

Submission Form

Please provide your contact details.

Name: OFFICE OF THE HEATH AND DISABILITY COMMISSIONER

Brief description of organisation:

The Health and Disability Commissioner's role is to promote and protect the rights of health and disability services consumers, as set out in the Code of Health and Disability Services Consumers' Rights (the Code). Under section 14(d) of the Health and Disability Commissioner Act (the HDC Act) one of my functions as Commissioner is to make public statements in relation to any matter affecting the rights of health and disability services consumers.

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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

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.

I support a case-by-case consideration of the use of gametes for research purposes by an independent body, using the guidelines developed as a result of this consultation. The Ethics Committee on Assisted Reproductive Technology (ECART) is the appropriate body to consider and determine applications for research using gametes or embryos. Comprehensive, clear and workable guidance should be given to ethics committees and researchers on the management of research proposals in this novel area. While research using gametes and embryos has the potential to contribute to scientific knowledge and understanding, and result in advances in healthcare, such research remains controversial and raises complex ethical and social concerns. Therefore it is important that it proceed only within well safeguarded parameters. Mandatory ethics committee review of all research using gametes or embryos will help to foster confidence in such research, and to safeguard against potential abuses. Ethics committee review should enable decisions to be made in an open and transparent way, assuring the public that consistent rules are applied across the country and that fundamental values are being protected.

The HDC Act and Code apply to consumers of fertility services, which within the definition of 'health services' under section 2 of the HDC Act. This means that people receiving services related to fertility, including when gametes are donated in the course of fertility treatment, have the protection of the ten rights in the Code. The Code rights also extend to those occasions when a consumer is participating in research (Right 9). Of particular relevance to research using gametes or embryos are Rights 4, 6, and 7, which state that every consumer has the right to:

- have those services provided with reasonable care and skill (Right 4(1)), and in accordance with legal, professional, ethical, and other relevant standards (Right 4(2));
- receive sufficient information (Right 6). In particular, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including (but not limited to): an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; notification of any proposed participation in teaching and research, including whether the research requires and has received ethical approval; and any other information required by legal, professional, ethical, and other relevant standards; and
- make an informed choice and give informed consent (Right 7). In particular, services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of the Code provides otherwise. Note that Right 7(6) of the Code requires informed consent to be in writing if the consumer is to participate in any research.

As outlined in the Discussion Document, Rights 7(9) and 7(10) are of particular relevance to research using gametes or embryos, containing provisions relevant to the use, return, and disposal of body parts and bodily substances. Right 7(9) provides that “every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure”. Right 7(10) provides that no body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than with the informed consent of the consumer, unless for the purposes of research that has received ethics committee approval or for quality assurance activities. In practice, this means that consumers should receive information and make a decision about how their gametes will be used, stored, and what will happen after the research is completed.

Section 2 of the Act gives a broad definition of ‘health care procedure’ that would encompass health research and fertility services. Although there is no definition in either the Act or the Code of ‘body part’ or ‘bodily substance’, sperm and eggs would be considered ‘bodily substances’. Therefore the relevant fertility treatment consumer has the right to make a decision about the return, storage or disposal of their eggs or sperm following that treatment. In my view, informed consent to the use of gametes for research purposes would be a fundamental requirement before ethics committee approval is given, and only in an exceptional case should an ethics committee approve research without such consent (as permitted by Right 7(10)(b)).

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?

Under the Code, an embryo created in a laboratory and outside of a woman’s uterus is unlikely to be regarded as a “body part or bodily substance” of either the genetic mother or father. Once fertilisation has taken place in the laboratory, a new entity comes into existence which may not qualify as a body part or bodily substance of the consumer for the purposes of Rights 7(9) and 7(10). However, if the Code did apply, both donors would be required to give their consent before the embryo could be stored, preserved or used. Assuming the Code does not apply, the common law applies (which, may mean that, if both donors disagree and no prior agreement as to the use of the embryos exists, the relative interests of the parties will be weighed before a decision is made as to the embryo’s use and destruction: see *Davis v Davis* 842 S.W. 2d 588).

However, regardless of legal technicalities, the general principles of the Code with regards to information and consent should apply. At the time gametes are extracted for fertility treatment, each consumer should be asked whether they wish any surplus embryos to be destroyed, or whether they would consider donating embryos surplus to their requirements for research. At the time specific consent is sought for the use of

the surplus embryos for research purposes, consumers should be fully informed and their informed consent obtained and recorded in writing.

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)

I support an approach that is consistent with the *Guidelines on Using Cells from Established Human Embryonic Stem Cell Lines for Research*, which are currently being developed by the Ministry of Health. The permitted purposes for conducting gamete and embryo research should include the contribution of the research to increasing knowledge about human diseases, fertility and infertility, or fundamental science. Consideration should also be given to whether an additional requirement that the research objective cannot be addressed through other types of research is necessary. The proposed use of gametes or embryos in research should be reviewed on a case-by-case basis, in light of the purpose of the research project and the potential benefit for humankind.

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)

From a consumer perspective, the primary issue is having control over how gametes (and any embryo created out of those gametes) will be stored, preserved or used. In my view, except in exceptional circumstances, the consent of the person from whom gametes are removed from should be required before those gametes (or any resulting embryo) are used for research. There should be strict criteria for ensuring proper informed consent before any research proposal using gametes or embryos is approved by the ethics committee. In some circumstances, it may be reasonable to ask donors to give some form of consent to future unspecified use of their gametes in research.

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)

No comment.

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)

No comment.

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)

There should be a moratorium on the import of gametes and embryos until such time as imported gametes and embryos can be assured to meet the same quality and safety standards required for those originating in New Zealand, including standards relating to consent, information provision and the treatment of donors. In my view, export of gametes and embryos should be prohibited, given the loss of control over the use of gametes and embryos exported from New Zealand. Gametes and embryos sent overseas may not receive the kind of ethical review that occurs locally, and New Zealand has no jurisdiction over processes that occur overseas. Moreover, it will not be possible in many cases to determine where gametes and embryos that are sent overseas will be stored, or to ensure that they are not provided to commercial biomedical companies or used in commercial research collaborations.

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)

See above, question 7.

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)

I commend ACART for identifying Maori concepts and perspectives that may be relevant to the issue of using gametes and embryos for research purposes. I strongly support public consultation with Maori to ensure that the regulation of gamete and embryo research recognises the needs, values and beliefs of Maori.

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)

Should research using gametes or embryos proceed on a case-by-case basis, comprehensive, clear and workable guidance in the form of Guidelines should be provided to the ethics committee. The Guidelines should require the ethics committee to consider the different ethical, spiritual, and cultural perspectives in society before approving any research. Public consultation should be undertaken and information provided to the public. The Guidelines should also include specific guidance on the social and cultural issues specific to New Zealand with this type of research. Given the strong cultural, spiritual, and religious beliefs many individuals have relating to the use of gametes and embryos, it is also important that the individual donating the gamete or embryo to research is able to specify conditions subject to which the gamete or embryo may be used.

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