

**Use of Gametes and Embryos in Human
Reproductive Research:
Determining Policy for New Zealand**

A Discussion Paper

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Chair's Foreword

Should human gamete and embryo research be undertaken in New Zealand, and if so, under what conditions?

These are important questions for New Zealanders to consider.

Internationally, scientific developments involving the use of gametes and embryos in research are taking place. These developments further our understanding of various disease states as well as our understanding of normal growth and development. New Zealand researchers would like the opportunity to contribute to this work. However the use of gametes and embryos for research raises ethical, spiritual and cultural issues, which we must also take into consideration.

Under the Human Assisted Reproductive Technology Act (the HART Act), the Advisory Committee on Assisted Reproductive Technology (ACART) must advise the Minister of Health on whether research using gametes and embryos should be allowed, and if so, whether limits should be placed on that research. In preparing their advice ACART must take into account the views of New Zealanders.

Accordingly, ACART has prepared a discussion paper to provide background material that we hope will assist you in your thinking. The paper presents information from a variety of perspectives: scientific, ethical, legal and policy.

Please take the time to consider the issues raised in this paper and to send us your views so that ACART can prepare advice based on as many views as possible. Where groups self-organise to consider the discussion paper and their submission, ACART will make every effort to attend if requested.

I look forward to receiving your opinions on this important issue.

Sylvia Rumball

Chair, Advisory Committee on Assisted Reproductive Technology

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Preface

Reproductive technologies have expanded greatly in the last 30 years, and there has been increased interest in the use of human gametes and embryos in research – including fundamental biological research, reproductive research, and as a source of stem cells.

Until 2004 clinical care and research in this area were regulated through a combination of professional self-regulation and indirect institutional and legislative requirements that necessitated ethical review. The National Ethics Committee on Assisted Human Reproduction (NECAHR) carried out this review.

Human Assisted Reproductive Technology (HART) Act 2004

The HART Act, which came into effect in 2004, establishes a legal framework for human assisted reproductive procedures and human reproductive research. The Act defines human reproductive research as ‘research that uses or creates a human gamete, a human embryo or a hybrid embryo’.

The HART Act has a number of purposes. These are:

- a) to secure the benefits of assisted reproductive procedures, established procedures, and human reproductive research for individuals and for society in general by taking appropriate measures for 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
- b) to prohibit unacceptable assisted reproductive procedures and unacceptable human reproductive research
- c) to prohibit certain commercial transactions relating to human reproduction
- d) to provide a robust and flexible framework for regulating and guiding the performance of assisted reproductive procedures and the conduct of human reproductive research
- e) to prohibit the performance of assisted reproductive procedures (other than established procedures) or the conduct of human reproductive research without the continuing approval of the ethics committee
- f) to establish a comprehensive information-keeping regime to ensure that people born from donated embryos or donated cells can find out about their genetic origins.

The HART Act contains seven principles, by which all persons exercising powers or performing functions under the Act must be guided. These are:

- a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure should be an important consideration in all decisions about that procedure
- b) the human health, safety, and dignity of present and future generations should be preserved and promoted
- c) 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
- d) no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent

- e) donor offspring should be made aware of their genetic origins and be able to access information about those origins
- f) the needs, values, and beliefs of Māori should be considered and treated with respect
- g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

The HART Act prohibits certain uses of human embryos. It is prohibited to artificially form and implant into a uterus a cloned embryo or a hybrid embryo.

It is also an offence to do anything to cause the development of an *in vitro* embryo outside the body beyond 14 days from its formation. In this discussion paper, all reference to embryos, therefore, refers to embryos only up to and including the 14th day after their formation. Extensive penalties can be applied to any person breaching these and other prohibitions.

The HART Act is discussed further, within the context of other relevant legislation, in chapter 6.

The HART Act established two committees: the Advisory Committee on Assisted Reproductive Technology (ACART) and the Ethics Committee on Assisted Reproductive Technology (ECART).

Advisory Committee on Assisted Reproductive Technology

ACART's role is to:

- issue guidelines and advice to the ethics committee on any matter relating to any kind of assisted reproductive procedure or human reproductive research
- provide the Minister with advice on aspects of, or issues arising out of, kinds of assisted reproductive procedure or human reproductive research
- monitor the application, and health outcomes, of assisted reproductive procedures and established procedures, and developments in human reproductive research.

The Minister of Health appoints members to ACART. The HART Act specifies that ACART's membership must include:

- one or more members with expertise in assisted reproductive procedures
- one or more members with expertise in human reproductive research
- one or more members with expertise in ethics
- one or more Māori members with expertise in Māori customary values and practice and the ability to articulate issues from a Māori perspective
- one or more members with expertise in relevant areas of the law
- one or more members with the ability to articulate the interests of children.

At least half the members of ACART must be laypersons.

Ethics Committee on Assisted Reproductive Technology

ECART's role is to consider and determine applications for approvals for assisted reproductive procedures or human reproductive research and keep under review approvals previously given. Approval can only be given if the activity is consistent with guidelines or advice given by ACART.

Fertility Services Standard

The HART Act deems fertility services to be included within the definition of 'specified health or disability services' set out in section 4(1) of the Health and Disability Services (Safety) Act 2001: the HDS(S) Act. The purpose of the HDS(S) Act is to:

- promote the safe provision of health and disability services to the public
- enable the establishment of consistent and reasonable standards for providing health and disability services to the public safely
- encourage providers of health and disability services to take responsibility for providing those services safely
- encourage providers of health and disability services to the public to continuously improve the quality of those services.

Section 81 of the HART Act outlines an interim arrangement by which services may be deemed to comply with the HDS(S) Act, and allows time for a fertility services standard to be developed and for providers to comply with that standard. Standards New Zealand is in the process of working with the sector and consumer groups to develop this standard. The standard will focus on the safety and quality of fertility services, including promoting ongoing quality improvement by services, and will set out the minimum requirements services must achieve in order to obtain certification under the HDS(S) Act.

1 Introduction

1. Section 37 of the HART Act sets out ACART's requirements to provide specific advice on human reproductive research. ACART must, within timeframes agreed with the Minister of Health, provide the Minister with information, advice and, if it thinks fit, recommendations on the following matters in relation to the use of gametes and embryos in human reproductive research:
 - cloned embryos
 - donations of human embryos
 - genetic modification of human gametes and human embryos
 - human gametes derived from foetuses or deceased persons
 - hybrid embryos
 - requirements for informed consent
 - the import into, or export from, New Zealand of human gametes or *in vitro* human embryos.
2. This discussion paper does not cover:
 - the use of gametes from foetuses – ACART will wait for the National Ethics Advisory Committee's findings on the research use of tissue from stillborn babies and foetuses before addressing the use of gametes from foetuses for research purposes
 - human assisted reproductive procedures – a discussion paper on assisted reproductive procedures will be released for consultation in April 2007.
3. This paper discusses:
 - embryo growth and development (chapter 2)
 - the possibilities for gamete and embryo research (chapter 3)
 - the needs, values and beliefs of Māori (chapter 4)
 - other ethical, spiritual and cultural perspectives (chapter 5)
 - regulation in New Zealand (chapter 6)
 - an international overview of gamete and embryo research, policy development and legislation (chapter 7).
4. The paper concludes with a summing up of the issues raised in previous chapters. Although both gamete and embryo research are covered in this paper, it is weighted towards a discussion of issues in embryo research. This is because ACART considers that embryo research raises more complex issues and is of greater concern to New Zealanders.
5. Embryo research is a complex area, both scientifically and ethically, and inevitably this discussion paper contains a number of terms that readers may find unfamiliar. As an aid to comprehension, where a technical term is used, it is given in bold on first occurrence and defined in the Glossary at the back of the discussion document.

6. Similarly, a large number of abbreviations can be off-putting and confusing. We have attempted to eliminate them where possible, and have only used abbreviations where a name is used so frequently that its repetition would be undesirable. These abbreviations are:

ACART	Advisory Committee on Assisted Reproductive Technology
ECART	Ethics Committee on Assisted Reproductive Technology
HART Act	Human Assisted Reproductive Technology Act 2004
HFEA	Human Fertilisation and Embryonic Authority (United Kingdom)
IVF	<i>in vitro</i> fertilisation
PGD	preimplantation genetic diagnosis
SCNT	somatic cell nuclear transfer.

All of these items are further explained in the Glossary.

7. ACART is working in partnership with Toi te Taiao: the Bioethics Council. Toi te Taiao has conducted a public consultation on the cultural, ethical and spiritual aspects of using human **embryos** for research. The aim of this dialogue was to encourage community discussion and to get people thinking about their own ethical, spiritual and cultural views on human embryos and what issues human embryo research might raise. Information about Toi te Taiao and this dialogue is available online at <http://www.bioethics.org.nz>.
8. The work of Toi te Taiao will feed into ACART's advice to the Minister in two ways. First, it will raise awareness and encourage people to make their own submissions to ACART. Second, Toi te Taiao plans to make its own submission to ACART, which will be informed by the various views expressed throughout the dialogue process. Both these streams will provide valuable information for ACART to consider when formulating its advice to the Minister of Health.
9. Some of you will have made a submission as part of the dialogue facilitated by Toi te Taiao, and though that information will be referred to ACART, you may wish to make a further submission directly to ACART based on the specific questions asked here.
10. The detachable submission form at the end of this paper sets out how you can have your say and poses some questions to help you in structuring your submission. All submissions will be analysed and taken into consideration by ACART when preparing its advice for the Minister of Health. The analysis of submissions will be made publicly available in due course.
11. ACART has carefully considered the type of information it should present to the public, and has concluded that the best course is to provide a substantive discussion of the scientific, ethical, spiritual, cultural and legal issues relating to **gamete** and embryo research. ACART will supplement this discussion paper with public meetings, which will be held in February 2007. In addition, where groups self-organise to consider their submission, ACART will make every effort to attend if requested. Further information is available in the section 'How to Contribute', at the end of this discussion paper.

2. Embryo Growth and Development

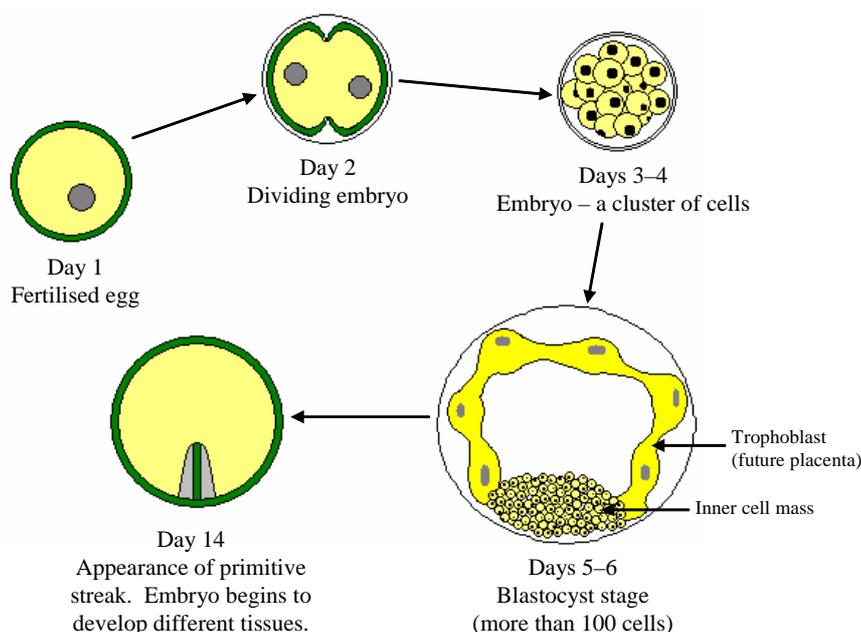
2.1 Embryo development

12. Human life begins from a single cell, which then divides many thousand times over to form all the different types of cells and tissues that make up the human body.
13. The earliest stage of the embryo (the fertilised egg) is sometimes referred to as the zygote. The term 'embryo' refers to the product of conception from the point of **fertilisation** up to the eighth week of gestation. After the eighth week of gestation, the embryo is then called a **foetus**, which is considered to be structurally complete in that all its organs have begun to form.
14. The initial eight-week period can be further divided into:
 - a) the pre-embryonic stage, which is the first 14 days after fertilisation, when the product of conception is known as the **pre-embryo** or **preimplantation** embryo
 - b) the embryonic stage, in the following six weeks (two to eight weeks after fertilisation), which is the embryo proper.

This chapter distinguishes between these two stages and uses the term 'pre-embryo'. The definition of embryo in the HART Act also refers to these first 14 days.

15. Embryonic development begins when an egg is successfully fertilised by a single sperm. This single cell eventually gives rise to both the foetus and the placenta. On the second day of development, the cell divides to form two daughter cells, each of which divides, producing four cells, then eight cells, and so on. These cells, known as the **blastomeres**, are identical, and at the eight-cell stage are only loosely associated with one another. At this point in development each of the blastomeres has the capacity to form a complete human being – they are **totipotent**. However, it is likely that by the 32-cell stage they have lost this equal developmental potential.

Figure 1. Normal gestation during the pre-embryo stage



16. By day five the pre-embryo consists of more than 100 cells. At this stage it is called a **blastocyst**, comprising a ball of cells enclosing a fluid-filled cavity and an interior cluster of cells. The external cells of the ball become firmly attached to each other and form what becomes the **trophoblast**, which eventually develops into the placenta. Many of the internal cells, called the **inner cell mass**, remain **undifferentiated** (unspecialised), which means they retain the potential to form every type of tissue involved in the construction of the foetus. This means the cells are **pluripotent**. Some of these cells will later form the embryo proper and subsequently the foetus.
17. By day seven the first sign of the beginning of **implantation** appears when the blastocyst becomes embedded in the wall of the uterus and the placenta begins to form. This will enable the exchange of food and fluids between the mother and the developing embryo (and later foetus). The process of implantation is usually complete by day 14.

2.2 The distinction between pre-embryo and embryo

18. The main focus of this section is the pre-embryonic stage. This is because under New Zealand law it is an offence to do anything to cause the *in vitro* development of a human embryo outside the body of a human beyond 14 days after its formation. There are a number of reasons why the pre-embryo has been accorded a different legal status.
19. The term 'pre-embryo' was coined by Professor Anne McLaren in 1986 to describe the product of the fertilised egg up to the point at which it completes implantation into the **uterus** (McLaren 1986). During the 14-day preimplantation period, the structure includes a relatively small number of cells that will form the embryo proper, as well as a much larger number of cells that will form support tissues for the embryo, such as the placenta (see above). In other words, the pre-embryo is far more than simply the precursor to the foetus. This is in comparison to the embryo proper, whose cells are wholly committed to forming the developing foetus.
20. In addition, around days 14 to 15 an aggregation of cells called the **primitive streak** appears in the midline of the embryo. This important development is discussed a great deal by ethicists for a number of reasons. For a start, its presence shows that the embryo is acquiring right and left sides. It also indicates the beginning of the establishment of the three basic embryonic **germ layers**, which lead to all the major tissues of the body. After this stage only a single individual can be formed if there is a single primitive streak (two primitive streaks are necessary for twins), and embryonic cells are now committed to forming specialised tissues and organs (the cells are now **multipotent**). The primitive streak is the first sign of the beginning of the nervous system.
21. It was recognition of these differences that led to the use of the term 'pre-embryo', with the implication that it may be accorded lesser moral status than the embryo proper. It has been argued that only after 14 days is there a spatially defined entity capable of developing into a foetus and infant. Day 14 is considered of such biological significance that even in societies that allow research on human embryos, no such research can be conducted on an embryo older than 14 days.

22. However, it cannot simply be assumed that these initial stages of development are of lesser significance morally than the later stages. To distance themselves from such a viewpoint, some authors avoid the term 'pre-embryo', instead using the more traditional terms associated with the entire eight-week embryonic period. Whatever the differences in terminology, it is important to be aware of the details of the first 14 days of development given that they are the focus of many scientific studies and the basis of debate on the conduct of embryo research. Furthermore, the HART Act excludes the possibility of research on embryos after the 14th day.

2.3 Established technical methods for creating embryos: IVF

(See question 4 in the submission form)

23. **In vitro fertilisation** (IVF) is the most commonly used method of assisted human reproduction. With this technique, eggs and sperm are mixed together *in vitro*; that is, in suitable chemical media in the laboratory. Embryos formed in this procedure are transferred into the uterus, usually at around the eight-cell stage. IVF is a procedure that attempts to reproduce what happens in non-assisted reproduction, the difference being that eggs and sperm are acquired and then fertilised in the laboratory rather than in a woman's fallopian tubes. The clinical application of this technology was realised in 1978 with the birth of Louise Brown by IVF in the United Kingdom.
24. IVF is constantly being refined through research and the development of various techniques. These techniques include **intracytoplasmic sperm injection**, which in some cases increases the chance that an embryo will be formed by directly injecting a single sperm into an egg. Improvements in culture media and techniques for transferring the embryo into the uterus have also increased IVF success rates.
25. As in non-assisted reproduction, live birth rates from IVF and its associated techniques are relatively low. In New Zealand and Australia in 2003, 23.7 percent of fresh non-donor embryo transfers resulted in live births, compared to 16.2 percent when using frozen embryos (Waters et al 2006). In comparison, the **Human Fertilisation and Embryonic Authority** (HFEA) reports an average of 25.4 percent live births from all embryos transferred, with the individual clinic success rate ranging from 42 percent to 12.1 percent (HFEA 2002). In the United States the average success rate has been reported as 31.9 percent for all embryos transferred (Society for Assisted Reproductive Technology and the American Society for Reproductive Medicine 2004).
26. Only around 60 percent of eggs fertilised *in vitro* develop into usable embryos on day three, and of these only 50–70 percent become usable blastocysts. Most embryos fail to develop because they have chromosomal abnormalities, the incidence of which is estimated to be around 70 percent, although it is lower in younger women and higher in older women. After implantation, further loss of embryos occurs.
27. These figures are similar to what happens in non-assisted reproduction, where birth rates show variation according to the age of both the male and female (though it appears to be mainly dependent on the female) and the day of sexual intercourse relative to the day of ovulation. The peak fertility of an average couple is estimated to be approximately 37 percent per monthly cycle (Dunston et al 2002).

2.4 Emerging technical methods for creating embryos

(See question 4 in the submission form)

28. Embryos can be created in ways other than by the process described above. Although some of the alternatives can occur during non-assisted reproduction (eg, through **embryo splitting**), it is the more recent attempts to produce embryos in the laboratory that have generated extensive debate.
29. A number of the methods described below go beyond the well-known process of IVF by attempting either to bypass fertilisation altogether or to modify it in some way. Although they are relatively undeveloped, having generally not yet progressed to the point of being tested on human tissue, the scientific and clinical potential of such methods is considerable. In theory they could lead to the formation of a structure that is in effect an embryo, with the potential of forming a foetus.

2.4.1 Cloning

30. The area of embryo creation that causes the greatest public interest and concern is 'cloning'. However, in science this broad term covers a variety of procedures, not all of which involve embryo creation, including:
 - molecular cloning, which involves making millions of identical copies of **genes**
 - cell cloning, where cell lines with identical properties are produced for the study of the biology of specific cells
 - **somatic cell nuclear transfer (SCNT)**, involving the production of one or more exact copies of any given cell, or a whole organism; this category can be further divided based on whether the technique produces cells and tissues (**therapeutic** or research **cloning**) or a new organism (**reproductive cloning**)
 - embryo splitting, where the embryo is divided into two embryos.¹

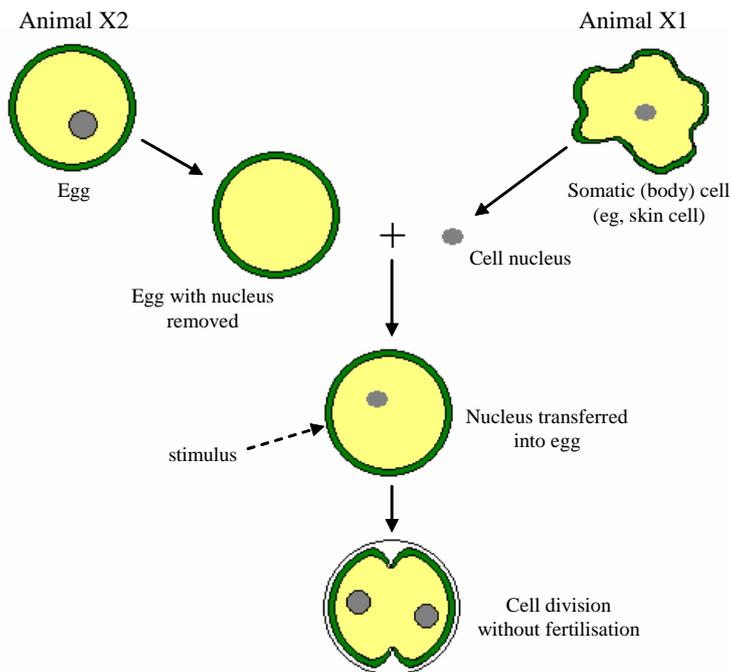
Of the above procedures, only the third and fourth are relevant to this discussion.

Somatic cell nuclear transfer (SCNT)

31. By removing the nucleus from a donor cell (such as a skin cell of animal X1) and introducing it to an **enucleated egg** of animal X2 (an egg that has had its nucleus removed), the nucleus from the donor cell becomes reprogrammed. The egg is then stimulated chemically or electronically, enabling the egg with its new nucleus to develop into an animal genetically identical to X1 when implanted into a uterus (see Figure 2). The new animal is a clone of X1. In SCNT, animals X1 and X2 are of the same species.

¹ This also occurs in non-assisted reproduction, resulting in identical twins.

Figure 2. SCNT: cell division without any preceding fertilisation



32. This technique has been used to clone sheep, cattle, goats, mice, pigs, cats and rabbits from adult body cells, but as yet has not produced rats or primates (Wilmut et al 2002). This method, known as reproductive cloning, was used to clone Dolly the sheep (Wilmut et al 1997). Strictly speaking, however, animals (clones) produced by this technique are not identical to their progenitors, as is often claimed, because they also contain **mitochondrial** genes from the cytoplasm of the host egg and because of the effects of **genetic imprinting**.
33. Another application of nuclear transfer is therapeutic cloning (sometimes called research cloning). Here SCNT is used to produce a very early embryo (zygote or blastocyst) to serve as a source of **embryonic stem cells**. In this case, the goal is to produce cells or tissues rather than complete offspring, and so there is no intention of implanting the very early embryo in a female's uterus.
34. At present, these cells or tissues produced via SCNT are mainly used in research on the earliest stages of cell development, and of cell and tissue **differentiation** and growth. The longer-term goal for human therapeutic cloning is to coax embryonic stem cells from **cloned embryos** to form specific cell types, which could then be used to produce newly generated tissues to replace damaged or defective tissues in patients, and so be used potentially to cure certain diseases.
35. With low success rates and high abnormality rates in the cloned offspring of experimental animals, both before and after birth, reproductive cloning continues to be associated with numerous scientific problems.

Embryo splitting

36. Embryo splitting is considered the most conservative of the human cloning techniques. It involves a process similar to the natural way in which identical twins or triplets are formed (although the natural process usually involves a subdivision of the inner cell mass). With embryo splitting, half the cells (blastomeres) will form one embryo, leaving the other half to form a second embryo. Theoretically it is possible to form more than two embryos in this way given that even a single blastomere can result in a complete embryo.

2.4.2 Parthenogenesis

37. Although **parthenogenesis** can be used to form an embryo, the technique moves further away from natural processes. Here an egg is encouraged to develop without first being fertilised by sperm. Parthenogenesis occurs naturally in lower animals, but in mammals this usually leads to death of the embryo within days.
38. In late 2004 and 2005, United Kingdom researchers discovered and applied a biological enzyme found in sperm to encourage the egg to divide (Rogers et al 2004). The scientists believe that this so-called ‘virgin conception’ may provide a more ethically acceptable way of creating embryonic stem cells, because the **parthenote** would not be classified as a true embryo with the potential for life (Kieślinski 2005). However, technical difficulties associated with the procedure may rule out its use as an efficient alternative source of embryonic stem cells.

2.4.3 Hybrid and chimeric embryos

39. The HART Act refers to ‘hybrid’ embryos. In the Act these are defined as embryos that are formed by mixing genetic material from two different sources or species, whether by normal fertilisation, cell nuclear transfer or otherwise. A ‘**chimeric**’ embryo is one that contains a mixture of cells from two or more different sources or species. Such embryos raise additional technical and safety issues, but could provide a resource for further research (House of Commons Science and Technology Committee 2005: 31–32).
40. Chimeric embryos are unlikely to develop very far, but they could be used to examine the proliferation and differentiation of human stem cells and to test the pluripotency of embryonic stem cells (Goldstein et al 2002; Muotri et al 2005). If injected cells integrate into the embryo and contribute to all tissues, they fulfil the requirements for pluripotency. In theory, the pluripotency of human embryonic stem cells could be evaluated by introducing them into an embryo of another species, hence forming an interspecies human chimeric embryo.
41. Forming a hybrid/chimeric embryo via cell nuclear transfer involves transferring nuclear DNA from one cell into the enucleated egg of another species in a process similar to somatic cell nuclear transfer (SCNT). For example, transferring a human nucleus into a rabbit egg would produce a human–rabbit hybrid that could be used as a source of human-like embryonic stem cells or as a model of human diseases. The use of non-human eggs would bypass the need for a large number of donated human eggs, as would be required to develop SCNT technology (see section 2.4.1). Permission to create a human–rabbit hybrid has recently been sought from the HFEA.²

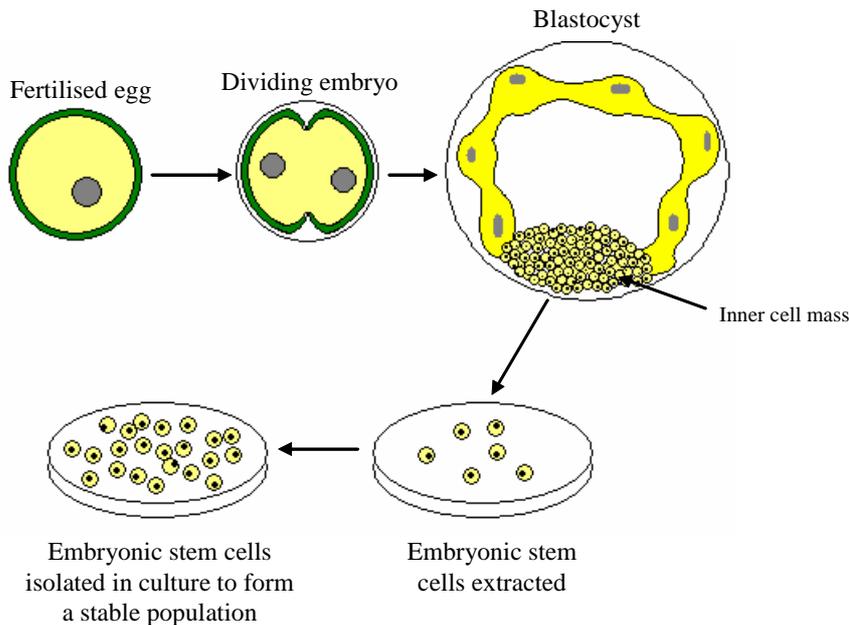
² <http://news.bbc.co.uk/1/hi/health/4605926.stm>

2.5 Human stem cells

2.5.1 Human embryonic stem cells

42. Human embryonic stem cells are derived from cells from the inner cell mass of the blastocyst (see Figure 3) (Reubinoff et al 2000; Lazendoff et al 2001). Once isolated, such cells can be grown in culture in the laboratory to form a human **embryonic stem cell line** and used for research purposes. Embryonic stem cell lines are derived from embryos, but they are not themselves embryos. Such cells cannot give rise to human beings. This is because the cells of both the inner cell mass, which are embryonic stem cells, and the trophoblast, which gives rise to tissues such as the placenta, are needed to allow an embryo to implant in the womb and grow to term. The inability of human embryonic stem cells to give rise to human beings means they are not totipotent.
43. Cells divide many times and very quickly in the embryonic and early foetal stages of development. As they divide, they differentiate into the vast array of different cell types found in adult humans. Some cells become skin cells, others become nerve cells, others blood cells, and so on. The process of differentiation begins very early in development. Human embryonic stem cells are relatively undifferentiated and have been shown to be able to give rise to a large number of cell types. Importantly, the cell types so far derived have come from all three of the body's basic germ layers, suggesting that human embryonic stem cells may have the potential to give rise to every cell type.
44. This ability to give rise to such a large and diverse range of cell types means that human embryonic stem cells are pluripotent. Combined with the human embryonic stem cell's ability to be cultured for long periods of time, this pluripotency is the main reason why many researchers believe such cells are crucial to our understanding of human development and disease (Thomson et al 1998).
45. Researchers have discovered that, under certain conditions, human embryonic stem cell lines can be maintained in an undifferentiated state in the laboratory for months, or even years. Other types of stem cells are not so easy to culture. For example, **adult** (or somatic) **stem cells** tend to differentiate spontaneously after a relatively short time. The ease with which human embryonic stem cell lines can be maintained gives them considerable promise as a research tool because a single line can be used for a number of research projects.
46. Researchers do not yet know what chemical signals are used to direct embryonic stem cells to differentiate into specialised cell types inside the human body. Although many of these chemical signals have been identified *in vitro*, it remains less clear what signals are involved if these cells are placed in humans. If researchers can identify these signals, they may eventually be able to influence the type(s) of cells into which embryonic stem cells mature, and then explore possible therapeutic applications of this technology. Continued study, including of safety issues, is necessary to see whether it is possible to achieve the ultimate aim of using embryonic stem cell technology to produce functional cells.

Figure 3. Extraction of embryonic stem cells from the blastocyst



2.5.2 Alternative sources of human stem cells for research

47. Because of the ethical debates associated with using human embryonic stem cells for research, efforts to create cells with the same properties as human embryonic stem cells in ways that do not require the destruction of human embryos have been taken very seriously. In the United States, the President's Council on Bioethics has recently reported on four such potential alternative sources of human pluripotent stem cells (President's Council on Bioethics 2005). These sources are:
 - cells obtained as part of embryo **biopsy**
 - 'biological artefacts' similar to embryos created via **altered nuclear transfer**
 - frozen embryos that fail to thrive after thawing and may therefore already be dead
 - adult (**somatic**) **stem cells**.
48. Preliminary animal studies have been conducted for the first two sources to show that the methods involved work in principle. 'Proof in principle' for the first was shown by removing a single cell from an eight-cell mouse blastocyst and, under the right conditions, prompting it to grow into a colony of embryonic stem cells (Chung et al 2005). This has also been shown in principle with human embryos (Klimanskaya et al 2006).
49. The second study, on 'biological artefacts', deliberately created an embryo with a disabled version of a gene that is crucial for the eventual growth of the placenta (Meissner and Jaenisch 2005). Without the placenta, the embryo has no chance of ever growing into a fully functional individual.
50. These alternative sources are currently considered to be highly experimental by most researchers. Further research may allow these cells to be used in place of human embryonic stem cells, although this is far from certain at present.

51. Although the embryo is the focus of this consultation, the ethical and societal ramifications of using embryos as the source of embryonic stem cells mean that it is also relevant to consider the potential of adult stem cells in alleviating diseases. The scientific merits of these two major categories of stem cells have been much debated in the scientific literature. In the ongoing scientific debate, it is likely that both embryonic and adult stem cells will be recognised as having contributions to make in the repair of damaged tissue.

3. Possibilities for Gamete and Embryo Research

52. The earliest stages of development, involving the progression from egg and sperm to zygote and embryo, are of considerable scientific interest. Research on these stages is motivated by the possibility of understanding why serious developmental anomalies are most likely to occur during the first few weeks of development, and thus of devising ways of treating and even preventing them.
53. However, before this goal can be achieved, knowledge of how the process works must improve so that it is possible to unravel the mechanisms by which cells develop into different cell and tissue types. It is realistic to expect that when these periods in human development are understood, control over these early stages will become feasible.
54. Such research goals have been made possible only by the availability of techniques to maintain embryos in the laboratory in a **viable** condition. As well as giving rise to all current testing and research procedures on embryos, these techniques have made possible well-established procedures such as IVF. They may continue to be critical in improving fertility treatments and devising therapies to overcome a range of diseases. Consequently embryo research is of interest and significance to a wide range of people, including the general public, intending parents, doctors, policy-makers, ethicists and scientists.

3.1 Sources of embryos for research

(See question 4 in the submission form)

3.1.1 Non-viable embryos

55. As in non-assisted reproduction, 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.
56. These embryos are considered '**non-viable**' and have been approved in New Zealand to be used in research. They are subject to the relevant interim guidelines (NECAHR 2005).

3.1.2 Surplus embryos

57. One of the consequences of creating embryos for IVF is sometimes having a surplus of embryos. This surplus occurs as a result of the hormonal regimen prescribed for women undergoing IVF, which causes them to superovulate and produce a number of eggs in a single cycle. The clinical advantage of this practice is that a number of eggs are available for fertilisation, so that the woman need not undergo further hormonal stimulation.
58. With modern techniques it is possible to create a large number of embryos as part of IVF treatment, and from this pool of embryos a choice can be made as to which of them is most suitable for transfer. Suitable embryos not transferred can be frozen for subsequent use. Nowadays, only one or two embryos are inserted into the woman's uterus in any one cycle (formerly it could be up to three), leaving a number to be frozen for subsequent use.

59. A consequence of this practice is the existence of embryos that will never be required for reproductive purposes. Such **surplus embryos** may continue to be stored, discarded, donated to others, or donated for use in research. The options available in different countries are limited by the regulatory and policy context within those countries. In New Zealand, for embryos stored after November 2004 there is a maximum storage period of 10 years; these embryos can also be discarded at any stage and, as of 2005, donated for reproductive purposes. This discussion paper seeks your comments (see question 4 in the submission form) on whether they should also be able to be donated for use in research.
60. Most embryos used in research overseas come from fertility clinics. Only a small proportion of people (between 5 and 11 percent) are willing to donate their surplus embryos to others for reproductive purposes (Van Voorhis et al 1999; Kovacs et al 2003). The estimated number of embryos in frozen storage in Australia and New Zealand is around 100,000 (Waters et al 2006). Although the number of frozen embryos is increasing, the rate at which this occurs is now slowing. Whereas formerly all the surplus embryos were frozen, they are now allowed to develop further to assess their viability, and only the viable embryos are then frozen.
61. **Preimplantation genetic diagnosis (PGD)** identifies those embryos that carry genetic diseases passed down from their parents, and these embryos can also be considered surplus because they may never be transferred to a woman's uterus. These embryos could also be used for research into specific hereditary diseases.

3.1.3 Embryos created specifically for research

62. Another possible source of embryos for embryonic stem cell research is those created specifically for research. There are a number of ways to do this. The first is by the *in vitro* fertilisation of an egg by a sperm. The creation of IVF embryos for research would currently require egg cells from the ovaries of female donors. There is also a future possibility that eggs could be matured from donated ovarian tissue.
63. Some researchers consider there may be significant advantages to creating embryos for research through IVF, such as allowing the study of embryonic stem cell lines with known genetic profiles. For example, it would be useful to study a line with a gene that causes susceptibility to a given condition in order to develop therapies for that condition.
64. Researchers can also create embryos for research using somatic cell nuclear transfer (SCNT), that is, by therapeutic cloning, where the resultant embryo would have the same genetic profile as the donor cell (see 2.4.1). These embryos could provide tissue or embryonic stem cells for therapeutic use. If a patient provided the donor nucleus, the transplanted tissues would be derived from the patient's own embryonic stem cells and so would be genetically identical to his or her own tissues, thereby eliminating the risk of tissue rejection by the immune system.
65. This would be a major advantage in terms of both cost and health outcomes, because **immunosuppressants** are expensive and cause a range of side effects. In addition, there could potentially be an unlimited supply of organs for transplant, because they could be grown in laboratories on demand. In the United Kingdom, 118 embryos were created by this means between 1991 and 1998 (Chief Medical Officer's Expert Group 2000). However, person-specific therapies using SCNT embryos will almost certainly not be developed for a number of years.

3.2 Scientific and clinical contributions of gamete and embryo research

(See question 3 in the submission form)

66. This section outlines the medical and scientific contributions of gamete and embryo research to:
- fundamental science
 - fertility and infertility
 - prevention of hereditary disease
 - treatment of human disease.

3.2.1 Contribution to fundamental science

67. Fundamental research is required to realise many of the therapeutic possibilities of embryo research. This basic research can be seen as a beneficial outcome in itself. Investigations into the developmental pathways that lead to the birth of normal, healthy human beings can contribute to understanding the causes of foetal developmental abnormalities, which lead to miscarriages or to the birth of children affected by developmental disorders.
68. The United Kingdom's Human Fertilisation and Embryology Authority (HFEA) has approved studies on embryonic biochemistry, metabolism and development (HFEA 2005). Such studies may enable the development of additional methods for detecting genetic abnormalities before implanting an embryo fertilised *in vitro*. Hybrid and/or chimeric embryos of human and non-human species could be used to increase understanding of the development and production of stem cells, and to test stem cells and other treatments for their therapeutic effectiveness.
69. Genetic modification of gametes and embryos has proven to be a useful research tool in animals. By manipulating certain genes, researchers are able to study their specific function, and this has been particularly helpful in identifying the genetic causes of certain diseases (Willer et al 2004; Li et al 2000).

3.2.2 Contribution to fertility and infertility

70. Research with gametes and embryos has contributed to advances in the treatment of infertility, increased knowledge about the causes of miscarriage, and the development of more effective contraception. Relevant areas of further research that may lead to improvements in IVF and other areas of fertility and infertility treatment include:
- the nature of the influences required for human gametes to mature *in vitro*
 - the optimal conditions – including the appropriate culture media – for culturing human embryos
 - the most efficient ways of determining embryo quality so that only the healthiest embryos are transferred to the uterus
 - the processes influencing successful implantation
 - the biochemical processes in the preimplantation embryo.
71. Many research projects certified by the HFEA have involved investigations in the above areas. For example, it has approved studies on embryo implantation, *in vitro* fertilisation of eggs, egg freezing, and the environmental sensitivity of preimplantation embryos (HFEA 2005: 38–9).

72. Discovering ways of improving gamete and embryo quality or of selecting embryos with the greatest potential for growth may improve the chances of a successful pregnancy. Progress in this area may also contribute to a reduction in miscarriage rates (Macklon et al 2002).
73. Good predictive markers of the developmental potential of both gametes and embryos have yet to be developed. However, techniques that provide a way of measuring this before an embryo is implanted are in use, such as preimplantation genetic diagnosis (PGD).
74. Embryo quality may be improved by correcting deficiencies in the embryos themselves. There are a number of methods that could be used to achieve this. Egg nucleus transfer may be utilised to overcome embryo loss due to mutations in the mitochondria, the energy-producing structures of a cell, which contain DNA that is inherited only from the mother. Defects in mitochondrial DNA are known to contribute to more than 50 inherited diseases. Such diseases could be avoided by transferring an egg **pronucleus** from a carrier mother to a non-affected, enucleated donor egg, producing an embryo with nuclear DNA from one woman and mitochondrial DNA from another. However, this technique presents several technical challenges, and the HFEA has only recently approved research into this field.³
75. Some factors relating to sperm can also reduce fertility. For example, the normal growth of an embryo may be constrained by defects in the **centrosome** in sperm, which normally allows embryonic cells to divide and proliferate over a sustained period and ensures correct chromosomal segregation. Transferring a centrosome from a non-affected man to sperm from an affected man may be one solution.
76. Another emerging technique that has been carried out on a small number of women involves manipulating the egg cytoplasm (**ooplasm**) to improve embryo quality. It is possible that deficiencies in the egg cytoplasm could contribute to developmental failure, perhaps by not providing the correct metabolic requirements for a developing embryo. This could contribute to the decline in fertility of women after 35 years of age. Transferring the ooplasm from the egg of a younger woman into a recipient egg may provide the requirements needed for maturation of the egg and development of the embryo (Hardy et al 2002). Further research could potentially improve this technique.

3.2.3 Contribution to the prevention of hereditary diseases

77. Preimplantation genetic diagnosis (PGD) is a procedure for testing the embryo for the presence of chromosomal disorders or defective genes. In this procedure, one or two cells (blastomeres) are extracted from the pre-embryo and tested. There is as yet no evidence to suggest that the cell biopsy adversely affects the health of the resulting child, although this has been questioned and longitudinal studies to examine any long-term effects have been called for (ESHRE PGD Consortium Steering Committee 2002; President's Council on Bioethics 2004).
78. PGD analysis can be used to check for any abnormalities in the number of genes or chromosomes. It can also be used to detect specific genes, as may be required in disorders such as **Duchenne's muscular dystrophy, haemophilia, haemoglobin diseases, cystic fibrosis, Huntington's disease** and **achondroplasia**. Parents may not be aware that they carry a genetic disorder until they have an affected child. PGD can then be used to avoid the condition in any subsequent children.

³ <http://news.bbc.co.uk/2/hi/health/4228712.stm>

79. Eggs can also be subjected to PGD techniques to diagnose defective maternal gametes before fertilisation. The egg itself cannot be tested as it would then be rendered unsuitable for fertilisation. However, the egg divides to produce a **polar body** – a small, non-functional, genetically identical cell – which can be removed and analysed in a polar body biopsy. This procedure, which involves a similar technique to the diagnosis of a blastomere, offers a way to select for only the healthiest eggs to be used in IVF. Its main disadvantage is that it does not allow analysis of the paternal contribution to the embryo, thus preventing diagnosis of autosomal dominant diseases and sexing of the embryo.
80. Embryo research in this area is directed at improving PGD techniques, to make it a more efficient and reliable procedure and to investigate the effect of blastomere removal on subsequent embryonic development. A technique that has emerged from such research is **comparative genomic hybridisation** (CGH) or array CGH. In contrast to current PGD techniques, in which only a limited number of chromosomes or genes can be analysed, CGH enables the analysis of all chromosomes in a blastomere or polar body (Wilton 2005).
81. Researchers are also exploring different methods of obtaining cells for biopsy, investigating novel diagnostic techniques and expanding the number of genetic disorders that can be detected through standard PGD procedures (HFEA 2005: 38–9).
82. The next step beyond screening out the embryos with undesired genes, as in PGD, is the possibility of ‘fixing’ those embryos by replacing undesired genes with desired ones; that is, undertaking gene therapy. However, the technical details of gene therapy on embryos present significant obstacles, such as how to insert and ensure correct expression of the gene. Also, genetically modifying the **germ-line** of an embryo and the ensuing adult raises significant concerns as to the long-term effect of the modifications being passed on to subsequent generations.
83. Research on genetic modification of embryos could theoretically be extended to produce children who are ‘better than well’ by the insertion of genes for desired traits such as beauty, intelligence and height. However, these aspirations are likely to be difficult if not impossible to achieve because of the complexity of genes related to any such trait and the significant influence of the environment on them (President’s Council on Bioethics 2003: 37–40).

3.2.4 Contribution to treating human disease

84. Although much of the research involving embryos relates to treatments for overcoming infertility, research into treatments for other medical conditions in adults is gaining funding and ethical approval around the world, particularly in the United Kingdom (HFEA 2005: 38–9).
85. Most of the therapeutic potential of embryo research is centred on the use of embryonic stem cells, and this is the major focus of this section. However, it should be noted that there are potential therapeutic benefits to embryo research aside from these cells. Basic research into cell growth, proliferation and differentiation may help to develop therapies for genetic disease, as well as suggesting ways of preventing such genetic diseases from forming.
86. Despite the debates surrounding embryonic stem cells, some jurisdictions are now allowing scientists to pursue research to unlock the therapeutic capacity of these unique cells. The HFEA has approved projects researching procedures necessary to

isolate human embryonic stem cells, culturing protocols, and how to direct differentiation of embryonic stem cells to specific tissue types (HFEA 2005: 38–9).

87. Most researchers see the main goal of human embryonic stem cell research as the development of new therapies through the discipline of regenerative medicine. Because human embryonic stem cells are able to give rise to any type of cell, they may be able to be used to replace cells lost through injury or disease. Some specific potential focuses of regenerative medicine are:
- the regeneration of heart muscle cells following a heart attack
 - the creation of replacement pancreatic cells for people with juvenile onset diabetes
 - the implantation of regenerated neurons or neural support cells for the treatment of neurological conditions such as stroke, Parkinson’s disease, Alzheimer’s disease, multiple sclerosis and spinal cord injury
 - the treatment of autoimmune diseases, where the immune system attacks healthy instead of foreign cells, such as in **lupus**, rheumatoid arthritis and **inflammatory bowel disease**. Treatment could involve replacing the defective immune system with one that does not attack body cells.
88. Human embryonic stem cells could also be used to treat burns, wounds, or coronary heart disease by manipulating the stem cells to create different cell types that are involved in these diseases and conditions. Although research on human embryonic stem cells is at an early stage, the potential benefits from this type of research are substantial. Nevertheless, therapies to treat disease and relieve human suffering will not be developed from human embryonic stem cells for a number of years. An appropriate degree of caution is therefore necessary in discussing the potential benefits of this research.

4. Needs, Values, and Beliefs of Māori

(See question 9 in the submission form)

89. The HART Act states that all persons exercising powers or performing functions under this Act must be guided by its principles, including that “*the needs, values and beliefs of Māori should be considered and treated with respect*”.
90. When developing advice to the Minister on the use of gametes and embryos in research, ACART will therefore consider and respect the needs, values and beliefs of Māori. However, as in other communities, Māori perspectives are diverse and may differ not only between but also within iwi, hapū, and whānau. It is unlikely that there will be a single Māori view on the use of gametes and embryos in research, although there may be concerns that are common arising from within te ao Māori (the Māori world view).
91. The Human Genome Research Project found that there was no dominant viewpoint on the appropriateness or otherwise of the termination of embryos through pre-birth genetic testing in relation to traditional practices (Human Genome Research Project 2006). Although the issues examined in this discussion paper are different, they are linked by the attitude towards the use of human embryos – either for research or during pre-birth genetic testing.
92. This chapter recognises the diversity of opinion among Māori on the use of gametes and embryos in research. This is a relatively new field of scientific research in New Zealand, and there is limited published information on Māori attitudes to the use of gametes and embryos in research. Consequently, this chapter seeks to foster debate in the Māori community by tentatively outlining some of the concepts, perspectives and tikanga that may be relevant to the issue. Here tikanga is taken to mean the ‘right ways’ of dealing with issues that arise in this topic.
93. It is therefore useful to think about the following concepts when considering the tikanga that may apply to the use of gametes and embryos in research:
- wairua
 - whakapapa
 - whanaungatanga
 - mauri
 - mana
 - kaitiakitanga and tino rangitiratanga.
- These concepts are briefly outlined below.
94. ACART welcomes your view on these and any other tikanga relevant to the use of gametes and embryos in research. As part of this consultation it is essential that Māori perspectives are known and understood by ACART so that it can provide informed advice to the Minister of Health on the use of gametes and embryos in research.

4.1 Wairua

95. The spirit within all things, wairua is the counterpoint to the physical element of existence (Barlow 1994). A key debate may be around when wairua enters the embryo – whether wairua takes hold at conception, during the embryonic stage, during the foetal stage or at birth. Some may hold the view that the wairua enters the embryo as soon as the sperm and the egg come together to form the zygote, while others may consider the wairua only enters when the new child is welcomed to the world at birth.

4.2 Whakapapa

96. Whakapapa is the genealogical descent of all living things from the gods to the present time (Barlow 1994). Te ao Māori has its roots deeply entrenched in whakapapa, with a focus on the importance of relationships between tangata whenua (people of the land) and the natural world. Whakapapa not only identifies links among Māori, but also links between Māori and the wider universe and the natural environment. Whakapapa is thus a fundamental way to understand the world and consequently the place of tangata whenua in it. It is the way the world and everything in it is balanced. A key concern for some Māori may be whether whakapapa would be disrupted through the use of human gametes and embryos in research.

4.3 Whanaungatanga

97. Whanaungatanga relates to an obligation of care and support among relatives. This suggests the importance of whānau considerations in any decision made involving donation of embryos or gametes to research, especially given that the whānau may be affected by the decision made by an individual.

4.4 Mauri

98. Mauri is the life force that permeates all things in te ao Māori – every living thing has a mauri. The use of embryos in research may involve debates over the origin of life and whether or not such an embryo has mauri. If an embryo does have mauri, there may be implications in using it for research. Further, there may be some questions about whether there is a difference in mauri between an embryo that is implanted in a uterus versus a preimplantation embryo held in a laboratory.

4.5 Mana

99. Mana is an abstract concept that implies authority, influence and prestige as well as the recognition of these qualities. Mana can be collective as well as individual, and may extend to include whānau, hapū, and iwi. There may be some concerns over who has the mana to make decisions in relation to Māori taking part in gamete and embryo research. This is a significant issue, especially if taking part in research or the research outcomes is seen as having effects on the mana of whānau, hapū, iwi or Māori in general. Māori may be concerned over whether the choice to be involved in this kind of research should be left to individuals or with a larger social grouping.

4.6 Kaitiakitanga and tino rangatiratanga

100. Kaitiakitanga means guardianship. This may refer to guardianship over genetic information or protecting the wellbeing of future generations. It is also about decision-making, discussion and debate, and the management and safeguarding of the physical, human and spiritual worlds.
101. There is a distinct relationship between kaitiakitanga and tino rangatiratanga (self-determination). Tino rangatiratanga involves the authority to make decisions about the future at both an individual and a collective level, and kaitiakitanga involves an obligation to safeguard future generations. It may be difficult for one to proceed without the other.
102. There may be some tension between the right of the individual to have a choice over engaging with gamete and embryo research versus the broader implications this involvement could have on whānau, hapū or iwi today and in the future. A concern may be to ensure the mana of all those affected by such research is maintained (and, ideally, increased).

5. Ethical, Spiritual and Cultural Perspectives

(See question 10 in the submission form)

5.1 Introduction

103. The HART Act states that all persons exercising powers or performing functions under this Act must be guided by its principles, including that “the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect”.
104. The earlier chapters on embryo growth and development and the possibilities for gamete and embryo research provide an outline of what can be done, or may in future be able to be done. Scientific knowledge is, however, of limited use in deciding what *should* be done. This needs to be informed by a society’s ethical, spiritual and cultural perspectives on gamete and embryo research.
105. New Zealanders will hold various spiritual and cultural values and beliefs that influence their perspectives on the use of gametes and embryos in research. There has been little research into New Zealanders’ attitudes to gamete and embryo research. The Royal Commission on Genetic Modification sought to understand New Zealanders’ attitudes to genetic modification, and while it may not be possible to relate the Commission’s findings directly to human reproduction, it can be noted that the Commission found that what people thought often arose from their ‘world view’ (Royal Commission on Genetic Modification 2001).
106. The Commission argued that in a pluralistic society such as New Zealand, people will draw their values from different sources and that it is not appropriate for one group to impose their values on another. What is important is to find some common core from which New Zealand can develop a framework for ethical decision-making (Royal Commission on Genetic Modification 2001).
107. Clearly, the topic of research using gametes and embryos raises complex and potentially divisive ethical and social questions. How individuals and different communities respond to questions about embryo research depends primarily on how they view the moral status of the embryo; that is, the extent to which the embryo should be recognised as a human being (person), with all the rights and protections associated with personhood.

5.2 Views concerning the status of the embryo

108. At one end of the spectrum are those who hold to the moral principle that the use of any embryo for research purposes, including stem cell research, is unethical and unacceptable. Their reasoning is usually that an embryo is entitled to full human status from fertilisation onwards, and that it is a ‘moral person’, capable of being harmed and benefited, just like children and adults. Consequently, destroying embryos would be considered akin to murder, and ethically comparable to killing a person. Embryos must be accorded the same rights and protections as adult humans. Arguing from this perspective, the destruction of embryos in the course of research cannot be justified.

109. At the other end of the spectrum are those who believe that the embryo (that is, the pre-embryo) has no moral status because it is not a human being and does not possess moral personhood. Some regard the embryo at its blastocyst stage as a mere collection of cells, lacking any of the rights of adult humans. Within such a view, embryos are not capable of being harmed or benefited. Their use is ethically defensible so long as other issues such as consent are adequately addressed. Arguing from this perspective, it is unethical *not* to use surplus IVF embryos for research that aims to alleviate human suffering.
110. Many other people adopt stances at various points between these two ends of the spectrum, considering that embryos have rights and are owed protections due to their potential to become moral persons that can be harmed and benefited, or to their shared genetic heritage. Nevertheless, these rights and protections exist to a lesser degree than do those of full moral persons. Within this view, embryos' rights and protections are to be weighed against the potential benefits of using embryos for research. Consequently, the ethical justification of research projects using human embryonic stem cells will depend on the potential benefits of the research and the quality of the scientific questions being asked.
111. Some research shows that different religious traditions, for example, have quite different perspectives on the moral status of the embryo and the relative weighing up of benefit versus harm involved in gamete and embryo research. There will also be differences within religious traditions.
112. The official position of Roman Catholicism is that life begins at conception. An embryo is, therefore, a human individual with a right to life. Any act that curtails its development is immoral, and no end believed to be good can justify the destruction of the embryo. Research that curtails the development of the embryo could not therefore be allowed (Walters 2004).
113. However, Christian views on the use of embryos and gametes in research are likely to be wide and diverse. Although the Vatican does not approve the use of embryos in research, other Christian churches may accept many of the applications of assisted reproductive technology (Schenker 2005). Some branches of Christian thought regard full human status as something that is acquired gradually, and that might therefore not be present in the early embryo. Consequently, it is difficult to categorise a single Christian view on the use of gametes and embryos in research.
114. In the Jewish tradition, the embryo is not accorded moral status before 40 days of gestation. The Jewish tradition also places a strong emphasis on healing and saving lives. This would permit some uses of embryos for research purposes (Walters 2004). An important feature of Jewish thinking in this area is that embryos outside the womb have no legal status unless parental intent gives them life potential by implantation and pregnancy. An embryo created for IVF treatment and maintained *in vitro* without the potential for implantation could be donated and used for therapeutic research in line with the lifesaving duty of Judaism (Serour 2002).
115. Within Islam there is no single perspective on the moral status of the embryo. However, a developmental view is taken and the embryo is not accorded moral status in its early stages of development. This would permit some uses of embryos for research purposes (Walters 2004), including their use for creating stem cells (Serour 2002).

116. The first position outlined above – that of according full moral status to the embryo – leads to opposition to embryo research. The second position, according the pre-embryo no moral status, allows embryo destruction. The third position, an umbrella position somewhere between the other two, allows embryo research but with a variety of restrictions. Most people who adopt this position look to signs of the primitive streak, which appears around 14 days after fertilisation, as a morally relevant developmental stage beyond which research cannot be conducted (see chapter 2).
117. The primitive streak may be morally relevant in two ways. First, it marks the beginnings of a nervous system in the embryo and thereby is relevant to questions of when the developing individual acquires the capacity to feel pain. Second, twinning cannot occur after the primitive streak has appeared. Those who see this as ethically significant argue that while the possibility of twinning remains, the embryo cannot be viewed as having a soul, because what is a single embryo could split into two (Knoepffler 2004). Thus they view 14 days post-fertilisation as significant because any embryo that develops after this point can only give rise to a single individual. Other stages along the developmental continuum are considered by some to be morally significant for the onset of personhood (Walters 2004).
118. Discussions of moral status usually do not take account of the location of the embryo (blastocyst). However, since a blastocyst has to be located in a woman's uterus to have the possibility of developing into an individual, Towns and Jones raise the question of whether a blastocyst in the laboratory has the same moral status as a blastocyst in a woman's uterus (Towns and Jones 2004a).

5.3 Potential sources of gametes and embryos for use in research

(See question 4 in the submission form)

119. As discussed in section 3.1, there are a number of potential sources of gametes and embryos that could be used for research if such research were to go ahead in New Zealand. However, if some form of research does proceed in New Zealand, a decision about which of these potential sources might be appropriate needs to be informed by society's ethical, spiritual and cultural perspectives.

5.3.1 Potential sources of gametes for use in research

120. Potential sources of sperm donated for use in research include surplus sperm collected in the course of IVF treatment, sperm from donors who no longer wish to have their sperm used for reproductive purposes, and sperm donated by donors specifically recruited to donate for research purposes. The key concern is likely to be informed consent. Provided that a man has given his informed consent, there would seem to be no broader ethical concerns.
121. Possible sources of eggs donated for use in research include eggs that have failed to fertilise in the course of IVF treatment, surplus eggs collected in the course of IVF treatment, and eggs donated by women recruited specifically to donate for research purposes. The collection of eggs carries some medical risks to women. In the short term these include discomfort and bleeding. Another important risk is ovarian hyperstimulation syndrome, which in severe cases requires hospitalisation, and in very rare cases results in death. There is also some concern that exposure to fertility drugs may increase the risk of ovarian cancer in later life, though there is no conclusive evidence on this (Steinbrook 2006).

122. Given the risks associated with the collection of eggs, it may be considered acceptable to allow the donation of unfertilised or surplus eggs collected in the course of IVF treatment, provided informed consent requirements have been met, but not from women who are not IVF patients because of the risks involved with no benefit to the patients.
123. Gametes could also be imported for research purposes. ACART is specifically required to consult on the import and export of *in vitro* gametes. The main concern appears to be that the quality, safety and ethical standards that exist in New Zealand must also exist in the source country. It may be considered acceptable to allow the import of gametes for research purposes providing the researcher can provide evidence for the quality, safety and ethical standards in the source country.
(See question 7 in the submission booklet)
124. Issues relating to the export of gametes are likely to be similar. New Zealanders may be concerned that any exported gametes should be used in ways that are subject to the same quality, safety and ethical standards that exist in New Zealand, and that donors have given their informed consent. In addition, Māori may have concerns about the export of genetic material.
(See questions 7 and 8 in the submission form)

5.3.2 Potential sources of embryos for use in research

(See question 4 in the submission section)

125. One potential source is non-viable embryos that have been created through IVF for the purpose of reproduction. Non-viable embryos have no potential to develop into a living individual and no potential to implant. They may be regarded by some as merely clusters of human cells (Bayliss 1990). However, they still represent human tissue, and should be treated with respect, in keeping with the Human Tissue Act 1964.
126. Surplus IVF embryos are another potential source of embryos for research. Surplus IVF embryos are those that have been created for potential implantation into a woman but are no longer required for reproductive purposes. Those embryos created after the HART Act was passed are subsequently destroyed after 10 years. They are distinct from non-viable embryos in that, if they were transferred into a woman's uterus, they would have the potential to form a living individual.
127. Although donation to an infertile couple is an alternative for couples who have surplus embryos, most choose not to donate for reproductive purposes. It is possible to separate the decision to destroy surplus embryos from the decision to use them for research (Jones and Towns 2006). This possibility is a distinctive feature of research involving surplus embryos. Thus a couple can first decide in principle to destroy their surplus embryos, and then be given the option of what to do with them, including donating them to research. Procedural separation is important in seeking to prevent exploitation and coercion. It may, however, be difficult to achieve this in practice due to the need to inform couples of the potential uses of their surplus embryos prior to treatment, thus raising the possibility of donation to research before any decision to destroy the embryos is made.
128. Embryos can also be created specifically for use in research. The ethical difference between creating embryos specifically for research purposes and the use of surplus embryos is that, with those created for research, the destruction of the embryos is premeditated, and there can be no separation of the decision to destroy the embryo and the decision to use it for research.

129. Surplus IVF embryos are created for potential implantation into a woman but are no longer required for reproductive purposes. In contrast, where embryos are created via IVF for research there is no intention that they will ever develop into human beings, so they are a means to an end, not an end in themselves. Some people consider the creation of embryos for research to be inconsistent with the principle of respect for human dignity, because it 'represents a further step in the **instrumentalisation** of human life' (European Group on Ethics 2000; Devolder 2005). Creating embryos specifically for research is viewed by some as treating them as a commodity, rather than bestowing dignity and respect on viable embryos as potential members of the human race.
130. However, arguments about dignity and respect are tempered for some people after consideration of the existing use of the embryo within New Zealand society. IVF, preimplantation genetic diagnosis and the creation, storage and destruction of surplus embryos are allowed, so only limited respect is currently given to the early embryo. It has to be decided whether the creation of embryos via IVF for research purposes diminishes the respect bestowed upon embryos, and whether there is a significant difference between allowing the creation of surplus embryos in IVF and the creation of embryos for research purposes.
131. Embryos for research could potentially be created via somatic cell nuclear transfer (SCNT), that is, by therapeutic cloning, where the resultant embryo would have the same genetic profile as the donor cell (see section 2.4.1). One argument against allowing therapeutic cloning is that it is the beginning of a 'slippery slope' towards reproductive cloning. The argument is that while SCNT may be considered acceptable, it will inevitably lead to reproductive cloning and a devaluation of human life in general.
132. There is not, however, a necessary connection between therapeutic and reproductive cloning. Some argue that it is entirely possible to legislate in favour of the creation of embryos for research purposes via SCNT but against reproductive cloning. Which is to say, safeguards can be put in place to draw a line between acceptable and unacceptable developments. For instance, the HART Act prohibits reproductive cloning and the implantation of any cloned embryo, and the penalties for such actions are significant.
133. The major difference between embryos created as part of IVF treatment and embryos created via SCNT lies in the potential to produce embryos that have the same genetic profile as the donor cell, and so could potentially provide immunologically matched tissue or embryonic stem cells for therapeutic use (see section 3.1.3).
134. Hybrid and chimeric embryos are another potential source (see section 2.4.3). As it is illegal under the HART Act to implant such embryos for reproductive purposes, they could, if allowed, be created only for research purposes.

5.4 Potential purposes of research using gametes and embryos

(See question 3 in the submission section)

135. Among those who support gamete and embryo research, it is generally considered that it can only be justified when as much information as possible has been obtained from non-human gametes and embryos.
136. Individuals and communities are likely to have different views on which purposes are acceptable, depending on how they view the relative harms and benefits of any research. These will be influenced by personal and collective values and beliefs, and by past experiences. For example, some individuals with life-threatening disease have spoken in support of research into curing human disease, whereas others consider that the potential benefits are so remote that the harm to the embryo does not justify such research. They may, however, be able to support research into infertility where the benefits may be more apparent to them. Whatever one's individual perspective, it will be important to consider what is best for New Zealand as a whole.
137. Generally, for medical research on human subjects to be considered ethical, there must be seen to be specific advantages of the research itself. The defining document on medical research involving human subjects is the Declaration of Helsinki (World Medical Association 1964). The Declaration of Helsinki restricts medical research on human subjects to research where 'the importance of the objective outweighs the inherent risks and burdens to the subject'. It stipulates that when healthy subjects are used, this is especially important. The Declaration also discusses research on those incapable of giving informed consent, such as children, and requires that research on such subjects only be allowed when it is 'necessary to promote the health of the population represented' and cannot be performed on legally competent individuals.
138. It is debatable whether the provisions of the Declaration of Helsinki apply equally to embryos. Embryo research is inherently different in that any research results in the destruction of the specific embryo under investigation, thereby preventing benefit to that particular embryo.
139. This discussion paper has outlined four broad areas of gamete and embryo research. These are its contribution to:
 - fundamental science to realise the therapeutic potential of gamete and embryo research
 - understanding of fertility and infertility
 - prevention of hereditary diseases
 - curing human disease in general.
140. Research into fundamental science is essential to the development of any area of gamete and embryo research. Without such research no other research can usefully proceed. As knowledge of the early embryo and its development is increased, the ability to treat fertility and infertility, and to prevent and cure disease will be further advanced. Research into fundamental science underlies all possible therapeutic applications of gamete and embryo research.
141. Using embryos for research into fertility and infertility may be seen as an indirect benefit to embryos as a whole. While not benefiting the specific embryo under investigation, the purpose of the research is to provide better knowledge to help in the areas of fertility and infertility. This has traditionally been an area in which embryos have been used for research. It then has to be decided whether research of benefit to embryos as a whole justifies the destruction of individual embryos.

142. Pre-implantation genetic diagnosis is the major application of research into the prevention of hereditary diseases. Although research into PGD, and other ways of preventing hereditary diseases, does not benefit those embryos used for the research, it may be argued that it benefits embryos as a whole, as well as the adult population.
143. Embryo research applied to wider therapeutic goals than infertility research is no longer focused on benefiting embryos as a whole. Rather, it focuses on children and adults and improving their quality of life. As such, it may be seen to be more controversial than research into fertility and infertility. On the other hand, the potential benefit from the prevention and treatment of serious disease and injury may be viewed as a more pressing social goal than the prevention and treatment of infertility. This is because serious disease and injury are likely to lead to more serious and unacceptable outcomes for the individuals concerned than for those affected by infertility.

5.5 Informed consent regarding the use of gametes and embryos for research

144. **Informed consent** is a person's voluntary agreement, based on adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. Informed consent consists of three basic components:
- adequate information is provided to enable an informed judgement to be made
 - the information provided is in a form and manner that will enable it to be understood by each individual
 - the consent is voluntary in nature (participation is free from manipulation, coercion, inducement or any other undue influence) (Ministry of Health 2006).
145. In New Zealand, the situation relating to consent to use gametes and embryos in research is clear. The HART Act requires that an ethics committee ensure that the informed consent of a person is obtained before embryos or gametes derived from them are used (HART Act, s 19(4)(b)). The requirement to obtain consent in such circumstances is consistent with the importance placed on consent by both the *Code of Health and Disability Services Consumers' Rights 1996* (Health and Disability Commissioner 1996), which requires informed consent for the research use of tissue in general, and the *Operational Standard for Ethics Committees* (Ministry of Health 2006), which lists informed consent as one of the main principles to be used by health and disability ethics committees in considering the research applications they receive.
146. However, if the donated embryos or gametes are to be used to form human embryonic stem cell lines, additional requirements may be needed to obtain informed consent from the embryo or gamete donor. This is because human embryonic stem cell lines may be cultured for long periods of time and used in a number of different research projects, some of which will not be able to be foreseen when consent is sought. The consent obtained from the donors would need to take this into account. It would be necessary to determine, prior to donation, the degree of control the donor would have over the research uses to which the subsequent embryonic stem cell line would be put. It would also be necessary to reach prior agreement on compensation – or lack of compensation – for any resulting profits from products or therapies created from stem cell lines derived from the donated embryos or gametes.

147. The HART Act does, however, ban the giving and receiving of payment or **valuable consideration** for the supply of human embryos and gametes. Valuable consideration is defined in the HART Act as including an inducement, discount or priority in the provision of a service. This legislative provision expresses values and beliefs about the commodification of early forms of human life.
148. Embryo research that creates human embryonic stem cell lines for future treatment also raises issues of informed consent for those participating in the research. Human subjects involved in innovative practice, intervention research (including clinical trials) and observational studies using human embryonic stem cells must give their informed consent to participate in such research. However, the issues relating to how and where these cells are used do not appear to be significantly different from those raised by other types of research on human subjects. Ethics committees regularly deal with these issues in line with the *Operational Standard for Ethics Committees* (Ministry of Health 2006) and other guidance. Existing provisions may be adequate.
149. ACART must provide specific advice to the Minister of Health on research using gametes from deceased persons. The substantive issue for this kind of research is gaining informed consent from the deceased person for the research that is to be carried out. Views on this may be expressed in question 11 in the submission booklet.
150. ACART is also required to provide specific advice on the import and export of gametes and embryos for research purposes. A key concern with respect to the import and export of gametes and embryos is whether they are subject to the same quality, safety and ethical (including informed consent) standards as would be expected of gametes and embryos donated and used for research within New Zealand (if the government decides to allow this to proceed). Māori may also have concerns about the export of genetic material.
(See questions 7 and 8 in the submission booklet)

6. Regulation in New Zealand

6.1 Introduction

151. A number of laws and regulations in New Zealand are relevant to the question of how gamete and embryo research should be regulated. Regardless of the content of any guidelines on embryo research, researchers are required to meet their obligations under these laws. These laws include the:
- Human Assisted Reproductive Technology (HART) Act 2004
 - Human Tissue Act 1964 (under review)
 - Hazardous Substances and New Organisms (HSNO) Act 1996
 - Medicines Act 1981 (under review)
 - Contraception, Sterilisation and Abortion Act 1977
 - Crimes Act 1961
 - Health and Disability Commissioner's Code of Health and Disability Services Consumers' Rights Regulation 1996.
152. The relevance of each of these laws and regulations to embryo research is explained below. The Human Tissue Act 1964 and associated review, the Hazardous Substances and New Organisms (HSNO) Act 1996 and the Medicines Act 1981 and associated review are all concerned specifically with the use of stem cells rather than embryo research in a broader sense. The Contraception, Sterilisation and Abortion Act 1977 and the Crimes Act 1961 do not deal with research on embryos, but are relevant because they deal with how the foetus and newborn child are to be treated within New Zealand society. The Health and Disability Commissioner's Code of Health and Disability Services Consumers' Rights Regulation addresses issues of informed consent.

6.1.1 The Human Assisted Reproductive Technology (HART) Act 2004

153. The Human Assisted Reproductive Technology (HART) Act 2004 establishes a clear legal framework for assisted reproductive procedures and human reproductive research, which is defined as 'research that uses or creates a human gamete, a human embryo, or a **hybrid embryo**'. Substantial penalties can be imposed where human reproductive research is carried out without the approval of ECART. The following actions are prohibited under the HART Act 2004:
1. Artificially form, for reproductive purposes, a cloned embryo. For the purposes of this item, a cloned embryo is not formed by splitting, on one or more occasions, an embryo that has been formed by the fusion of gametes.
 2. Artificially form, for reproductive purposes, a hybrid embryo.
 3. Implant into a human being a cloned embryo.
 4. Implant into a human being an animal gamete or embryo.
 5. Implant into a human being a hybrid embryo.
 6. Implant into an animal a human gamete or human embryo.
 7. Implant into an animal a hybrid embryo.

8. Implant into a human being a genetically modified gamete, human embryo, or hybrid embryo.
 9. Implant into a human being gametes derived from a foetus, or an embryo that has been formed from a gamete or gametes derived from a foetus.
154. It is also an offence under the HART Act to cause the further development of, possess or use an embryo beyond the 14th day after its formation. The HART Act is discussed more fully in the preface.

6.1.2 The Human Tissue Act 1964 (under review)

155. Another piece of legislation relevant to human embryonic stem cells is the Human Tissue Act 1964. This Act is currently under review, with new legislation introduced in November 2006. This new legislation will address, among other things, the use of all human tissue in research, including issues of consent, safety, storage and disposal. However, although it will explicitly *not* regulate human tissue covered by the HART Act (gametes and embryos), it is intended that the Human Tissue Act will regulate the use of established embryonic stem cell lines.

6.1.3 The Hazardous Substances and New Organisms (HSNO) Act 1996

156. The HSNO Act 1996 exists to protect the environment and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances and new organisms. The definition of a 'new organism' includes genetically modified human cells. The HSNO Act is therefore relevant to research using human embryos where those embryos have been genetically modified or where the research involves genetic modification.
157. Where human embryo research involves importing or developing genetically modified embryos, the law requires approval from the Environmental Risk Management Authority (ERMA New Zealand). ERMA New Zealand approval is additional to other forms of approval or review that may be required. Failure to gain ERMA New Zealand approval where it is required is a serious offence, punishable by a fine of up to \$500,000 and up to three months' imprisonment. Concurrent approval for research on human embryos is also required under the HART Act, and may also be required under the Medicines Act 1981.

6.1.4 The Medicines Act 1981 (under review)

158. The Medicines Act 1981 ensures that medicines are safe to use in New Zealand by establishing a regulatory regime for medicines, medical products and related products. Under this Act, a medicine is defined as an article administered to one or more human beings for a therapeutic purpose. Where products derived from embryo research are administered for a therapeutic purpose, they will be subject to the provisions of the Medicines Act. All medicines must go through a registration process before they can be sold or distributed.
159. This Act provides for the use of pre-registration medicines in clinical trials. Under these provisions, clinical trials involving human embryos or products derived from them will require the approval of the Director-General of Health, on the recommendation of the Health Research Council of New Zealand.

160. Legislation to establish a trans-Tasman regulator is currently being negotiated by officials and Ministers in New Zealand and Australia. This legislation will replace the Medicines Act in New Zealand. Researchers who wish to carry out clinical trials, including clinical trials involving human embryonic stem cells, will be required to comply with the provisions of this new legislation.
161. The Medicines Act 1981 was amended in May 2002 to provide temporary measures to control the use of cloning procedures. The amendment prohibits the implantation into a human being of embryos that are genetically modified or created by somatic cell nuclear transfer (SCNT), unless the researcher gains the approval of the Minister of Health. The establishment of the HART Act has overridden this section.

6.1.5 The Contraception, Sterilisation and Abortion Act 1977

162. This Act allows for the termination of a pregnancy in a number of cases, including where the continuation of the pregnancy would result in serious danger to the life of the mother. In these cases, the competing interests of the mother and the foetus are weighed, and the mother's interests are found to be more significant even where the foetus must be destroyed to protect them. Most developed nations, including those that outlaw destructive embryo research, take a similar view. The Republic of Ireland is an exception.

6.1.6 The Crimes Act 1961

163. A child becomes a human being within the meaning of the Crimes Act 'when it has completely proceeded in a living state from the body of its mother, whether it has breathed or not, whether it has an independent circulation or not, and whether the navel string is severed or not' (section 159). Developing foetuses and embryos therefore do not enjoy the same rights and protections as infants; for example, a foetus cannot be murdered. However, the Crimes Act does make it a criminal offence to cause 'the death of any child that has not become a human being in such a manner that he would have been guilty of murder if the child had become a human being', although the penalty for this crime is less than that prescribed for murder (section 182).

6.1.7 The Health and Disability Commissioner's Code of Health and Disability Services Consumers' Rights Regulation 1996

164. The Health and Disability Commissioner's Code of Health and Disability Services Consumers' Rights Regulation (the Code of Rights) confers 10 rights on consumers of health and disability services in New Zealand. Providers have a duty to give effect to these rights. The Code of Rights addresses the right of every consumer to be fully informed and the right to make an informed choice and to give informed consent to services (Right 6 and Right 7). The rights in the Code of Rights extend to research in Right 9.
165. Of particular relevance to research undertaken in line with the HART Act are Rights 7(9) and 7(10), which deal with decisions about the return, disposal, storage or use of any body part or bodily substances. The Health and Disability Commissioner has stated that it is unlikely that the Code of Rights would extend to the act of donating a surplus embryo, because an embryo is not a body part or bodily substance of either of the genetic donors. However, gametes would be included as a body part or bodily substance. ACART's own advice to the Minister of Health will have to be consistent with requirements for informed consent under this Code.

7. International Overview of Embryo Research, Policy Development and Legislation

166. This chapter examines the legislative arrangements in seven countries – the Republic of Ireland, Germany, Canada, France, Australia, the United Kingdom and Singapore – in relation to these policy positions. These countries were chosen because they represent a variety of positions and highlight the range of positions adopted by other jurisdictions.
167. The legislative arrangements in these seven countries fall into four main policy positions, as follows:
- A. ban the use of embryos in research, and ban the use of established human embryonic stem cells in research
 - B. ban the use of embryos in research, but allow the use of established human embryonic stem cells in research
 - C. allow surplus *in vitro* fertilisation embryos to be used in research, and allow the use of established human embryonic stem cells in research
 - D. allow surplus *in vitro* fertilisation embryos and embryos created specifically for research to be used in research, and allow the use of established human embryonic stem cells in research (Townes and Jones 2004b).
168. It will be noted that the USA is not cited as an example. Despite its prominence in the area of assisted human reproduction, there has been little by way of regulation as an arm of public policy, and what regulation there has been has not extended to the private sector. This leaves the enormous private sector unregulated. Although there is a significant private sector in the United Kingdom and New Zealand, public policy applies to both the private and public sectors.
169. In light of the scientific challenges and ethical concerns, reproductive cloning is explicitly banned through specific legislation in most countries throughout the world. It is also the subject of an international agreement, the United Nations Declaration on Cloning 2005, which calls for a total ban on human cloning throughout the world, including both reproductive and therapeutic cloning. The Declaration was adopted by the United Nations on 18 February 2005, but it remains non-legally binding. New Zealand did not support this declaration, because the HART Act only prohibits reproductive cloning and at the time New Zealand had not determined its own position on therapeutic cloning.

7.1 Republic of Ireland (position A)

Constitution of Ireland (Bunreacht na hÉireann)

170. The Republic of Ireland has no specific legislation regarding embryo research or the use of human embryonic stem cells. However, its constitution implicitly prohibits research on the embryo, as the state ‘acknowledges the right to life of the unborn’ and ‘guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right’ (Article 40.3.3).

171. In 2005 the Commission on Assisted Human Reproduction published a report on IVF practices in the Republic of Ireland (Department of Health and Children 2005). In this report the Commission almost unanimously recommended that surplus embryos created via IVF be permitted to be used for research (recommendation 34). The majority of the Commission also recommended that embryos created *in vitro* only be given legal protection when placed in a woman's body (recommendation 16). However, experimentation on, or destruction of, embryos is generally considered unacceptable, and it appears unlikely that embryo, or embryonic stem cell, research will be permitted in the near future.

7.2 Germany (position B)

Embryo Protection Act 1990 Stem Cell Act 2002

172. Any use of an embryo 'not suiting its own preservation' is banned in Germany under the Embryo Protection Act 1990. However, embryonic stem cells do not count as embryos for the purposes of the Embryo Protection Act. Specific legislation for research on imported human embryonic stem cells exists in Germany. The Stem Cell Act 2002 bans, as a matter of principle, the import and use of embryonic stem cells, but provides for exceptions to this ban under certain circumstances (Stem Cell Act, s 1).
173. Only embryonic stem cells that were derived from surplus IVF embryos before 1 January 2002 may be imported and used for research in Germany. In addition, the derivation of the embryonic stem cells must not have been obviously contrary to major principles of the German legal system (Stem Cell Act, s 4).
174. Embryonic stem cell research may only be carried out where:
- the research serves 'eminent research aims' in basic research or for the development of medical procedures to be applied to humans
 - according to the state of the art in biomedical science, the questions studied by the research have been examined as far as possible using animals
 - the research cannot be carried out using any other type of cell (Stem Cell Act, s 5).
175. There are two components to the oversight of embryonic stem cell research in Germany: the 'competent agency' and the Central Ethics Commission on Stem Cell Research (ZES). The competent agency can approve the import and use of embryonic stem cells if it is satisfied that the criteria described above have been met. The competent agency must also store basic information about approved research using embryonic stem cells in a publicly accessible registry (Stem Cell Act, s 11). The competent agency must consider the opinion of the ZES when deciding whether or not to approve an application to import and use embryonic stem cells (Stem Cell Act, ss 6 and 7).
176. The German government is also required by the Stem Cell Act to submit a report to the lower house of the German parliament detailing the results of approved research using embryonic stem cells (Stem Cell Act, s 15).

177. The Stem Cell Act does not contain detailed consent requirements, because it only addresses imported embryonic stem cells. However, the Act does require that the embryonic stem cells be derived in accordance with relevant legislation in the country of origin and that no compensation or financial benefit be given in exchange for the embryos used (Stem Cell Act, s 4).

7.3 Canada (position C)

Act Respecting Assisted Human Reproduction and Related Research 2004

178. On 11 February 2004 the Canadian Parliament passed Bill C-6, the Act Respecting Assisted Human Reproduction and Related Research. The Act establishes the Assisted Human Reproductive Agency of Canada, which is responsible to the Minister of Health. One of the functions of the Agency is to grant licences for embryo research using surplus human embryos. The Act also prohibits a range of research activities involving human embryos, including:
- the creation of embryos for non-reproductive purposes
 - the creation and use of cloned human embryos
 - maintaining an embryo outside the body after the 14th day of development
 - the commercial production of embryos
 - alterations to the genome of a cell of a human embryo that is capable of being inherited
 - creating hybrid embryos for the purpose of reproduction.
179. The new legislation permits researchers to use excess embryos for research, including embryonic stem cell research, subject to any conditions imposed by a licence or by regulation.
180. Canada has involved the public and has ascertained their thinking on embryo research issues. When legislation was being prepared and considered at select committee hearings there was further opportunity for public input.

7.4 France (position C)

Bioethics Law 2004

181. France adopted a new Bioethics Law on 6 August 2004, replacing previous legislation prohibiting all embryo research. Under the new law, embryo research is still banned in principle. However, a five-year moratorium is placed on this prohibition where a number of conditions are met. Only embryos surplus to fertility treatment may be used for research, and French law specifically prohibits the creation of embryos for research (Bioethics Law, 2151–2). At the end of the five-year trial period the regulations will be re-evaluated.
182. Research on embryos, including research to derive human embryonic stem cell lines, may only be carried out where it is:
- likely to result in major therapeutic advances
 - unable to be carried out in any other way, according to the state of scientific knowledge (Bioethics Law, 2151–5).

183. All research using human embryos must be authorised by the Agence de la Biomédecine (the French Biomedicine Agency), whose decisions are communicated to the Ministers of Health and Research. These Ministers retain the power to stop research for a number of reasons (Bioethics Law, 2151–5).
184. Following informed consent the couple donating the embryos must be given three months in which to change their mind before research begins.

7.5 Australia (position C)

Research Involving Human Embryos (RIHE) Act 2002 Prohibition of Human Cloning Act 2002

185. The Research Involving Human Embryos (RIHE) Act 2002 originally restricted embryo research to excess IVF embryos that were created before 5 April 2002 (RIHE Act, s 24). However, this provision expired in April 2005. Research may now be carried out on any embryonic stem cell line derived from a surplus IVF embryo (RIHE Act, s 46). Research and therapeutic cloning are banned, as is reproductive cloning, under the Prohibition of Human Cloning Act (s 9).
186. This legislation has recently come under review. After public consultation the committee, chaired by John Lockhart, presented its findings to Parliament in December 2005 (Legislation Review Committee 2005).
187. Among the recommendations of this committee, those set out below are particularly relevant to this discussion paper. The group recommended that the following methods may be used to create embryos as long as these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.
 - Human somatic cell nuclear transfer (SCNT) should be permitted, under licence, to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells (ESCs). The committee believed it to be inconsistent to prohibit the destruction of embryos created for research while allowing the creation and destruction of embryos in IVF.
 - In order to reduce the need for human eggs, transfer of human somatic cell nuclei into animal eggs should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human ESCs.
 - Research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division should be permitted for research, training and improvements in clinical practice of assisted reproductive technology.
 - The creation of human embryos and human embryo clones by means other than fertilisation of an egg by a sperm (such as nuclear or pronuclear transfer and parthenogenesis) should be permitted, under licence, for research, training and clinical applications, including the production of human ESCs.
 - The creation of human embryos using the genetic material from more than two people, or including heritable genetic alterations, should be permitted, under licence, for research, training and clinical applications, including the production of human ESCs.

- The creation of embryos using precursor cells from a human embryo or a human foetus should be permitted, under licence, for research, training and clinical applications, including the production of human ESCs.
 - A national stem cell bank should be established.
 - Consideration should be given to the use of cytoplasmic transfer (including transfer of mitochondrial DNA), under licence, for research on mitochondrial disease and other uses to improve assisted reproductive technology treatment.
 - Testing of human eggs for maturity by fertilisation up to, but not including, the first cell division (approximately 20 hours after fertilisation) or by parthenogenetic activation should be permitted for research, training and improvements in the clinical practice of assisted reproductive technology.
 - Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to facilitate assisted reproductive technology training and practice.
188. The adoption of these recommendations would give Australia a particularly liberal policy and place it in position D. However, the recommendations of the Lockhart Review led to significant debate within the Australian Government and Parliament. A bill came before Parliament and a conscience vote was taken by the upper house of the Australian Parliament in November 2006 which narrowly supported legalising cloning human embryos for stem cell research. The Bill was subsequently passed by the House of Representatives, in early December 2006.
189. Decisions about whether or not to allow an embryo research project to proceed in Australia are made with regard to ‘the likelihood of significant advances in knowledge or improvement in technologies for treatment as a result of excess (IVF) embryos proposed in the application, which could not be reasonably achieved by other means’ (RIHE Act, s 21(4)). All research uses of embryos, including embryonic stem cell research, require the researcher to obtain a licence from the licensing committee of the National Health and Medical Research Council (NHMRC) (RIHE Act, ss 20–28).
190. The woman for whom an embryo was created, and, if applicable, her spouse at the time the embryo was created, must have given written authority for the research use of the embryo or have determined in writing that the embryo was excess to her/their needs (RIHE Act, s 9). The licensing committee and ethics committee must also take into account guidelines issued by the NHMRC on relevant matters in deciding on applications for licences. The *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (NHMRC 2004) contain a more detailed discussion of the consent requirements for research involving excess IVF embryos, including embryonic stem cell research.

7.6 United Kingdom (position D)

Human Fertilisation and Embryology Act 1990

Human Fertilisation and Embryology (Research Purposes) Regulations 2001

191. There is no prohibition on the creation of embryos for research in British law. The first licence to create embryos for research was issued in August 2004. However, most embryo research involves excess IVF embryos.
192. Under the Human Fertilisation and Embryology Act 1990 and Human Fertilisation and Embryology (Research Purposes) Regulations 2001, embryo research is permitted to:
- promote advances in the treatment of infertility
 - increase knowledge about the causes of congenital disease
 - increase knowledge about the causes of miscarriage
 - develop more effective techniques of contraception
 - develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation (Human Fertilisation and Embryology Act, schedule 2, s 3(2))
 - increase knowledge about the development of embryos
 - increase knowledge about serious disease
 - enable any such knowledge to be applied in developing treatments for serious disease (Human Fertilisation and Embryology (Research Purposes) Regulations, s 2(2)).
193. The Human Fertilisation and Embryology Authority (HFEA) licenses and monitors clinics that carry out research on human embryos. The HFEA considers applications for research licences for research involving human embryos, including the use of embryos to extract human embryonic stem cells. Approval by a properly constituted external research ethics committee is a necessary condition for considering any application. All applicants must also:
- justify the use of human embryonic stem cells rather than adult stem cells
 - provide detailed information about the fate of the stem cells throughout the process
 - place a sample of all cell lines in the United Kingdom Stem Cell Bank.
194. The HFEA is not directly involved in the use of established embryonic stem cell lines held in the Stem Cell Bank. Oversight of all embryonic stem cell lines is through the United Kingdom's Medical Research Council.
195. The HFEA has requirements relating to the consent that must be obtained from those who donate embryos for research. In particular, donors must be informed:
- of the details of the specific research project
 - that any stem cell lines created may continue indefinitely and be used in many different research projects
 - that the decision to donate will not affect their treatment in any way
 - whether the embryos will be made anonymous
 - whether information will be fed back to the donors

- that donors can vary or withdraw the terms of their consent until the point where the embryos are used
 - that once a researcher has established a line using embryonic stem cells, the donors have no control over the future use of the cells
 - that stem cells derived will be deposited in the United Kingdom Stem Cell Bank and may be used for other projects
 - that cell lines and discoveries made using those cell lines may be patented, and the donor will not benefit financially
 - of how the research is funded, including the benefits that will accrue to researchers and their departments.
196. The Human Fertilisation and Embryology Act 1990 is currently under review. The House of Commons Science and Technology Committee issued a report on its review of the Act in March 2005. The notable recommendations included:
- allowing sex selection via preimplantation genetic diagnosis for family balancing
 - allowing genetic modification of human embryos
 - allowing the creation of human–animal hybrid and chimeric embryos
 - reopening the debate about human reproductive cloning
 - modifying the licensing powers of the HFEA.
197. Despite the fact that the review included public consultation, some of the recommendations appear to go against mainstream public and even majority scientific opinion. Five of the eleven committee members disavowed the report, labelling it ‘an extreme libertarian approach’ (Inman 2005). The review is still under way and so no changes to the existing law have yet been made. However, Parliament has already rejected the recommendation to reopen the debate on human reproductive cloning (Department of Health [UK] 2005).

7.7 Singapore (position D)

Human Cloning and Other Prohibited Practices Act 2004

198. The Human Cloning and Other Prohibited Practices Act 2004 was passed after the government accepted the recommendations of the Bioethics Advisory Committee’s (2002) report on embryo research. The Act prohibits reproductive cloning and the development of *in vitro* embryos beyond the 14th day, but allows therapeutic cloning.
199. Although these rulings are fairly straightforward, Singapore holds an unusual position on the regulation of embryo research in that the sources of embryos for research are ranked in a clearly defined moral hierarchy. Research involving a more extreme source will only be licensed once the more conservative sources have been proven to be inadequate. The pertinent recommendations of the Bioethics Advisory Committee are as follows.
- Research involving the derivation and use of embryonic stem cells is permissible only where there is strong scientific merit in, and potential medical benefit from, such research.
 - Where permitted, embryonic stem cells should be drawn from sources in the following order: (1) existing embryonic stem cell lines, originating from embryonic stem cells derived from embryos less than 14 days old; (2) surplus human embryos created for fertility treatment that are less than 14 days old.

- The creation of human embryos specifically for research can only be justified where (1) there is strong scientific merit in, and potential medical benefit from, such research; (2) no acceptable alternative exists; and (3) on a highly selective, case-by-case basis, with specific approval from the proposed statutory body.

200. Singapore’s regulations are designed to encourage ‘the pursuit of social benefits’ via flexible licensing, while minimising the more objectionable uses of embryos and thus ‘avoiding or ameliorating potential harm’ (Bioethics Advisory Committee 2002: 21).

7.8 A summary of positions adopted internationally

201. The following table sets out the policy and legislative positions of various countries regarding embryo research. New Zealand is not included, because feedback on this discussion document will inform ACART’s recommendations to the Minister of Health. These recommendations will result in the Government making policy decisions as to New Zealand’s position on gamete and embryo research. Under the HART Act, human reproductive research is not explicitly prohibited. However, with the exception of research using donated non-viable embryos, which is covered by a guideline, it cannot proceed.

202. The countries set out in the second row of Table 1 are those discussed above. The countries set out in the third row give an indication of the positions of a broader range of countries than it has been possible to discuss in detail in this discussion paper.

Table 1. International positions on embryo research policy and legislation*

Position A	Position B	Position C	Position D
The use of embryos in research is banned. The use of established human embryonic stem cells in research is banned.	The use of embryos in research is banned. The use of established human embryonic stem cells in research is not banned.	The use of surplus IVF embryos in research is not banned. The use of established human embryonic stem cells derived from such embryos in research is not banned.	The use of embryos created for research and surplus IVF embryos in research is not banned. The use of established human embryonic stem cells derived from such embryos in research is not banned.
Republic of Ireland	Germany	Canada Australia France	United Kingdom Singapore
Austria Norway Poland	Italy	Czech Republic Denmark Finland Greece Hungary Russia Spain Switzerland Taiwan	Belgium China India Israel Netherlands South Korea Sweden

* The United States is excluded from this table as there has been little by way of regulation and what regulation has occurred varies between states, and does not extend to the private sector.

8. Determining Policy for New Zealand

203. A number of factors are relevant to considering whether gamete and embryo research should be allowed, and if so, where the line should be drawn to safeguard New Zealanders' ethical, spiritual and cultural concerns. These factors include the extent to which decisions on future gamete and embryo research should be influenced by precedents in current policy settings and legislation which take an implicit or explicit position on the moral status of the embryo, as set out in chapter 6, and by international developments, as set out in chapter 7.
204. Under the HART Act, human reproductive research on embryos is not explicitly prohibited. However, only research using donated non-viable embryos can proceed, as a guideline is in place only for research using embryos from this source.
205. This consultation process is the first step in determining whether gamete and embryo research should be allowed in New Zealand, and if so, what the boundaries should be. Following consultation, ACART will make recommendations to the Minister of Health. The Minister is responsible for making the final decisions on whether and, if so, how gamete and embryo research should proceed in New Zealand.
206. Under the HART Act there are three possible ways that gamete and embryo research, or aspects of it, can be regulated. Gamete and embryo research could be:
- prohibited
 - subject to a moratorium
 - regulated through setting requirements out in guidelines to allow research to proceed subject to ethical committee approval on a case-by-case basis.
207. If a decision is made to allow research in some form, subsequent decisions would have to be made as to the acceptable sources of gametes and embryos to be used in research. The sources covered in this discussion paper include:
- donated non-viable embryos created via IVF treatment
 - donated viable surplus embryos created via IVF treatment
 - embryos created via IVF specifically for research purposes
 - embryos created via somatic cell nuclear transfer (SCNT) specifically for research purposes
 - hybrid/chimeric embryos created specifically for research purposes
 - the creation of embryos incapable of further development specifically for research purposes
 - donated gametes.
208. Decisions would also need to be made on the acceptable purposes for which any research may be undertaken. The following purposes have been outlined in this discussion paper:
- contribution to fundamental science to realise the therapeutic potential of gamete and embryo research
 - contribution to understanding of fertility and infertility
 - contribution to prevention of hereditary diseases
 - contribution to curing of human disease in general.

209. Under the HART Act, any human reproductive research that does proceed would do so only within guidelines containing specific boundaries. Any such guidelines would need to take account of the principles of the HART Act including “the needs, values and beliefs of Māori”, and “the different ethical, spiritual and cultural perspectives in society” regarding gamete and embryo research.
210. The HART Act also requires ACART to consult on two specific issues: the genetic modification of gametes and embryos for use in research, and the import into, or export from, New Zealand of *in vitro* human gametes or *in vitro* human embryos.
211. This discussion paper has canvassed all of these issues. Suggestions for further reading to assist you in considering your submission are set out on page 47 of this discussion paper.
212. The detachable submission form at the end of this paper sets out some specific questions for consideration. New Zealanders’ responses to these questions will assist ACART in determining its advice to the Minister of Health on future policy for gamete and embryo research in New Zealand.

Glossary

Achondroplasia	Dwarfism.
Adult stem cell	An undifferentiated, multipotent cell found in differentiated tissue in the body.
Advisory Committee on Assisted Reproductive Technology (ACART)	The advisory committee established under New Zealand's Human Assisted Reproductive Technology Act 2004.
Altered nuclear transfer	A procedure that involves altering a gene essential to development before performing cell nuclear transfer, creating an impaired 'embryo' that could never develop. Altered nuclear transfer may be considered to provide a less ethically problematic source of embryonic stem cells.
Biopsy	Removal of a sample of tissue for diagnostic examination.
Blastocyst	The appearance of the embryo at day five or six; the spherical blastocyst is made up of an outer ring of cells (the trophectoderm), which enclose a fluid-filled cavity and an interior cluster of cells (the inner cell mass).
Blastomere	One cell of a blastocyst.
Comparative genomic hybridisation	A technique to analyse all of the chromosomes in a polar body or egg.
Centrosome	A region of undifferentiated cytoplasm that organises the spindle fibres that function in mitosis and meiosis.
Chimeric embryo	An embryo composed of a mixture of cells from different sources or species.
Chorionic villus sampling	A prenatal diagnostic test in which a small sample of the placenta is removed to test for abnormalities in the foetus.
Chromosomes	Nucleic acid protein structures contained in the nucleus of the cell.
Cloned human embryo	A human embryo that is a genetic copy (whether identical or not) of a living or dead human being, a still-born child, a human embryo, or a human foetus.
Comparative genomic hybridisation (CGH)	A method of molecular analysis used to compare chromosomal gains and losses in DNA content between cells.
Cystic fibrosis	A common hereditary disease that affects the entire body, causing progressive disability and early death.
Differentiation	The process by which an unspecialised cell becomes specialised. In embryonic development, cells take on particular forms and functions, organising themselves into tissue and organs.
Donor offspring	<p>In relation to a donor, means a person formed from a donated embryo, or a donated cell, that is derived wholly or partly from the donor's body.</p> <p>In relation to a provider, means the person formed from a donated embryo or a donated cell, used in a service performed or arranged by the provider.</p>

Duchenne's muscular dystrophy	An inherited disorder characterised by rapidly progressive muscle weakness of the legs and pelvis, later affecting the whole body. It appears in early childhood and survival is rare beyond the late 20s.
Ethics Committee on Assisted Reproductive Technology (ECART)	The ethics committee established under New Zealand's Human Assisted Reproductive Technology Act 2004.
Embryo	Includes a zygote and a cell or group of cells that has the capacity to develop into an individual, but does not include stem cells derived from an embryo.
Embryo splitting	A procedure that involves splitting or separating the blastomeres of early preimplantation embryos to increase the number of embryos.
Embryonic stem cell	An undifferentiated pluripotent cell found in the early embryo.
Embryonic stem cell line	A stable population of embryonic stem cells that can self-replicate and remain undifferentiated for long periods of time in culture outside of the body.
Enucleated egg	An egg that has had its nucleus removed.
Fertilisation	The process (over 22–24 hours) whereby the male and female gametes unite, forming a single cell, called a zygote.
Foetus	The early human form from week eight until the birth of a child.
Gamete	An egg or a sperm, whether mature or not, or any other cell (whether naturally occurring or artificially formed or modified) that (i) contains only one copy of all or most chromosomes and (ii) is capable of being used for reproductive purposes.
Gene	A section of the DNA molecule that contains a distinct package of genetic material and is located in a specific site on a chromosome.
Genetic imprinting	The phenomenon by which the expression of certain genes is determined by whether the gene is inherited from the male or female parent.
Germ layer	A layer of cells formed during embryo formation that will eventually give rise to all of an animal's tissues and organs.
Germ-line	The body's reproductive cells. Germ-line DNA becomes incorporated into the DNA of every cell in the body of the offspring.
Haemoglobin	A very large protein molecule designed to transport oxygen.
Haemophilia	An inherited lifelong blood condition, carried on the X chromosome, in which an essential clotting factor is either partly or completely missing. This causes a person with haemophilia to bleed for longer than normal and, in some cases, bleeding can occur without cause.
Human Assisted Reproductive Technology (HART) Act 2004	An Act to secure the benefits of, and regulate, assisted reproductive technology and human reproductive research.
Human Fertilisation and Embryology Authority (HFEA)	The Human Fertilisation and Embryology Authority is the United Kingdom's independent regulator overseeing safe and appropriate practice in fertility treatment and embryo research. Online at http://www.hfea.gov.uk

Huntington's disease	A rare genetic disease that causes cell death in selective areas of the brain, resulting in abnormal body movements and some reduced mental abilities.
Hybrid embryo	<p>The HART Act defines a hybrid embryo as one that is formed:</p> <ul style="list-style-type: none"> • by fusing a human gamete with a non-human gamete, or • by fusing or compacting a cell of a human embryo with the 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 human embryo. <p>This definition is broader than that found in the scientific literature and includes both hybrid and chimeric embryos. This paper distinguishes between hybrids and chimerics. A hybrid embryo is more commonly defined as one that has been created by the mixing of genetic material from different sources or species (eg, via fertilisation or cell nuclear transfer).</p>
Immunosuppressants	Drugs that inhibit the activity of the immune system, used to prevent the rejection of a transplant.
Implantation	The embedding of the early embryo in the lining of the uterus.
Inflammatory bowel disease	Occurs when the immune system contributes to damage of the gastrointestinal tract by causing inflammation.
Informed consent	A person's voluntary agreement, based on adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure.
Inner cell mass	The cluster of cells inside the blastocyst. These cells give rise to the embryonic disc, which forms the embryo proper.
Instrumentalisation	Using somebody or something as a means to achieving an end.
Intracytoplasmic sperm injection	A procedure in IVF where one selected sperm is injected into the cytoplasm of an egg.
<i>In vitro</i>	In relation to an embryo, a foetus, gamete or cell, means an embryo, foetus, gamete or cell that is outside a living organism.
<i>In vitro</i> fertilisation (IVF)	The uniting of egg and sperm <i>in vitro</i> (in the laboratory).
Lupus	A chronic, potentially debilitating or fatal autoimmune disease in which the immune system attacks the body's cells and tissue, resulting in inflammation and tissue damage.
Mitochondria	Organelles in the cell cytoplasm that convert energy into forms the cell can use for its various processes.
Morphology	Form or structure.
Multipotent cell	A cell that is already differentiated but has the potential to give rise to a limited number of other cell or tissue types.

Non-viable embryo	Either an embryo where less than 50% of the cells have survived following thawing, or an embryo that would otherwise be discarded because it is unsuitable for freezing (because of arrested growth or a high degree of fragmentation).
Ooplasm (ooplasmic cytoplasm)	The substance that surrounds the nucleus of an egg.
Parthenogenesis	The process by which an egg resumes development without first being fertilised by a sperm; asexual reproduction.
Parthenote	An embryo-like entity formed by parthenogenesis.
Pluripotent cell	A cell that has the potential to form all of the 200 types of cell that comprise the body; ie, a cell in the embryonic inner cell mass (embryonic stem cell).
Polar body	A small, non-functional cell that results from unequal division of the egg after the first meiotic division. It can be used to biopsy the egg to verify the health of the female contribution to the zygote.
Pre-embryo	The product of the fertilised egg up to day 14 of development.
Preimplantation	The state of an embryo before it adheres to the lining inside the uterus. In most successful human pregnancies, the preimplantation state lasts for 8 to 10 days.
Preimplantation genetic diagnosis (PGD)	The genetic testing of an embryo before it is implanted into the uterus. Either the polar body of the egg or a cell from the four- to eight-cell embryo may be extracted for biopsy.
Prenatal diagnosis	A medical test intended to detect a disorder in the foetus during pregnancy; it includes amniocentesis, ultrasound and chorionic villus sampling.
Primitive streak	A heaping up of cells along the midline of the embryonic disc, which is the first indication of the nervous system.
Pronucleus	The nucleus of a sperm or egg before fertilisation (it therefore carries only half the number of chromosomes of other cells).
Reproductive cloning	The procedure whereby a cloned embryo is replaced into the uterus of a woman or female of the species, where it may implant and grow.
Somatic cell nuclear transfer (SCNT)	The transfer of a nucleus from a somatic (body) cell into an egg that has had its nucleus removed.
Somatic stem cells	Another name for adult stem cells.
Stem cell	A cell that gives rise to specialised cells.
Surplus (viable) embryos	Embryos created as a part of fertility treatment that are left over once the treatment has finished. They are capable of development but were not implanted because more embryos were created than were ultimately required.
Therapeutic cloning	A procedure whereby the cloned embryo is not placed into the uterus of a woman, but is created for the purposes of extracting stem cells that can be used for therapeutic purposes (eg, to grow a replacement organ, or piece of nerve tissue, or quantity of skin). Also known as research cloning.

Totipotent cell	A cell that has the potential to develop into an entire individual. Totipotent cells can form the cells of the future foetus and extra-embryonic tissues such as the placenta. The cells of the early embryo are totipotent until they begin to form a blastocyst.
Trophoblast	The outer layer of cells of the mammalian blastocyst that gives rise to the placenta.
Undifferentiated	Having not yet developed into a specialised cell type.
Uterus	The womb; the female reproductive organ in which a fertilised egg implants and a foetus develops.
Valuable consideration	Defined in section 5 of the HART Act as including an inducement, discount or priority in the provision of a service.
Viable embryo	An embryo that has the potential to survive following implantation.
Zygote	The product of the fusion of an egg and a sperm. It contains two copies of each chromosome, one from each parent. The zygote develops into an embryo.

Further Reading

Canadian Biotechnology Advisory Committee. 2003. *Stem Cells: Opportunities and challenges*. Advisory memorandum, 15 January 2003.

Chief Medical Officer's Expert Group. 2000. *Stem Cell Research: Medical progress with responsibility: A report from the Chief Medical Officer's Expert Group Reviewing the Potential of Developments in Stem Cell Research and Cell Nuclear Replacement to Benefit Human Health*. London: Department of Health [UK].

Commission of European Communities. 2003. *Report on Human Embryonic Stem Cell Research*. Commission staff working paper. SEC(2003) 441. Brussels: Commission of European Communities.

European Group on Ethics in Science and New Technologies to the European Commission (EGE). 2000. *Ethical Aspects of Human Stem Cell Research and Use: Opinion No. 15*. URL: http://ec.europa.eu/european_group_ethics/publications/.

House of Lords Stem Cell Research Committee. 2002. *Report from the Select Committee, Stem Cell Research*. URL: <http://www.publications.parliament.uk/>.

Hurlbut WD. 2004. *Altered Nuclear Transfer as a Morally Acceptable Means for the Procurement of Human Embryonic Stem Cells*. Working paper. President's Council on Bioethics. URL: <http://bioethicsprint.bioethics.gov/background/hurlbut.html>.

International Bioethics Committee of UNESCO. 2001. *The Use of Embryonic Stem Cells in Therapeutic Research: Report on the ethical aspects of human embryonic stem cell research*. URL: <http://www.unesco.org>.

Ministry of Health. 2005. *Guidelines on Using Cells from Established Human Embryonic Stem Cell Lines for Research: Discussion document*. Wellington: Ministry of Health. URL: <http://www.moh.govt.nz>.

Nuffield Council on Bioethics. 2001. *Stem Cell Therapy: The ethical issues: a discussion paper*. URL: <http://www.nuffieldbioethics.org>.

People, Science and Policy Ltd. 2006. *Report on the Consultation on the Review of the Human Fertilisation and Embryology Act 1990*. Prepared for the Department of Health. URL: http://www.peoplescienceandpolicy.com/downloads/DH_consultation.pdf.

President's Council on Bioethics. 2002. *Human Cloning and Human Dignity: An ethical Inquiry*. Washington, DC: President's Council on Bioethics.

President's Council on Bioethics. 2004. *Reproduction and Responsibility: The regulation of reproductive technologies*. Washington, DC: President's Council on Bioethics.

Swedish National Council on Medical Ethics. *Statement of Opinion on Embryonic Stem Cell Research*. URL: <http://www.smer.gov.se/>.

The Nathaniel Report. A publication of the Nathaniel Centre – the New Zealand Catholic Bioethics Centre. URL: <http://www.nathaniel.org.nz>.

UNESCO. 2004. *Human Cloning: Ethical Issues*. Paris: UNESCO.

UNESCO. 2004. *National Legislation Concerning Human Reproductive and Therapeutic Cloning*. Paris: UNESCO.

Members of ACART

Professor Sylvia Rumball (Chairperson) is Assistant to the Vice Chancellor (Ethics and Equity) at Massey University. She has a PhD in chemistry and for many years taught chemistry and undertook research in structural biology at Massey University. She has extensive international, national and local experience on ethics committees through past membership of the UNESCO International Bioethics Committee, the Health Research Council Ethics Committee and the Massey University Human Ethics Committee, and current membership of the Ethics Advisory Panel of the Environmental Risk Management Authority and the MASH Trust Ethics Committee, and as past Chair of the National Ethics Committee on Assisted Human Reproduction, and as current Chair of the Massey University Human Ethics Chairs Committee. Professor Rumball is also a member of the recently established International Council for Science Committee on Freedom and Responsibility in Science, a member of the Massey University Council and an auditor for the New Zealand Universities Academic Audit Unit. In 1998 she was made an Officer of the New Zealand Order of Merit for services to science. She is also the recipient of a Palmerston North City Council Civic Award, a Distinguished Alumni Award from the University of Canterbury and a New Zealand Science and Technology medal.

Professor Gareth Jones (Deputy Chair) is Deputy Vice-Chancellor (Academic and International) at the University of Otago, where he is also Professor of Anatomy and Structural Biology. He qualified in medicine and neuroscience (BSc Hons, MBBS) at University College London, and has DSc and MD degrees from the University of Western Australia and University of Otago in science and bioethics respectively. He was made Companion of the New Zealand Order of Merit in 2004 for his contributions to science and education. He has published extensively in neuroscience, anatomy education and bioethics. His recent books include: *Speaking for the Dead: Cadavers in biology and medicine* (2000), *Stem Cell Research and Cloning* (editor, 2004), *Medical Ethics* (co-author, 4th edition, 2005) and *Designers of the Future* (2005).

Professor Ken Daniels is Adjunct Professor in the School of Social Work and Human Services at the University of Canterbury. He was appointed to establish social work education and training at Canterbury in 1975 and retired in 2004. For over 30 years he has been actively involved in studying, writing, counselling and policy development in the psychosocial aspects of assisted reproductive technology (ART). His particular focus has been on the children and families that result from ART. He served for nine years on the National Ethics Committee on Assisted Human Reproduction, the last three as Deputy Chair. Professor Daniels has carried out research in a number of countries and has been used as a policy consultant in several overseas jurisdictions. He has published extensively and his book *Building a Family with the Assistance of Donor Insemination* is used by parents and professionals throughout the world. Professor Daniels is also a Board member of Richmond Fellowship of New Zealand.

Dr Mavis Duncanson is the Principal Advisor – Research and Policy in the Office of the Children’s Commissioner and is the Commissioner’s representative on ACART. The Commissioner is required by statute to raise awareness and understanding of and act as an advocate for children’s interests, rights and welfare, and to monitor application of the United Nations Convention on the Rights of the Child by Crown agencies. Dr Duncanson is a public health physician with previous experience in communicable disease and fire safety research.

Dr Richard Fisher is a gynaecologist with a sub-specialty practice in reproductive medicine. He is a co-founder of Fertility Associates and has been an active advocate for infertile couples for 20 years. He is the only New Zealander to have been elected President of the Fertility Society of Australia. Dr Fisher is a member of a number of professional associations

and of the Institute of Directors. He is married and has four children. Dr Fisher brings a medical professional viewpoint to ACART, which is tempered by recognition of the need for community involvement and decision-making in this area.

John Forman is a parent of adult twins with a rare genetic disorder, Alpha Mannosidosis, and his family experience with physical and intellectual disability has drawn him into a range of health and disability sector networks in the past 30 years. He has also spent many years in disability support service provision, mainly in community mental health. Since the late 1990s John has focused on the development of patient–family support networks in New Zealand and internationally, with an emphasis on partnership with health professionals, policy agencies and researchers to promote prevention, treatments and cures for rare disorders. He has volunteer roles on the board of several local and international advocacy groups. His paid role is as Executive Director of the New Zealand Organisation for Rare Disorders, where he advocates for increased application of genome knowledge and biotechnology to control health and disability problems, with a sharp eye on the ethical issues to ensure safety for the patient and their family.

Professor Mark Henaghan is Professor and Dean of Law at Otago University and Principal Investigator of the New Zealand Law Foundation sponsored Human Genome Project, Law and Ethics for the Future. Professor Henaghan’s primary research interests in are family law and medico legal law involving children.

Philippa McDonald is from Te Aupōuri and Ngāti Porou. She has worked in law and policy in Australia and New Zealand. She was a member of the Human Rights Review Tribunal for 10 years and of the research ethics committees of Victoria University Council. Ms McDonald is a board member of the Post Polio Support Society and a member of the Disability Reference Group of the Kapiti Coast District Council. She is a founder member of Te Aupōuri ki Pōneke Trust. She was a member of the National Ethics Committee on Assisted Human Reproduction for one year before it was replaced by ACART and ECART in 2005.

Mihi Namana has a formal training as a secondary school teacher and spent four years teaching at Kingswell College in Invercargill. In the early 1980s she worked extensively with Ngāi Tahu elders to assist with the completion of their ancestral meeting house by managing the Marae Development Project under the Labour Department. After the completion of this project in 1987, she stayed on with the Labour Department as a liaison officer working with gangs. In 1989 she was appointed as a cultural advisor for the South Canterbury, Dunedin and Southland branches of the Labour Department. By 1991 Ms Namana and her husband had moved to the Wairarapa, where she worked as a career consultant for secondary schools in the Wairarapa and Wellington regions. In 1996 she became principal of the local kura kaupapa, a position she held until her diagnosis with cancer in 1998. In 2000 she was appointed to her current position of Iwi and Māori Health Co-ordinator for the Wairarapa DHB. In 2003 Ms Namana was made a Companion of the Queen’s Service Order for community service.

Christine Rogan has worked to actively promote health for 15 years. She is a past President and life member of the Auckland Infertility Society and became the first National Development Officer for the New Zealand Infertility Society (now Fertility New Zealand). Currently she is a health promotion advisor with a non-government public health organisation. In addition, Ms Rogan is a non-medical Performance Assessment Committee member for the Medical Council and the Dental Council. She has a tertiary qualification in the social sciences from Massey University and lives on the North Shore of Auckland with her daughter.

Associate Professor Andrew Shelling is head of the Medical Genetics Research Group, which is primarily interested in understanding the molecular changes that occur during the development of genetic disorders, focusing on infertility and reproductive cancers, but also including cardiac disorders and inflammatory bowel disease. He is currently an Associate Editor for the Human Reproduction journal, which is one of the leading journals in the area of Reproductive research. Dr Shelling has a special interest in understanding the cause of premature menopause, and his research is internationally recognised for identifying genetic causes of this common cause of infertility. He initiated the development of a support group for women with premature menopause in New Zealand. Dr Shelling is currently Deputy Head of Department of Obstetrics and Gynaecology, and is extensively involved in teaching reproduction, genetics and cancer at the University of Auckland. Dr Shelling has recently served as President of the New Zealand branch of the Human Genetics Society of Australasia. Dr Shelling has recently been appointed to be a Trustee for the Nurture Foundation for Reproductive Research.

David Tamatea is a New Zealand Māori with Taranaki iwi affiliations, is married to Olivia, and has two daughters and 10 grandchildren. He has been actively involved in a number of administrative and governance bodies for many years, and also has a wide breadth of experience and contacts in the community health and disability sectors. In 1998 Mr Tamatea completed the National Certificate in Human Services (Disability Support). He is a positive and proactive person who likes to be involved with helping people. He has the skills and ability to motivate and encourage others, particularly those facing barriers or with a disability.

References

- Barlow C. 1994. *Tikanga Whakaaro: Key concepts in Māori culture*. Auckland: Oxford University Press.
- Baylis FE. 1990. The ethics of *ex utero* research on spare 'non-viable' IVF human embryos. *Bioethics* 4(4): 311–29.
- Bioethics Advisory Committee [Singapore]. 2002. Ethical, Legal and Social Issues in Stem Cell Research, Reproductive and Therapeutic Cloning. URL: <http://www.bioethics-singapore.org/resources/reports1.html>.
- Chief Medical Officer's Expert Group. 2000. *Stem Cell Research: Medical progress with responsibility*. London: Department of Health [UK].
- Chung Y, Kliminskaya I, Becker S, et al. 2005. Embryonic and extraembryonic stem cell lines derived from single mouse blastomeres. *Nature* 439: 216–19.
- Department of Health [UK]. 2005. *Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law*. London: The Stationery Office Ltd. URL: <http://www.dh.gov.uk/assetRoot/04/11/78/74/04117874.pdf>.
- Department of Health and Children [Republic of Ireland]. 2005. *Report of the Commission on Assisted Human Reproduction*. URL: <http://www.dohc.ie/publications/cahr.html>.
- Devolder K. 2005. Creating and sacrificing embryos for stem cells. *Journal of Medical Ethics* 31: 366–70.
- Dunson D, Colombo B, Baird DD. 2002. Changes with age in the level and duration of fertility in the menstrual cycle. *Human Reproduction* 17(5): 1399–403.
- ESHRE PGD Consortium Steering Committee. 2002. ESHRE Preimplantation Genetic Diagnosis Consortium: data collection III (May 2001). *Human Reproduction* 17(1): 233–46.
- European Group on Ethics in Science and New Technologies to the European Commission (EGE). 2000. *Ethical Aspects of Human Stem Cell Research and Use: Opinion No. 15*. URL: http://ec.europa.eu/european_group_ethics/publications/.
- Goldstein RS, Drukker M, Reubinoff BE. 2002. Integration and differentiation of human embryonic stem cells transplanted to the chick embryo. *Developmental Dynamics* 225(1): 80–6.
- Hardy K, Wright C, Rice S, et al. 2002. Future developments in assisted reproduction in humans. *Reproduction* 123: 171–83.
- Health and Disability Commissioner. 1996. *Code of Health and Disability Services Consumers' Rights 1996*. URL: <http://www.hdc.org.nz/theact/theact-thecode>.
- HFEA (Human Fertilisation and Embryology Authority). 2002. *The Patients' Guide to IVF Clinics*. London: HFEA.
- HFEA (Human Fertilisation and Embryology Authority). 2005. *Fourteenth Annual Report and Accounts*. London: HFEA.
- Holland S, Lebacqz K, Zaloth L (eds). 2001. *The Human Embryonic Stem Cell Debate: Science, ethics and public policy*, pp 37–49. Cambridge, MA: MIT Press.
- House of Commons Science and Technology Committee. 2005. *Human Reproductive Technologies and the Law: Fifth report of session 2004-05*, vol. 1, pp. 31–32. London: The Stationery Office Ltd. URL: <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7i.pdf>.
- Human Genome Research Project. 2005. *Choosing Genes for Future Children: Regulating preimplantation genetic diagnosis*. Dunedin: Human Genome Research Project.

- Inman M. 2005. Divided committee urges less restriction on embryo research. *Science* 308: 30.
- Jones DG, Towns CR. 2006. Navigating the quagmire: the regulation of human embryonic stem cell research. *Human Reproduction* 21: 1113–16.
- Kiessling AA. 2005. Eggs alone. *Nature* 434: 145.
- Klimanskaya I, Chung Y, Becker S, et al. 2006. Human embryonic stem cell lines derived from single blastomeres. *Nature* advance online publication, 23 August 2006. www.nature.com
- Knoepffler N. 2004. Stem cell research: an ethical evaluation of policy options. *Kennedy Institute of Ethics Journal* 14(1): 55–74.
- Kovacs GT, Breheny SA, Dear MJ. 2003. Embryo donation at an Australian university in-vitro fertilisation clinic: issues and outcomes. *Medical Journal of Australia* 178: 127–9.
- Lanzendorf SE, Boyd CA, Wright DL, et al. 2001. Use of human gametes obtained from anonymous donors for the production of human embryonic stem cell lines. *Fertility and Sterility* 76: 132–7.
- Legislation Review Committee. 2005. *Reports on the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002*. URL: <http://www.lockhartreview.com.au/public/content/ViewCategory.aspx?id=35>.
- Li H, Wang J, Wilhelmsson H, et al. 2000. Genetic modification of survival in tissue-specific knockout mice with mitochondrial cardiomyopathy. *Proceedings of the National Academy of Sciences of the United States of America* 97(7): 3467–72.
- Macklon NS, Geraedts JP, Fauser BC. 2002. Conception to ongoing pregnancy: the 'black box' of early pregnancy loss. *Human Reproduction Update* 8(4): 333–43.
- McLaren A. 1986. Prelude to embryogenesis. In: CIBA Foundation, *Human Embryo Research: Yes or No*, pp 5–23. London: Tavistock Publications.
- Meissner A, Jaenisch R. 2005. Generation of nuclear transfer-derived pluripotent ES cells from cloned *Cdx2*-deficient blastocysts. *Nature* 439: 212–15.
- Ministry of Health. 2006. *Operational Standard for Ethics Committees*. Wellington: Ministry of Health.
- Muoti AR, Nakashima K, Toni N, et al. 2005. Development of functional human embryonic stem cell-derived neurons in mouse brain. *Proceedings of the National Academy of Sciences of the United States of America* 102(51): 18,644–8.
- NECAHR (National Ethics Committee on Assisted Human Reproduction). 2005. *Guidelines for Research on Gametes and Non-viable Embryos*. Unpublished.
- NHMRC (National Health and Medical Research Council). 2004. *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*. URL: <http://www7.health.gov.au/nhmrc/>.
- President's Council on Bioethics. 2003. *Beyond Therapy: Biotechnology and the pursuit of happiness*. Washington DC: President's Council on Bioethics.
- President's Council on Bioethics. 2004. *Reproduction and Responsibility: The regulation of reproductive technologies*. Washington DC: President's Council on Bioethics.
- President's Council on Bioethics. 2005. *Alternative Sources of Human Pluripotent Stem Cells*. Washington DC: President's Council on Bioethics.
- Reubinoff BE, Pera MF, Fong CY, et al. 2000. Embryonic stem cell lines from human blastocysts: somatic differentiation *in vitro*. *Nature Biotechnology* 18: 399–404.
- Rogers NT, Hobson E, Pickering S, et al. 2004. Phospholipase C α causes Ca²⁺ oscillations and parthenogenetic activation of human oocytes. *Reproduction* 128: 697–702.

- Royal Commission on Genetic Modification. 2001. *Report of the Royal Commission on Genetic Modification*. URL: <http://www.mfe.govt.nz/publications/organisms/royal-commission-gm/index.html>.
- Schenker JG. 2005. Assisted reproductive practice: religious perspectives. *Reproductive Biomedicine Online* 10: 310–19.
- Serour GI. 2002. Attitudes and cultural perspectives on infertility and its alleviation in the Middle East area. In: *Current Practices and Controversies in Assisted Reproduction*. Geneva: WHO.
- Society for Assisted Reproductive Technology and the American Society for Reproductive Medicine. 2004. Assisted reproductive technology in the United States: 2000 results generated from the American Society for Reproductive Medicine / Society for Assisted Reproductive Technology registry. *Fertility and Sterility* 81: 1207–20.
- Steinbrook R. 2006. Egg donation and human embryonic stem-cell research. *New England Journal of Medicine* 354: 4.
- Thomson JA, Itskovitz-Eldor J, Shapiro SS, et al. 1998. Embryonic stem cell lines derived from human blastocysts. *Science* 282: 1145–7.
- Towns CR, Jones DG. 2004a. Stem cells, embryos, and the environment: a context for both science and ethics. *Journal of Medical Ethics* 30(4): 410–13.
- Towns CR, Jones DG. 2004b. Stem cells: public policy and ethics. *New Zealand Bioethics Journal* 5: 22–8.
- Van Voorhis BJ, Grinstead DM, Sparks AE, et al. 1999. Establishment of a successful donor embryo program: medical, ethical, and policy issues. *Fertility and Sterility* 71: 604–8.
- Walters, LeRoy. 2004. Human embryonic stem cell research: an intercultural perspective. *Kennedy Institute of Ethics Journal* 14(1): 3–38.
- Waters A-M, Dean JH, Sullivan EA. 2006. *Assisted Reproduction Technology in Australia and New Zealand 2003*. AIHW Cat. No. PER 31. Assisted Reproduction Technology Series No. 9. Sydney: AIHW National Perinatal Statistics Unit.
- Willer T, Prados B, Falcon-Perez JM, et al. 2004. Targeted disruption of the Walker-Warburg syndrome gene *Pomt1* in mouse results in embryonic lethality. *Proceedings of the National Academy of Sciences of the United States of America* 101(39): 14,126–31.
- Wilmut I, Beaujean N, De Sousa PA, et al. 2002. Somatic cell nuclear transfer. *Nature* 419: 583–7.
- Wilmut I, Schneike AE, McWhir J, et al. 1997. Viable offspring derived from fetal and adult mammalian cells. *Nature* 385: 10–13.
- Wilton L. 2005. Preimplantation genetic diagnosis and chromosome analysis of blastomeres using comparative genomic hybridization. *Human Reproduction Update* 11(1): 33–41.
- World Medical Association. 1964. *World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects*. URL: <http://www.wma.net/e/policy/b3.htm>.

How to Contribute

Your feedback is important to assist ACART to advise the Minister of Health on future policy for gamete and embryo research in New Zealand. Please take this opportunity to have your say. You may make a submission on your own behalf or as a member of an organisation. A summary of the submissions will be released following completion of the consultation process.

ACART welcomes your views on any or all of the issues raised. There are some key questions we would like you to think about and comment on. These questions are set out after the following instructions on how to contribute.

There are a number of ways to contribute to this consultation:

1. Attend a public meeting. Details will be posted on ACART's website in January 2007 and advertised in major newspapers.
2. Make a formal oral submission. Please advise the ACART Secretariat as soon as possible, but no later than 5 pm Friday 2 March 2007 if you would like to make an oral submission (acart@moh.govt.nz or 04 496 2000).
3. Write down your comments on the following detachable pages and post to:
The Secretariat
Advisory Committee on Assisted Reproductive Technology
PO Box 5013
WELLINGTON.
4. Fill in the online submission form on the ACART website: www.newhealth.govt.nz/acart.
5. Download the submission form in Word format from www.newhealth.govt.nz/acart, save it to your computer, fill it in and email it to acart@moh.govt.nz.
6. Email your comments to acart@moh.govt.nz. If you choose to do this, it would help in the analysis of the submissions if, in your comments, you note which paragraph or section number of the discussion paper you are referring to.

If you cannot attend a public meeting, you may wish to consider setting up your own group to prepare a submission, or to use a group that meets regularly for a related or different purpose. Where a significant number of people are meeting to consider their submission, ACART will make every effort to attend, if you would find that useful. Our ability to attend will, of course, depend on the number of requests we receive. Please advise the ACART Secretariat if your group is planning to discuss your submission and would like a member of ACART to attend.

The closing date for submissions is 5 pm, Friday 2 March 2007.

All submissions will be considered before ACART determines its advice to the Minister of Health.

Additional copies of this discussion paper are available from the ACART website (www.newhealth.govt.nz/acart) or from:

Wickliffe Press
PO Box 932
Dunedin
Phone: (04) 496 2277
Email: moh@wickliffe.co.nz

When ordering this discussion paper from Wickliffe, please quote HP4339.

Submission Form

Please provide your contact details.

Name:

If this submission is made on behalf of an organisation please name it:
.....

Brief description of organisation (if applicable):.....
.....

Address/email:.....

Interest in this topic (eg, user of fertility services, health professional, member of the public, etc):

Please note that all correspondence may be requested under the Official Information Act 1982. If there is any part of your correspondence that you consider should properly be withheld under the Act, please point this out, noting the reasons why you would want it to be withheld.

If your submission is requested under the Official Information Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, as opposed to an organisation, the Ministry will remove your personal details from the submission if you check the following box.

I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged by ACART and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Do you wish to receive a copy of the summary of submissions?

Yes

No

1. What are your views on whether research, or aspects of research, using **gametes** should be:
- prohibited
 - subject to a moratorium
 - regulated through the development of guidelines to allow research to proceed subject to ethical approval on a case-by-case basis?

Please give reasons for your views.

2. What are your views on whether research, or aspects of research, using **embryos** should be:
- prohibited
 - subject to a moratorium
 - regulated through the development of guidelines to allow research to proceed subject to ethical approval on a case-by-case basis?

Please give reasons for your views.

The remaining questions seek the views of those who believe that research on gametes and embryos should be allowed in some form. If you believe no research should be permitted, then you may not want to comment further. If, however, you nevertheless wish to share your views on the questions below, then ACART would welcome them.

3. The discussion paper outlines four purposes for conducting **gamete and embryo** research. These are the contribution of research to:

- fundamental science
- fertility and infertility
- prevention of hereditary diseases
- curing of human diseases in general.

What are your views on whether each of these purposes should be prohibited, subject to a moratorium or regulated through the development of guidelines to allow research to proceed subject to ethical approval on a case-by-case basis?

(See section 3.2 and chapter 3 generally in the discussion paper)

4. The discussion paper outlines a number of possible sources of **gametes and embryos** for use in research. These include:

- donated non-viable embryos created via IVF treatment
- donated viable surplus embryos created via IVF treatment
- embryos created via IVF specifically for research purposes
- embryos created via somatic cell nuclear transfer (SCNT) specifically for research purposes
- hybrid embryos created specifically for research purposes
- donated gametes.

What are your views on whether each of these sources should be prohibited, subject to a moratorium or regulated through the development of guidelines to allow research to proceed subject to ethical approval on a case-by-case basis?

(See sections 2.3, 2.4, 3.1 and chapter 3 generally in the discussion paper)

The HART Act requires ACART to give advice specifically on the genetic modification of gametes and embryos and the import and export of **gametes and embryos**.

- 5. What are your views on whether genetic modification of **gametes** should be prohibited, subject to a moratorium or regulated through the development of guidelines to allow research to proceed subject to ethical approval on a case-by-case basis?

Please give reasons for your views.

(See section 3.2 in the discussion paper)

- 6. What are your views on whether genetic modification of **embryos** should be prohibited, subject to a moratorium or regulated through the development of guidelines to allow research to proceed subject to ethical approval on a case-by-case basis?

Please give reasons for your views.

(See section 3.2 in the discussion paper)

7. What are your views on whether the import and export of **gametes** should be prohibited, subject to a moratorium or regulated through the development of guidelines to allow research to proceed subject to ethical approval on a case-by-case basis?

Please give reasons for your views.

(See section 5.4 in the discussion paper)

8. What are your views on whether the import and export of **embryos** should be prohibited, subject to a moratorium or regulated through the development of guidelines to allow research to proceed subject to ethical approval on a case-by-case basis?

Please give reasons for your views.

(See section 5.4 in the discussion paper)

9. Principle (f) of the HART Act states that the needs, values, and beliefs of Māori should be considered and treated with respect. We are interested in your views on how this principle could be incorporated into New Zealand’s policy position on **gamete and embryo** research.

What are your views on the tikanga outlined in chapter 4 and their relevance to the use of **gametes and embryos** in human reproductive research?

Are there any other tikanga that ACART should take into consideration?

What are your views on how this principle could inform ACART’s advice to the Minister, and, if research does proceed in some form, how it could be reflected in guidelines?

(See chapter 4 of the discussion paper)

10. Principle (g) of the HART Act states that the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

We are interested in your views on how this principle could be incorporated into New Zealand’s policy position on **gamete and embryo** research.

What are your views on how this principle could inform ACART’s advice to the Minister, and, if research does proceed in some form, how it could be reflected in guidelines?

(See chapter 5 of the discussion paper)

11. Do you have any further comments to make that have not been covered in the questions set out above?

