and Medical Research Council, *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*, 2004.

15.4 Minimise risks

Researchers must ensure that any risks of involvement in the research are appropriate for the type of research.

15.4.1 Where clinical care is combined with research, the risks of research should be balanced by the possibility of intended benefits from the research (see paragraph 1.6 of the National Statement).

15.4.2 For research undertaken solely to develop new knowledge, any risks (particularly any long-term risks to persons born) should be minimal.

16.4 Minimise risks

Researchers 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.

15.5 Offer separate decision-making processes for clinical care and research

It is unethical to coerce potential research participants in any way into taking part in the research. Consent must be freely given and be explicit for the proposed research. Any concealment of the purposes of a study from the persons responsible is unethical and excludes informed and voluntary consent.

Proposals for research must include procedures to ensure that the process of providing information and obtaining consent for involvement in the research is clearly separated from clinical care.

Information sheets for research projects must be completely separate from, and capable of being read independently of, written information provided to a patient in the course of routine clinical care.

15.6 Provide information

Participants in research are often vulnerable and can easily misunderstand the purpose and nature of the research. Researchers must provide information to

participants, at their level of comprehension, about the purpose, methods, demands, risks, inconveniences, discomforts and possible consequences of the research (including the likelihood and form of publication of the research results). Section 9 provides guidelines on information giving and counselling for clinical practice; and the same principles must be applied for research.

16.5 Provide information

Researchers must give gamete providers (and their spouses or partners, if any), and any persons for whom an embryo may be created, all relevant information about the research.

16.5.1 The information provided should include a full explanation of any consequences and risks involved for any embryo created and any person born after implantation of the embryo, and how they are balanced by potential benefits.

15.8 Keep detailed records

Good record keeping is an essential component of research. Researchers must keep accurate records of their research, including records of all gametes and embryos in their care, and the outcomes of the research.

Section 10 provides guidelines on record keeping for clinical practice. The same principles must be applied for research.

15.10 Assess and monitor outcomes for all participants (present and future)

All clinical research requires evaluation. For research involving participants in reproductive treatment, researchers must 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).

15.11 Disclose financial interests

The participants in research are entitled to know about any financial benefits that the researcher or clinic may gain from the research. Researchers must disclose in the project proposal to be submitted to the HREC, any financial interests they have in the research. The HREC must consider the extent to which disclosure of relevant financial aspects of research should be made known to the participants. For example, where researchers plan to request donation of embryos with the intention of undertaking research that may ultimately yield commercial profit, this must be clear to the donors before consent is obtained.

15.12 Respect conscientious objections

Conscientious objectors are not obliged to be involved in the procedures or programs to which they object. If any member of staff or student expresses a conscientious objection to the research involving ART procedures conducted by the clinic, the clinic must allow him or her to withdraw from involvement in the research to which he or she objects. Clinics must also ensure that staff and students are not disadvantaged because of a conscientious objection.

16.3 Use valid scientific protocols

Research must be justified in terms of its potential contribution to knowledge or technical application.

16.5 Obtain consent

Researchers must obtain consent from the gamete providers (and their spouses or partners, if any), and from any persons for whom an embryo may be created, that the gametes will be the subject of research, following which fertilisation may be attempted to create an embryo for transfer to the uterus of the recipient to achieve a pregnancy.

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