Where does New Zealand stand on permitting research on human embryos?

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Abstract

In many respects New Zealand has responded to the assisted reproductive technologies (ARTs) as positively as many comparable societies, such as Australia and the UK. Consequently, *in vitro* fertilisation (IVF) and pre-implantation genetic diagnosis (PGD) are widely available, as is non-commercial surrogacy utilising IVF. These developments have been made possible by the Human Assisted Reproductive Technology (HART) Act 2004, overseen by its two committees, the Advisory Committee on Assisted Reproductive Technology (ACART) and the Ethics Committee (ECART). However, New Zealand stands apart from many of these other societies by the lack of permission for scientists to conduct research using human embryos. There is no doubt this reflects strongly held viewpoints on the part of some that embryos should be protected and not exploited. Legitimate as this stance is, the resulting situation is problematic when IVF is already designated as an established procedure. This is because the development of IVF involved embryo research, and continuing improvements in procedures depend upon ongoing embryo research.

While prohibition of research on human embryos gives the impression of protecting embryos, it fails to do this and also fails to enhance the health and wellbeing of children born using IVF. This situation will not be rectified until research is allowed on human embryos.

Since the late 1960s *in vitro* fertilisation (IVF) has been developed to combat infertility, a process dependent upon research using human embryos.¹ Currently, the production of embryos surplus to the requirements of those undergoing IVF treatment leads to the storage of these embryos, of which there are over 11,000 in New Zealand.² Many of these will not be required for subsequent attempts to produce a child and will be discarded for legal reasons.³ PGD is made possible by IVF, and is a procedure that involves discarding embryos that will develop into individuals who would suffer from an unwanted genetic condition.

While IVF has been widely available for 30 years, and has been in the mainstream of medicine for most of those years, the research involved in this has brought the moral status of the embryo into stark relief. While this presents few problems for many people longing for their own child, the spectre of conducting research on human embryos presents imponderable ethical hurdles for others.

Consequently, one very occasionally encounters a situation such as that in New Zealand, which permits IVF and PGD (in both of which embryos are discarded), but prohibits research on any of these shortly to be discarded embryos. At face value there appears to be an ethical inconsistency here, with destruction being deemed
permissible in the former but not in the latter. No case has been made for this judgement.

The prohibition of research on surplus embryos has repercussions for the scientific community and hence for ongoing research into infertility and an understanding of developmental processes in early human development. It also means that embryos cannot be used as a source of human embryonic stem cells (hESCs) in this country. This in turn limits medical research opportunities likely to lead to innovative treatments for diseases. Important as these areas are, both they and the production of research embryos, are only referred to in passing in this paper.

**Policy and regulatory frameworks governing embryo research**

Regulations governing embryo research are considered in relation to the ability or otherwise to extract hESCs from embryos. They fall into four dominant positions designated A to D by Jones and Towns.\(^4\)

Position A encompasses countries that prohibit all embryo research and therefore the extraction of hESCs. Position B confines the use of embryonic stem cells to those currently in existence, in that they were extracted prior to a specified date, thereby prohibiting the extraction of hESCs and utilisation of hESCs derived in the future. Position C allows for the use and ongoing isolation of hESCs from surplus IVF embryos from IVF programs. Position D allows the creation of human embryos specifically for research via both fertilisation and somatic cell nuclear transfer (SCNT).

The Hinxton Group (An International Consortium on Stem Cells, Ethics and Law)\(^5\) again identified four groups: Prohibitive (equivalent to A), Restrictive Compromise (B), Permissive Compromise (C), and Permissive (D). The classification adopted by the European Science Foundation\(^6\) is similar, but omits a position B equivalent.

The groups are Very Restrictive (corresponding to A), Permissive (C), and Very Permissive (D), with further categories of Restrictions by Default (where legislation is not explicit but national practices are quite restrictive in practice), and Unlegislated (where there is no legislation on human ESCs).

The current situation is exemplified by the following examples:

**A (Prohibition):** Italy, Slovakia, Tunisia.

**B (Restrictive Compromise):** USA – use of federal funds under President Bush.

**C (Permissive [Compromise]):** numerous countries including Australia, Canada, China (Hong Kong), Denmark, France, Iran, Netherlands, Norway, Switzerland, Taiwan, USA – use of federal funds under President Obama.

**D ([Very] Permissive):** Belgium, Israel, Japan, UK, Singapore, South Korea, Sweden, certain states in USA using private funds.

**Restrictive by Default:** New Zealand, Romania, Turkey.

**Unlegislated:** Austria, Ireland, Luxembourg, Poland.
Of the three countries in the Restrictive by Default category, Romania allows stem cell research under official approvals, but there is no regulation on IVF, research on embryos, or embryonic stem cells. In the case of Turkey, hESC research is prohibited, although non-embryonic hematopoietic stem cell research is allowed by law, under informed consent, and if officially approved.6

New Zealand has been placed in the ‘restrictive by default’ category on the basis of the 2012/2013 annual report of ACART.7 In the section on advice to the Minister of Health on human reproductive research, it states:

“Section 37 of the HART Act requires ACART to provide the Minister of Health with information, advice and, if it thinks fit, recommendations on certain matters in relation to the use of gametes and embryos in human reproductive research.

In June 2007 ACART provided the then Minister of Health with advice on human reproductive research following extensive public consultation in the 2006/07 financial year. At the request of the Minister, ACART has not undertaken any work to develop guidelines or further advice.

The current Guidelines for Research on Gametes and Non-Viable Embryos, developed by the former National Ethics Committee on Assisted Human Reproduction, remain in force”. (These allow research on sperm and eggs, and also on embryos lacking the potential to develop into a fetus due to arrested growth, defects of their cells, or other abnormalities.)

ACART is required to monitor developments in human reproductive research by Section 35(2) of the HART Act 2004, and so is fully aware of the human reproductive research currently approved in Australia and the UK. It also emerges from the above that in 2007 ACART recommended to the Minister that embryo research of some description should be permitted in New Zealand. This is because ACART requires the Minister’s go-ahead to develop guidelines for ECART. In the absence of these embryo research cannot be undertaken.

**Approaching the HART Act**

The HART Act regulates the assisted reproductive technologies (ARTs) in New Zealand, with the aim of protecting the wellbeing of those affected by IVF and related procedures, namely, the health and well-being of children born using ARTs, the health, safety, and dignity of present and future generations, and the health and well-being of women.

Informed choice on the part of all involved is crucial, while donor offspring are to be made aware of their genetic origins and are to be able to access information about those origins. Additionally, the needs, values, and beliefs of Māori are to be considered and treated with respect, as are the range of ethical, spiritual, and cultural perspectives within society.8

**Finding a place for embryos**—While many important ethical values are encompassed by these principles, there is no direct reference to the moral worth to be ascribed to human embryos in the HART Act. This becomes particularly important when the nature of ART research affecting embryos is under consideration. However,
there are indirect allusions to embryos elsewhere in the Act, that raise the possibility that developing humans, particularly early embryos, may not have the same rights and protections as children or adult humans. For instance, the HART Act makes it an offence to allow an in vitro embryo to develop beyond 14 days gestation. Prior to this point in development, embryos may in principle be used in human reproductive research (subject to prior approval by ECART), imported and exported, and developed outside the womb, subject in all cases to guidelines and comprehensive ethical oversight, and approval by the Minister of Health. The HART Act also restricts the maximum time of storage. As it is extremely unlikely that all stored embryos will be implanted and thereby given a chance to become future individuals, this provision of the HART Act implicitly requires the destruction of human embryos.

However, embryos may be seen as having a special status warranting protection. One indication of this is found in the Human Tissue Act 2008, with its note that: “A human embryo or human gamete is not human tissue for the purposes of any provision of this Act,” pointing to a protected status. Nevertheless, this does not amount to human rights as afforded to those who have been born, or the legal protections afforded to the fetus.

Established procedures and prohibitions—The HART Act stipulates that some activities can be designated as ‘established procedures’ that may be carried out as routine clinical procedures without requiring ethical approval. These include artificial insemination, collection of eggs or sperm for purposes of donation; egg and embryo cryopreservation; IVF; intracytoplasmic sperm injection (ICSI); and PGD. Prohibited actions include the artificial formation for reproductive purposes or implantation of a cloned or hybrid embryo; the implantation of an animal gamete or embryo into a human and vice versa; and the implantation of genetically modified gametes/embryos, or gametes/embryos derived from a foetus. Also prohibited are the development of an in vitro embryo beyond 14 days, and the commercial supply of human embryos or human gametes. Also restricted is the selection of embryos for implantation on the basis of sex unless it was performed to prevent or treat a genetic disorder.

Research on human embryos does not fit into a prohibited category, neither is it an established procedure nor one requiring ECART approval. Currently, research on viable human embryos (as opposed to non-viable ones) is in limbo depending upon agreement of the Minister of Health to the positive recommendation from ACART to proceed. It has similarities to the European Science Foundation category of ‘restrictive by default.’

This position satisfies no one. For those who would like to see a very restrictive regime in place, there is no assurance that this is the case. This was evident in submissions made to the ACART discussion document, Use of gametes and embryos in human reproductive research, where there was widespread opposition to the use of embryos in research on the grounds that they are human life and any manipulation, including in vitro fertilisation (IVF) and pre-implantation genetic diagnosis (PGD) is akin to harming or killing a person.”
Additionally, there was “opposition to the use of gametes in research on the grounds that they are human life.” These responses clearly enunciate the view that some of those opposed to research on human embryos are also opposed to IVF and indeed any research of embryos (and in some cases even gametes). For those expressing these viewpoints it is the availability of IVF that should be queried and reviewed. Perhaps inadvertently, this stance uncovers inconsistency between policies, since these submitters are correct in realising that embryos are not protected in IVF or PGD.

Those in favour of at least some uses of embryos in research did so “on the grounds that they have a lesser moral status than persons who have been born, provided that such research has scientific merit and potential to benefit human health.”

Users of fertility services expressed the view that they wanted the choice to donate their surplus embryos for research purposes, in addition to current choices of donating them to another couple or discarding them (“allowing them to thaw and perish”).

**Embryos, IVF and infertility**

The HART Act accepts the permissibility of IVF and its associated procedures. This, in turn, accepts the validity of embryo research (albeit undertaken in other countries), even if some discussants either fail to recognise this or disagree with it. It is within this context that the debate on embryo research is situated, since ongoing research on human embryos is required to support IVF and associated procedures, as well as having been implicit within its development. Neither destructive embryo research nor clinical trials of IVF procedures are to be regarded as optional add-ons.

The ethical literature from the 1980s onwards falls into two clearly delineated responses to IVF: the **negative**, with its suspicion of IVF and in some cases rejection of it; and the **positive** with its stress on the needs of the infertile and openness to acceptance of IVF. The arguments of those who are negative towards IVF pay particular attention to protection of the embryo, in contrast to those who are positive, where the emphasis is on the needs of the infertile.

Within a pluralist society, balance has to be found between these two positions, since each represents different and in this case incompatible conceptions of the good. Public policy should not reflect either extreme to the exclusion of the other. There is no escape from the competing interests of those intent on protecting embryos, those with infertility problems, and those wishing to address genetic- and chromosomally-based illnesses.

A society like that of New Zealand is not starting with a clean slate in its response to human embryos. Designating IVF as an established procedure may have been based on inadequate appreciation of its implications, as demonstrated by the subsequent negativity towards embryo research as a step too far. However, the existence of IVF and associated procedures continues to depend upon research on human embryos, albeit conducted in other countries, including the UK, USA and Australia.
Against this background, consider four possible models of embryo protection:

**Model 1: Consistent protection of embryos.** Rejection of embryo research; rejection of IVF and PGD due to the destruction of embryos inherent in these processes, including the production of surplus embryos.

**Model 2: Acceptance of existing policies.** Rejection of embryo research; acceptance of IVF and PGD, since governing policies and procedures are currently in existence. Reject any experimental procedures in New Zealand that would place further embryos at unnecessary risk.

**Model 3: Acceptance of embryo research outside New Zealand.** Rejection of embryo research in New Zealand but accept that it may be conducted in other countries; accept IVF and PGD and modifications utilising research data based on research in other countries.

**Model 4: Acceptance of embryo research.** Accept IVF and PGD employing only surplus embryos, or these plus embryos produced for research; to support ARTs, and/or hESCs and other biological issues.

Of these models, 1 and 4 are consistent in their stances, prohibition in model 1 and permission (within whatever experimental limits are in place) in model 4. The two intervening models (2 and 3) are less consistent in that they accept to differing degrees the results of research on embryos, either in the past and/or on a continuing basis. While they aim to protect embryos in the future, they are prepared to benefit from data and procedures obtained from embryo destruction in the past (and possibly in the present in other countries).

The ethical inconsistency inherent within both Models 2 and 3 requires justification. On what grounds can it be acceptable to destroy (or allow to perish) embryos surplus to the requirements of a clinical fertility program, but refuse to allow the use of these about-to-be-destroyed embryos for research which is aimed at contributing to an understanding of the causes of infertility? Holm describes this as ‘performative inconsistency.’ This stems from allowing surplus embryos to die, while prohibiting the destruction of other embryos in research (or accepting that they are destroyed in other countries).

These responses tend to reiterate well-rehearsed positions on the status of the embryo. For instance, the stance is upheld by arguing that (i) surplus embryos should be allowed to perish naturally; or (ii) surplus embryos have the potential to give rise to new individuals and hence are equivalent in status to in utero embryos; or (iii) it is important ethically to protect all embryos regardless of their fate.

The problem with answers like these is that they ignore the context provided by IVF. Research using embryos is intimately woven through every aspect of IVF. If it is argued that the moral worth of surplus embryos resides in their potential for further development, any wrong exists in ending this potential, not in how it is ended.

The destruction will occur regardless of whether any research will be carried out on the embryos. This is an unavoidable situation of loss, including potential benefits for human health from research on early embryological development. These are unwanted embryos that have no valuable future. This is because their parents have consented to their use in research, no longer requiring them to produce a child and not
wishing to donate them to another couple. Hence, their existence *in vitro* means they have no future as human beings.

A counter argument to this is that a benefit should not be rejected because it depends on a preceding evil, namely, research on embryos. Hence, accepting IVF today may be better than rejecting it, even if its origins, with their dependence upon embryo research, are considered unethical. Since none of that work was carried out in New Zealand, there is no moral complicity involved. This argument should be rejected because ongoing research on infertility is required, and any results from this are accepted and utilised clinically even though they may have been generated in other countries.

But is this research required? There is a moral imperative to protect children and families who use IVF. Green argues that "we have a duty to minimise the health risks to which we expose future children." This is of considerable relevance to the HART Act with its principle of protecting children.

It can be argued that a society that allows IVF, also has a duty to be involved in ongoing research that will increase the efficacy and safety of the procedures being used. Without this one is entirely dependent upon research carried out in other societies. This precludes practitioners in this country from improving the safety and protocols of their practice, with its input into the health of resulting children. In these terms alone research can be justified (compare Holm’s argument with relation to embryonic stem cells).

On the other hand, if these stipulations do not apply, and if IVF as currently undertaken is completely safe and totally effective, no further research should be undertaken, and one might be able to defend the New Zealand position of approving IVF and prohibiting embryo research. This is a scientific and clinical argument rather than a moral one. However, current evidence suggests that ongoing research is vital, if IVF is to continue to be regarded as an established procedure.

The relationship between embryos and future children is an intimate one whenever the existence of the latter depends upon a technological procedure like IVF. Without IVF they would not exist; with it not only do they exist but many aspects of their health and well-being depend upon the protocols employed in the clinic.

The present situation in New Zealand means that it is not possible to conduct clinical trials on the efficacy of different IVF procedures, such as the cumulative pregnancy rates following transfer of embryos at day 3 (cleavage stage) compared with day 5 (blastocyst stage). Both are routinely used in clinical practice, without good evidence as to which is the better of the two.

Unfortunately, a study comparing the two procedures falls under the rubric of research using embryos, even though the aim is to compare the best outcomes in terms of healthy live births. Such a study would potentially be of benefit to the embryos involved in the clinical trial, Since it does not place these embryos at additional risk, it lies outside the four models of embryo protection referred to above.
Conclusion

The argument of this paper is that IVF is intimately linked to embryo research, both in the past and present. This poses problems for a society that does not permit research to be conducted on human embryos.

The intimate link between a technological procedure like IVF based on the utilisation of embryos, and ongoing research, has repercussions for both ethics and public policy. Any carelessness or neglect in IVF will wrong the child-to-be, and a research underpinning is essential to minimise any such wrongdoing. While political compromise is inevitable in any pluralist society, this should not ignore the need for ongoing scientific research into technological procedures that are approved by society.

Until there is clarification of these issues in New Zealand, fertility specialists (and the public) will continue to rely on research conducted by others in overseas jurisdictions.

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References and endnotes:

3. ACART, Advisory Committee on Assisted Reproductive Technology. Guidelines on Extending the Storage Period of Gametes and Embryos. Wellington: ACART, 2012. The current 10-year storage period under the HART Act expires on 22 November 2014, and can only be extended with approval from ECART.

10. s16, s19(b)


12. Human Tissue Act 2008, s 7(2)

13. Part 1 of the Schedule to the Human Assisted Reproductive Technology Order 2005

14. Schedule 1

15. s 9

16. s 13

17. s 11


