

Human Assisted Reproductive Technology Order 2005

Silvia Cartwright, Governor-General

Order in Council

At Wellington this 27th day of June 2005

Present:

Her Excellency the Governor-General in Council

Pursuant to section 6 of the Human Assisted Reproductive Technology Act 2004, Her Excellency the Governor-General, acting on the advice and with the consent of the Executive Council, makes the following order.

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Order

1 Title

This order is the Human Assisted Reproductive Technology Order 2005.

2 Commencement

This order comes into force on 22 August 2005.

3 Interpretation

In this order, unless the context otherwise requires,—

Act means the Human Assisted Reproductive Technology Act 2004

brother, in relation to a person, means a brother of full-blood or half-blood, a stepbrother, or a brother by adoption

cousin, in relation to a person, means a cousin of any degree donated eggs—

- (a) means eggs that are donated for reproductive purposes; but
- (b) does not include eggs contributed by the spouse or partner of the patient

donated sperm-

- (a) means sperm that is donated for reproductive purposes;
- (b) does not include sperm contributed by the spouse or partner of the patient

family member, in relation to a person, means—

- (a) any other person who is or has been related to the person by blood, marriage, civil union, de facto relationship, or adoption:
- (b) any other person who is a member of the person's whānau or other culturally recognised family group

partner, in relation to a person, means-

- (a) the person's civil union partner; or
- (b) the person's de facto partner

patient, in relation to donated eggs or donated sperm, means the person who is the subject of the procedure in which the eggs or sperm are used

sister, in relation to a person, means a sister of full-blood or half-blood, a stepsister, or a sister by adoption.

4 Purpose

The purpose of this order is—

(a) to declare certain medical procedures to be established procedures under section 6 of the Act for the purposes

- of the definition of assisted reproductive procedure in section 5 of the Act; and
- (b) in so doing, to specify those medical procedures that do not require the approval of the ethics committee under the Act.

5 Established procedures

Each medical procedure described in the Schedule is an established procedure.

Schedule Established procedures

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Part 1 Descriptions of established procedures

Artificial insemination

A procedure in which sperm is artificially introduced into a woman's body and that includes any of the following undertaken for, or in connection with, that procedure:

- (a) collection of sperm:
- (b) preparation of sperm:
- (c) placing prepared sperm into the cervix, uterus, or Fallopian tubes:
- (d) alteration of hormonal control of the ovaries and uterus using drugs:
- (e) stimulation of multiple follicle development using drugs:
- (f) triggering ovulation using drugs.

Assisted hatching

A procedure that involves thinning or making a hole in the zona pellucida of an embryo by mechanical, chemical, or laser means.

Blastocyst culture

A procedure in which the culture of an embryo or embryos outside the body is prolonged so that embryos might reach the stage of blastocyst.

Collection of eggs for purposes of donation

A procedure in which eggs are collected for the purposes of donation and that includes any of the following undertaken for, or in connection with, that procedure:

- (a) recruitment of an egg donor, either by the clinic or the egg recipient:
- (b) alteration of hormonal control of the ovaries and uterus using drugs:
- (c) stimulation of multiple follicle development using drugs:
- (d) triggering ovulation using drugs:
- (e) the egg donor undertaking procedures that may be undertaken for, or in connection with, in vitro fertilisation up to and including egg collection:
- (f) discarding of eggs.

Collection of sperm for purposes of donation

A procedure that involves either or both of the following:

- (a) recruitment of a sperm donor, either by the clinic or the sperm recipient:
- (b) collection and preparation of sperm.

Egg cryopreservation

A procedure in which eggs are maintained as potentially viable over a period of time by freezing them and that includes any of the following undertaken for, or in connection with, that procedure:

- (a) collection of eggs:
- (b) in vitro culture of eggs:
- (c) preparation of eggs for freezing:
- (d) freezing of eggs:
- (e) storage of eggs at low temperatures:
- (f) thawing of eggs
- (g) alteration of hormonal control of the ovaries and uterus using drugs:
- (h) stimulation of multiple follicle development using drugs:
- (i) triggering ovulation using drugs:
- (j) discarding of eggs.

Embryo cryopreservation

A procedure in which embryos are maintained as potentially viable over a period of time by freezing them and that includes any of the following undertaken for, or in connection with, that procedure:

- (a) preparation of embryos for freezing:
- (b) freezing of embryos:
- (c) storage of embryos at low temperatures:
- (d) thawing of embryos:
- (e) in vitro culture of embryos:
- (f) inspection and grading of embryos:
- (g) alteration of hormonal control of the ovaries and uterus using drugs:
- (h) stimulation of multiple follicle development using drugs:
- (i) triggering ovulation using drugs:
- (i) embryo transfer into the uterus or Fallopian tubes:
- (k) discarding of embryos.

Gamete intrafallopian transfer (GIFT)

A procedure in which eggs are combined with sperm outside the body and transferred into the Fallopian tubes of a woman and that includes any of the following undertaken for, or in connection with, that procedure:

- (a) collection of eggs:
- (b) preparation of sperm:
- (c) in vitro culture of eggs:
- (d) transfer of sperm and eggs into the Fallopian tubes:
- (e) any other steps of in vitro fertilisation using sperm and eggs not transferred to the Fallopian tubes.

Intracytoplasmic sperm injection (ICSI)

A procedure that may involve collection and preparation of sperm in which sperm is injected into an egg outside the body.

In vitro fertilisation (IVF)

A procedure in which the eggs of a woman are combined with the sperm of a man outside the body and that includes any of the following undertaken for, or in connection with, that procedure:

(a) collection of eggs:

- (b) collection and preparation of sperm:
- (c) in vitro culture of eggs:
- (d) in vitro culture of sperm:
- (e) addition of sperm to eggs:
- (f) in vitro culture of embryos:
- (g) inspection and grading of embryos:
- (h) embryo transfer into the uterus or Fallopian tubes:
- (i) alteration of hormonal control of the ovaries and uterus using drugs:
- (j) stimulation of multiple follicle development using drugs:
- (k) triggering ovulation using drugs:
- (1) discarding of eggs and embryos.

Ovarian tissue cryopreservation

A procedure in which ovarian tissue is collected and maintained as potentially viable over a period of time by freezing it and that includes any of the following undertaken for, or in connection with, that procedure:

- (a) collection of ovarian tissue:
- (b) preparation of the ovarian tissue for freezing:
- (c) freezing of ovarian tissue:
- (d) storage of ovarian tissue at low temperatures:
- (e) thawing of ovarian tissue:
- (f) discarding of ovarian tissue.

Pre-implantation genetic diagnosis (PGD)

A procedure for genetically testing embryos for specific genetic conditions or chromosomal abnormalities prior to embryo transfer and that includes any of the following undertaken for, or in connection with, that procedure:

- (a) biopsy of embryos to remove 1 or more cells:
- (b) transportation of the cells to an approved laboratory:
- (c) analysis of the genetic or chromosomal constitution of cells obtained by biopsy:
- (d) selection of embryos for transfer on the basis of the results from analysis.

Sperm cryopreservation

A procedure in which sperm are maintained as potentially viable over a period of time by freezing them and that includes any of the following undertaken for, or in connection with, that procedure:

- (a) collection of sperm:
- (b) freezing of sperm:
- (c) storage of sperm at low temperatures:
- (d) thawing of sperm:
- (e) discarding of stored sperm.

Part 2 Provisions applicable to procedures generally

- Despite the descriptions of established procedures in Part 1, a procedure is not an established procedure if it involves the use of donated eggs that—
 - (a) have been donated by a family member of the patient other than a sister or a cousin of the patient; or
 - (b) have been donated by a sister or cousin of the patient if, at the time of donation, either the donor or the patient was under 20; or
 - (c) are used in conjunction with donated sperm.
- 2 Despite the descriptions of established procedures in Part 1, a procedure is not an established procedure if it involves the use of donated sperm that—
 - (a) has been donated by a family member of the patient other than a brother or cousin of the patient; or
 - (b) has been donated by a brother or cousin of the patient if, at the time of donation, either the donor or the patient was under 20; or
 - (c) is used in conjunction with donated eggs.
- Despite the descriptions of established procedures in Part 1, a procedure is not an established procedure if it involves the use of ovarian tissue or eggs that have previously undergone cryopreservation.

- Despite the descriptions of established procedures in Part 1, a procedure is not an established procedure if it involves the collection of immature eggs or the use of eggs that have been matured by in vitro maturation.
- Despite the descriptions of established procedures in Part 1, a procedure is not an established procedure if it involves the use of sperm that was collected from a person, who has since died, who did not give consent to the specific use of the sperm before that person's death.
- Despite the descriptions of established procedures in Part 1, a procedure is not an established procedure if it involves the use of pre-implantation genetic diagnosis for purposes other than the prevention or treatment of a genetic disorder or disease by—
 - (a) diagnosis of familial single-gene disorders where—
 - the disorder has been identified in the family or whānau; and
 - (ii) there is a 25% or greater risk of an affected pregnancy; and
 - (iii) there is evidence that the future individual may be seriously impaired as a result of the disorder; or
 - (b) sex determination where—
 - (i) a familial sex-linked disorder has been identified in the family or whānau; and
 - (ii) there is a 25% or greater risk of an affected pregnancy; and
 - (iii) no specific test for the particular mutation that causes the disorder is available; and
 - (iv) there is evidence that the future individual may be seriously impaired as a result of the disorder; or
 - (c) diagnosis of familial chromosomal disorders where
 - the disorder has been identified in the family or whānau; and
 - (ii) there is a 25% or greater risk of an affected pregnancy; and

- (iii) there is evidence that the future individual may be seriously impaired as a result of the disorder; or
- (d) diagnosis of non-familial chromosomal disorders (aneuploidy testing) where—
 - (i) the woman is of advanced reproductive age; or
 - (ii) the woman has had recurrent implantation failure or recurrent miscarriage.

Diane Morcom, Clerk of the Executive Council.

Explanatory note

This note is not part of the order, but is intended to indicate its general effect.

This order, which comes into force on 22 August 2005, is made under section 6 of the Human Assisted Reproductive Technology Act 2004 (the **Act**). It declares various medical procedures to be established procedures for the purposes of the definition of **assisted reproductive procedure** in section 5 of the Act. The broad effect of this is that the requirement under the Act for the approval of the ethics committee will not apply to those established procedures.

Issued under the authority of the Acts and Order Publication Act 1989. Date of notification in *Gazette*: 30 June 2005. This order is administered in the Ministry of Health.

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