

House of Representatives

Supplementary Order Paper

Tuesday, 29 April 2003

Human Assisted Reproductive Technology Bill

Proposed amendments

Hon Lianne Dalziel, in Committee, to move the following amendments:

Clause 1

To omit *subclause (2)* (line 1 on page 2).

Clauses 2 to 7

To omit these clauses from pages 2 to 4, and substitute the following Part:

Part 1AA **Preliminary provisions**

2 Commencement

- (1) This Part, **subpart 1 of Part 1**, the provisions of **section 62(a) and (b)(i), sections 63 to 69**, the provisions of **section 70(1)** (except **paragraphs (a) and (b)**), **sections 71, 73, 74, and 76**, and **Schedules 1 and 2** come into force on the day after the date on which this Act receives the Royal assent.
- (2) The rest of this Act comes into force on the expiry of 9 months after the date on which it receives the Royal assent.

3 Purposes

This Act has the following purposes:

- (a) to prohibit unacceptable assisted reproductive procedures and unacceptable human reproductive research;
- (b) to provide for prohibitions under **paragraph (a)** to be kept up to date by Orders in Council approved by the House of Representatives;
- (c) to prohibit certain commercial transactions relating to human reproduction:

- (d) to provide a 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 an ethics committee:
- (f) to establish a comprehensive information-keeping regime to ensure that people born as a result of donated cells can find out about their genetic origins.

4 Principles

All persons exercising powers or performing functions under this Act must be guided by each of the following principles that is relevant to the particular power or function:

- (a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure should be paramount in all decisions about that procedure:
- (b) human health, safety, and dignity should be preserved and promoted:
- (c) 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 been given an opportunity to make an informed choice to submit or to refuse to submit to the procedure or the research:
- (d) donor offspring should be made aware of their genetic origins and be able to access information about those origins:
- (e) the needs, values, and beliefs of Maori should be considered and treated with respect:
- (f) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

5 Interpretation

- (1) In this Act, unless the context otherwise requires,—

advisory committee means the committee established under **section 31**

approval, in relation to an ethics committee, means an approval given by the ethics committee under **section 17**

assisted reproductive procedure or procedure—

- (a) means a medical, scientific, or technical procedure performed for the purpose of assisting human reproduction; and
- (b) includes a procedure performed for that purpose that involves—

- (i) the creation outside the human body of an embryo; or
 - (ii) the storage, manipulation, or use outside the human body of a human gamete or embryo; or
 - (iii) the use outside the human body of cells derived from an embryo; but
- (c) does not include an established procedure

authorised person—

- (a) means a person authorised in writing by the Director-General of Health to enter and inspect premises for the purposes of this Act; and
- (b) includes the Director-General of Health

cloned embryo means an embryo that is a genetic copy (whether identical or not) of a living or dead human being, a still-born child, an embryo, or a foetus

donated cell means the whole or part of a human gamete or other human cell that—

- (a) has been donated for the purpose of forming an embryo that is to be used for reproductive purposes; and
- (b) is being, or has been, kept outside the human body for that purpose

donor means a person from whose body a donated cell is derived; and,—

- (a) in relation to a donor offspring, means the donor of a donated cell from which the donor offspring was formed; and
- (b) in relation to an embryo formed from a donated cell, means the donor of that cell; and
- (c) in relation to a provider, means the donor of a donated cell used or available for use in a service performed or arranged by the provider

donor offspring—

- (a) in relation to a donor, means a person formed from a donated cell from the donor's body; and
- (b) in relation to a provider, means a person formed from a donated cell used in a service performed or arranged by the provider

embryo includes a zygote and a cell or a group of cells that has the capacity to develop into an individual; but does not include stem cells derived from an embryo

established procedure means any procedure, treatment, or application declared to be an established procedure under **subsection (3)**

ethics committee means a committee designated under **section 24**

gamete means—

- (a) an egg or a sperm, whether mature or not; or

- (b) any other cell (whether naturally occurring or artificially formed or modified) that—
 - (i) contains only 1 copy of all or most chromosomes; and
 - (ii) is capable of being used for reproductive purposes

guardian, in relation to a donor offspring, means the donor offspring's guardian within the meaning of the Guardianship Act 1968

human reproductive research means research that uses or creates a human gamete, a human embryo, or a hybrid embryo

hybrid embryo means an embryo that is formed—

- (a) by fusing a human gamete with a non-human gamete; or
- (b) by fusing or compacting a cell of a human embryo with the cell of a non-human embryo; or
- (c) by transferring the nucleus of a human cell into a non-human egg or a non-human embryo; or
- (d) by transferring the nucleus of a non-human cell into a human egg or an embryo

identifying information, in relation to any person, means that person's name, address, or contact details; and includes any information that is likely to enable another person to ascertain that person's name, address, or contact details

implant includes insert into and inject into

Minister means the Minister of Health

person responsible, in relation to an activity approved by an ethics committee, means the person for the time being approved under **section 18**

provider—

- (a) means a person who, in the course of a business (whether or not carried on with a view to making a profit), performs, or arranges the performance of, services in which donated cells are used; and
- (b) includes a successor provider

Registrar-General means the person for the time being appointed to that office under section 79(1) of the Births, Deaths, and Marriages Registration Act 1995

still-born child has the meaning given to it by section 2 of the Births, Deaths, and Marriages Registration Act 1995

successor provider means the successor, receiver, or liquidator of any provider or successor provider

surrogacy arrangement means an arrangement under which a woman agrees to become pregnant for the purpose of surrendering custody of a child born as a result of the pregnancy

valuable consideration includes an inducement, discount, or priority in the provision of a service.

- (2) In this Act, unless the context otherwise requires, a reference to an embryo or a foetus is a reference to a human embryo or human foetus.
- (3) The Governor-General may, by Order in Council made on the recommendation of the Minister, declare any of the following to be an established procedure for the purposes of the definition of **assisted reproductive procedure** in **subsection (1)**:
 - (a) a medical, scientific, or technical procedure:
 - (b) a medical treatment:
 - (c) an application of a medical, scientific, or technical procedure:
 - (d) an application of a medical treatment.

6 Act binds the Crown
This Act binds the Crown.

Part I

To omit this Part from pages 4 and 5, and substitute the following Part:

Part 1
Prohibited and regulated activities

Subpart 1—Prohibited actions

7 Prohibited actions

- (1) Every person commits an offence who takes an action described in **Schedule 1**.
- (2) Every person commits an offence who, knowing that a gamete, any kind of embryo or foetus, or a being has been formed by an action described in **Schedule 1**, imports into, or exports from, New Zealand that gamete, embryo, foetus, or being.
- (3) Every person commits an offence who, knowing that a gamete, any kind of embryo or foetus, or a being has been formed by an action described in **Schedule 1**, possesses, without reasonable excuse, that gamete, embryo, foetus, or thing.
- (4) A person who commits an offence against this section is liable on conviction on indictment to imprisonment for a term not exceeding 5 years or a fine not exceeding \$200,000, or both.

8 Amendment of Schedule by Order in Council

- (1) The Governor-General may, by Order in Council made on the recommendation of the Minister, amend **Schedule 1** by adding a further description of an action.
- (2) Sections 5 to 10 of the Regulations (Disallowance) Act 1989 do not apply to an order under **subsection (1)**.

9 Commencement and expiry of orders

- (1) An order under **section 8(1)** (an **amending order**) comes into force only in accordance with an order under **subsection (2)**.
- (2) The Governor-General may, by Order in Council, bring into force an amending order that has been approved by a resolution of the House of Representatives.
- (3) An amending order expires if—
 - (a) a motion that the House of Representatives resolve to approve it is defeated; or
 - (b) it is not approved by a resolution of the House of Representatives within 12 months after it is made.

10 Duty to stop development of embryos outside human body

- (1) This section applies to an embryo that—
 - (a) has been artificially formed (whether in New Zealand or elsewhere); and
 - (b) is outside the body of a human being.
- (2) Every person commits an offence who, knowing that the embryo has been developing for more than 14 days following its formation, intentionally—
 - (a) imports the embryo into New Zealand or exports the embryo from New Zealand; or
 - (b) does anything to cause the further development of the embryo outside the body of a human being.
- (3) Every provider and every person responsible for an activity approved by an ethics committee commits an offence who fails to take all practicable steps to ensure that the embryo does not continue to develop outside the body of a human being at any time after the 14th day following its formation.
- (4) For the purposes of this section, any day during which the development of the embryo is suspended may not be counted as a day following its formation.
- (5) Every person who commits an offence against **subsection (2)** is liable on summary conviction to imprisonment for a term not exceeding 2 years or to a fine not exceeding \$100,000, or both.
- (6) Every person who commits an offence against **subsection (3)** is liable on summary conviction to a fine not exceeding \$50,000.

11 Commercial supply of embryos or human gametes prohibited

- (1) Every person commits an offence who gives or receives, or agrees to give or receive, valuable consideration for the supply of an embryo or human gamete.
- (2) Every person who commits an offence against **subsection (1)** is liable on summary conviction to imprisonment for a term not exceeding 1 year or a fine not exceeding \$100,000, or both.

12 Status of surrogacy arrangements and prohibition of commercial surrogacy arrangements

- (1) A surrogacy arrangement is not of itself illegal, but is not enforceable by or against any person.
- (2) **Subsection (1)** does not affect the Status of Children Amendment Act 1987.
- (3) Every person commits an offence who gives or receives, or agrees to give or receive, valuable consideration for his or her participation, or for any other person's participation, or for arranging any other person's participation, in a surrogacy arrangement.
- (4) **Subsection (3)** does not apply to a payment that the party who, under the surrogacy arrangement, is to have custody of a child makes—
 - (a) to the provider concerned for any necessary expenses incurred for any of the following purposes:
 - (i) collecting, storing, transporting, or using an embryo or human gamete;
 - (ii) counselling 1 or more parties in relation to the surrogacy agreement;
 - (iii) insemination or in vitro fertilisation;
 - (iv) ovulation or pregnancy tests; or
 - (b) to a legal adviser for independent legal advice to the woman who is, or who might become, pregnant under the surrogacy arrangement.
- (5) Every person who commits an offence against **subsection (3)** is liable on summary conviction to imprisonment for a term not exceeding 1 year or a fine not exceeding \$100,000, or both.

13 Advertising for illegal action prohibited

- (1) No person may, with the intention of obtaining responses from members of the public, publish, or arrange for any other person to publish, any material that invites persons to participate, or to inquire about opportunities for participating, in actions that are prohibited by **section 7 or section 11 or section 12**.
- (2) For the purposes of **subsection (1)**, **publish** means—
 - (a) insert in any newspaper or other periodical publication printed, published, or distributed in New Zealand; or
 - (b) send to any person, by post or otherwise; or
 - (c) deliver to any person or leave upon premises occupied by any person; or
 - (d) broadcast within the meaning of the Broadcasting Act 1989; or
 - (e) include in any film or video recording; or
 - (f) include in any disk for use with a computer; or
 - (g) disseminate by means of the Internet or any other electronic medium; or

- (h) distribute by any means; or
 - (i) display by way of a sign, notice, poster, or other means; or
 - (j) bring to the notice of the public in New Zealand in any other manner.
- (3) Every person who commits an offence against **subsection (1)** is liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding \$2,500, or both.

Subpart 2—Activities requiring approval of ethics committee

Activities to proceed only in accordance with approvals and regulations

14 Assisted reproductive procedures and human reproductive research only to proceed with prior approval

- (1) Every person commits an offence who performs an assisted reproductive procedure or conducts human reproductive research without the prior approval in writing of an ethics committee.
- (2) Every person who commits an offence against **subsection (1)** is liable on summary conviction to a fine not exceeding \$50,000.

15 Approved activities must proceed in accordance with applicable conditions and regulations

The person responsible for an activity approved by an ethics committee must ensure that the activity is undertaken in accordance with—

- (a) any conditions imposed by the committee under **section 17 or section 19**; and
- (b) any regulations made under **section 70** that for the time being govern the activity.

Matters to be considered and decided by ethics committees

16 Applications for approval

- (1) An ethics committee may receive a written application for an approval for an assisted reproductive procedure or for human reproductive research if the application—
 - (a) is in a form approved by the ethics committee; and
 - (b) describes the activity for which approval is sought; and
 - (c) states the purpose of the proposed activity; and
 - (d) nominates an appropriate person who is to be responsible for the activity.
- (2) If the kind of activity for which an approval is sought is not covered in guidelines or advice previously issued or given by the advisory committee, the ethics committee must either—

- (a) refer the application to the advisory committee; or
 - (b) decline the application.
- (3) The ethics committee may, for any reason that it considers appropriate, reconsider an application that it has previously declined if relevant new information becomes available.

17 Approval of assisted reproductive procedure or research

- (1) An ethics committee may give its written approval—
- (a) for the performance of assisted reproductive procedures by a nominated person; or
 - (b) for the conduct of human reproductive research by a nominated person.
- (2) An ethics committee may not give an approval unless it is satisfied that the activity proposed to be undertaken under the approval is consistent with relevant guidelines or relevant advice issued or given by the advisory committee.
- (3) The ethics committee may give an approval subject to any conditions it thinks fit to impose, which may, without limitation,—
- (a) limit the duration of the approval; or
 - (b) limit the individual or individuals on whom any assisted reproductive procedure may be performed to a particular individual or to particular individuals or to a class or classes of individual.
- (4) The ethics committee must impose any conditions that it considers are required to ensure that the informed consent of any person is obtained before—
- (a) the person is involved in an activity to be undertaken under the approval; or
 - (b) 1 or more gametes derived from the person are used.

18 Person responsible for activity

- (1) Before an ethics committee gives an approval for an activity, it must approve a person nominated by the applicant as the person responsible for the activity to be undertaken under the approval.
- (2) If, at any time, the person responsible for an activity undertaken under an approval is, for any reason, unable or unwilling to perform the person's duties, the activity under the approval must be suspended until the ethics committee concerned approves, or 1 or more members of the committee authorised by the committee in that behalf approve, another person nominated by the applicant as the person responsible for the activity.
- (3) Before the ethics committee approves a person under this section, the committee must be satisfied that the person—

- (a) is able to ensure that the activity concerned will be undertaken in a manner that is consistent with relevant guidelines or relevant advice issued by the advisory committee; and
 - (b) is willing to assume responsibility for the activity.
- (4) Every person appointed under this section must be a natural person.

19 Ethics committee may change conditions

- (1) An ethics committee may change an approval in 1 or more of the following respects:
- (a) by varying a condition previously imposed on the approval;
 - (b) by revoking a condition previously imposed on the approval;
 - (c) by imposing 1 or more new conditions on the approval.
- (2) The ethics committee may change the approval on its own initiative only if it is satisfied that the change is necessary—
- (a) to ensure consistency with this Act or relevant guidelines or relevant advice issued or given by the advisory committee before or after the date on which the approval was granted; or
 - (b) to correct an error or omission made by the ethics committee.
- (3) The ethics committee may change the approval at the request of the person responsible for the activity undertaken under the approval if it is satisfied that the change is consistent with relevant guidelines or relevant advice issued or given by the advisory committee before or after the date on which the approval was granted.
- (4) In any case where the person responsible for the activity requests the ethics committee to exercise its power under **subsection (1)(a)**, the power may be exercised by 1 or more members of the committee authorised by the committee in that behalf.
- (5) The ethics committee may not change the approval on its own initiative unless it has first—
- (a) informed the person responsible for the activity undertaken under the approval concerned why it is considering the change; and
 - (b) given that person a reasonable time to make written submissions and be heard on the question, either personally or by his or her representative; and
 - (c) considered any submissions made in that time.

20 Ethics committee may cancel approval

- (1) This subsection applies to an approval if the ethics committee that granted it is satisfied—
 - (a) that—
 - (i) 1 or more conditions stated in the approval have been breached; or
 - (ii) the activity undertaken under the approval is inconsistent with the description set out in the application that sought the approval; and
 - (b) that the activity undertaken under the approval—
 - (i) is inconsistent with any relevant guidelines issued by the advisory committee on or before or after the date on which the approval was granted; or
 - (ii) breaches or has breached regulations made under **section 70**.
- (2) The ethics committee may cancel an approval to which **subsection (1)** applies.
- (3) The ethics committee may not cancel the approval unless it has first—
 - (a) informed the person responsible for the activity under the approval why it is considering cancelling the approval; and
 - (b) given that person a reasonable opportunity to make written submissions and be heard on the question, either personally or by his or her representative.
- (4) If the ethics committee cancels the approval, it may give directions on how the activity to which it relates is to be terminated.
- (5) Directions under **subsection (4)** may, without limitation, relate to the preservation, custody, or disposal of human gametes, human embryos, hybrid embryos, or foetuses.

21 If approval cancelled, activity must be terminated

- If an ethics committee cancels an approval, the person who, immediately before the cancellation, is the person responsible for the activity under the approval must—
- (a) ensure that the activity is terminated; and
 - (b) comply with any directions given, under **section 20(4)**, about the termination.

Moratorium for particular forms of assisted reproductive procedure or human reproductive research

- 22 Moratorium may be imposed on forms of assisted reproductive procedure or human reproductive research**
- (1) For the purpose of allowing time for the development of advice or guidelines, or both, about any kind of assisted reproductive procedure or human reproductive research, the Governor-General may, by Order in Council made on the recommendation of the Minister, declare a particular kind of assisted reproductive procedure or human reproductive research to be subject to a moratorium for a period not exceeding 18 months.
 - (2) The Governor-General may, by Order in Council made on the recommendation of the Minister, extend a moratorium imposed under **subsection (1)** for 1 further period not exceeding 18 months.
- 23 Committees must not consider applications for approvals subject to moratorium**
- During any time that a kind of assisted reproductive procedure or human reproductive research is subject to a moratorium imposed under **section 22**, no ethics committee may consider or grant a request to approve a proposal for that form of procedure or research.

Designation, functions, and jurisdiction of ethics committees

- 24 Designation of ethics committees**
- (1) The Minister may, by written notice given to any committee, designate the committee as an ethics committee for the purposes of this Part.
 - (2) The Minister may designate a committee—
 - (a) that the Minister establishes for the purpose of this section; or
 - (b) that has been established for another purpose.
 - (3) If a committee is established for the purposes of this section, the Minister may, by written notice,—
 - (a) appoint any person to be a member or chairperson of the ethics committee; and
 - (b) terminate the appointment of a member or chairperson of the ethics committee.
 - (4) Each member of an ethics committee established for the purposes of this section is appointed on any terms and conditions (including terms and conditions as to remuneration and travelling allowances and expenses) that the Minister determines by written notice to the member.
 - (5) A change in the membership of a committee designated under this section does not affect its designation.

25 Functions of ethics committees

- (1) For the purposes of this Part, an ethics committee has the following functions:
 - (a) to consider and determine, to the extent permitted by any notice in effect under **section 26(1)**, either alone or with 1 or more other ethics committees, applications for approvals for the performance of assisted reproductive procedures or the conduct of human reproductive research;
 - (b) to keep under review any approvals previously given;
 - (c) to liaise with the advisory committee on general and specific matters relating to assisted reproductive procedures and human reproductive research;
 - (d) to consult with any persons who, in the opinion of the committee, are able to assist it perform its functions;
 - (e) any other functions that the Minister assigns to the committee by written notice.
- (2) For the purpose of assisting each ethics committee in the performance of its functions under this Part, the Director-General of Health must provide the committee with administrative support.

26 If more than 1 ethics committee is designated, jurisdictions must be defined

- (1) If the Minister designates, under **section 24**, more than 1 ethics committee, the Minister must, by notice in writing given to each committee, define the categories of application that each committee may consider under **section 25(1)(a)**, so as to ensure that each application may not be considered otherwise than by—
 - (a) only 1 committee; or
 - (b) jointly by 2 or more committees.
- (2) For the purposes of **subsection (1)**, the Minister may define categories of application by reference to—
 - (a) the subject matters of proposals; or
 - (b) the geographical areas in which activities are to be undertaken; or
 - (c) a combination of both.

27 Cancellation of designation

- (1) The Minister may, at any time, by written notice to an ethics committee, cancel its designation under **section 24**.
- (2) The cancellation may be given for any reason that, in the Minister's opinion, justifies the cancellation.
- (3) Following the cancellation, the Minister may, by written notice to another ethics committee, appoint the other ethics committee (**committee A**) to be the successor of the committee whose designation has been cancelled (**committee B**).

- (4) Committee A may consider any requests to approve proposals that are pending before committee B at the time of the cancellation.
- (5) For the purposes of this Act, every lawful approval granted by committee B that is in effect at the time of the cancellation is to be taken to have been granted by committee A.

Duties of ethics committees in relation to advisory committee

28 Ethics committees must operate in accordance with guidelines of advisory committee

In the performance of its functions and the exercise of its powers, each ethics committee must operate in accordance with any guidelines issued by the advisory committee.

29 Advisory committee to be informed of approvals

As soon as practicable after an ethics committee grants an approval, it must give a copy of the approval and the relevant proposal to the advisory committee.

Presentation and publication requirements

30 Information about ethics committees must be made public

- (1) As soon as practicable after giving a notice of the kind specified in **subsection (2)**, the Minister must present a copy of the notice to the House of Representatives.
- (2) The kinds of notice are as follows:
 - (a) a notice designating an ethics committee under **section 24**;
 - (b) a notice assigning a function to an ethics committee under **section 25(1)(e)**;
 - (c) a notice under **section 26** defining the categories of application that each ethics committee may consider;
 - (d) a notice under **section 27(1)** cancelling the designation of a committee;
 - (e) a notice under **section 27(3)** appointing a committee to be the successor of a committee whose designation has been cancelled.
- (3) In every annual report of the Ministry of Health, the Ministry must publish—
 - (a) the name of the chairperson of each ethics committee; and
 - (b) the names of the members of each ethics committee.

Subpart 3—Advisory committee

Establishment, appointments, and functions

31 Advisory committee must be established

The Minister must establish a committee to be known as the Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research.

32 Number of members and procedure

The advisory committee—

- (a) consists of the number of members that the Minister determines by written notice; and
- (b) may, subject to this Act and any directions that the Minister gives by written notice to the committee, regulate its procedure in any manner that the committee thinks fit.

33 Appointment of members

- (1) The Minister may, after consultation with the Minister of Women's Affairs, by written notice, appoint any person to be a member or chairperson of the advisory committee.
- (2) The Minister may, by written notice, terminate the appointment of a member or chairperson of the advisory committee.
- (3) Each member of the advisory committee is appointed on any terms and conditions (including terms and conditions as to remuneration and travelling allowances and expenses) that the Minister determines by written notice to the member.
- (4) The advisory committee must include—
 - (a) 1 or more members with expertise in assisted reproductive procedures; and
 - (b) 1 or more members with expertise in human reproductive research; and
 - (c) 1 or more members with expertise in ethics; and
 - (d) 1 or more Maori members with expertise in Maori customary values and practice and the ability to articulate issues from a Maori perspective.
- (5) At least half the members of the advisory committee must be laypersons.
- (6) For the purposes of **subsection (5)**, a layperson is a person who, at no time during the person's membership of the advisory committee or in the 3 years before becoming a member of the committee,—
 - (a) is a registered health professional within the meaning of the Health and Disability Commissioner Act 1994; or
 - (b) is involved in health research.

34 Functions of advisory committee

- (1) The advisory committee has the following functions:
- (a) to advise the Minister or an ethics committee on aspects of, or issues arising out of, kinds of assisted reproductive procedure or human reproductive research:
 - (b) to issue guidelines to ethics committees on any matter relating to any kind of assisted reproductive procedure or human reproductive research:
 - (c) to monitor developments in assisted reproductive procedures and human reproductive research with a view to considering whether—
 - (i) the advisory committee should issue, amend, or revoke guidelines; or
 - (ii) any particular form of assisted reproductive procedure or human reproductive research should be regulated or prohibited:
 - (d) to keep guidelines previously issued under review:
 - (e) to advise the Minister as to whether—
 - (i) any procedure, treatment, or application should be declared to be an established procedure under **section 5(3)**; or
 - (ii) any Order in Council made under **section 5(3)** should be amended or revoked:
 - (f) to monitor developments in the application of established procedures:
 - (g) to liaise with ethics committees on general and specific matters relating to assisted reproductive procedures or human reproductive research:
 - (h) to consult with any persons who, in the opinion of the advisory committee, are able to assist it perform its functions:
 - (i) any other function that the Minister assigns to the advisory committee by written notice.
- (2) For the purpose of assisting the advisory committee in the performance of its functions, the Director-General of Health must provide the committee with administrative support.

*Guidelines and advice***35 Advisory committee to publish and notify guidelines**

- (1) When the advisory committee issues guidelines, it must—
- (a) send copies of the guidelines to each ethics committee; and
 - (b) publish the guidelines on the Internet and in any other publications (if any) that the committee thinks appropriate; and
 - (c) give public notice of the issue of the guidelines by publishing in any publication that it considers appropriate for the purpose a notice that states—

- (i) the date and subject matter of the guidelines; and
 - (ii) the Internet website on which they are published.
- (2) The Director-General of Health must ensure that there are—
 - (a) sufficient copies of guidelines published under this section available for public inspection, free of charge, at the Head Office of the Ministry of Health during normal office hours; and
 - (b) sufficient copies of those guidelines available, either for distribution free of charge or for purchase at a reasonable price during normal office hours, at places designated by the Director-General of Health.

36 Advisory committee must provide specific advice

- (1) The advisory committee must, within time frames agreed with the Minister, provide the Minister with information, advice, and, if it thinks fit, recommendations on each of the following matters:
 - (a) the creation and use of hybrid embryos for non-reproductive purposes;
 - (b) the use of embryos outside the human body in human reproductive research and assisted reproductive procedures, including—
 - (i) embryo donation;
 - (ii) embryo cloning for non-reproductive purposes;
 - (iii) embryo selection;
 - (iv) embryo splitting;
 - (c) germ line genetic modification;
 - (d) storage of human gametes or embryos;
 - (e) the use of gametes derived from fetuses.
- (2) This section does not limit the advisory committee's functions stated in **section 34**.

37 Requirement to consult

- (1) Before the advisory committee gives advice to the Minister or issues guidelines to ethics committees, it must consult with—
 - (a) any members of the public that the committee considers appropriate;
 - (b) any instrument of the Crown involved in the regulation or funding of the activities to which the proposed advice or guidelines relate;
 - (c) any other person or group that the committee considers appropriate.
- (2) Before the advisory committee issues guidelines to ethics committees, it must consult with the Minister.

38 Advisory committee must consider desirability of activities

- (1) Before it gives advice or formulates guidelines on an activity, the advisory committee must consider whether, and the extent to which, the activity is necessary or desirable—
 - (a) for promoting advances in the treatment of infertility; or
 - (b) for increasing scientific knowledge that, directly or indirectly, advances the prevention or treatment of human disease or disorder; or
 - (c) for developing more effective techniques of contraception.
- (2) To avoid doubt, **subsection (1)** does not limit **section 4**.

*Presentation and publication requirements***39 Information about advisory committees to be made public**

- (1) As soon as practicable after giving a notice of the kind specified in **subsection (2)**, the Minister must present a copy of the notice to the House of Representatives.
- (2) The kinds of notice are as follows:
 - (a) a notice appointing a member or chairperson of the advisory committee under **section 33(1)(a)**;
 - (b) a notice terminating the appointment of a member of the advisory committee under **section 33(1)(b)**;
 - (c) a notice assigning a function to the advisory committee under **section 34(1)(g)**;
 - (d) a notice giving directions as to the procedure of the advisory committee under **section 32(b)**.
- (3) The advisory committee must, as soon as practicable after each 12-month period ending on 30 June, give the Minister a report—
 - (a) on its progress in carrying out its functions; and
 - (b) on the number and kinds of approvals given by ethics committees in that period.
- (4) As soon as practicable after receiving a report under **subsection (3)**, the Minister must present the report to the House of Representatives.

Part II

To omit this Part from pages 5 to 8.

Part III

To omit this Part from pages 8 to 10.

Part IV

To omit this Part from pages 10 to 11, and substitute the following Part:

Part 4
**Information about donors of donated cells
and donor offspring**

Application

40 No retroactive application

This Part—

- (a) applies to an embryo or a donor offspring if, and only if, every donated cell from which the embryo or donor offspring was formed was donated after the commencement of this Part; and
- (b) applies to a donated cell if, and only if, it was donated after the commencement of this Part.

41 Provisions not applicable to all information

The provisions of this Part apply to information only if the information is required to be kept by this Part.

*Duties of keepers of information when information requests
are made*

42 Duty to ensure that person requesting information is authorised

- (1) When a person requests a provider or the Registrar-General to give the person access to information required to be kept by this Part, the provider or the Registrar-General must not give the person access to that information unless satisfied about the identity of the person who is making the request.
- (2) Each provider and the Registrar-General—
 - (a) must adopt appropriate procedures to ensure that any information intended for a person is received—
 - (i) only by that person; or
 - (ii) if the request is made by an agent of the person, only by that person or his or her agent; and
 - (b) must ensure that, if the request is made by an agent of the person, the agent has the written authority of that person to obtain the information or is otherwise properly authorised by that person to obtain the information.

Advice to prospective donors

43 Providers must give advice to prospective donors

- (1) A provider must ensure that, before a person consents to donating a donated cell to or through the provider, or to any service performed or arranged by the provider that involves a donated cell, the person is told the things described in **subsection (2)**.
- (2) The things are as follows:

- (a) which information about donors is obtained and kept by providers:
- (b) how long the information is kept:
- (c) why the information is obtained and kept:
- (d) which part of the information is forwarded to, and kept indefinitely by, the Registrar-General:
- (e) the rights given by this Act to donor offspring, the guardians of donor offspring, and other people to obtain information about donors:
- (f) the rights given by this Act to donors and other people to obtain information about donor offspring:
- (g) which provisions of this Act require the information to be obtained, kept, or forwarded, or give the rights.

Information about donors

44 Providers must obtain and accept information about donors

- (1) When a donor donates a donated cell to or through a provider, the provider must ensure that the provider has obtained the following information about the donor:
 - (a) the donor's name and the date, place, and country of the donor's birth:
 - (b) the donor's height:
 - (c) the colour of the donor's eyes and hair:
 - (d) the donor's ethnicity:
 - (e) any aspects, considered significant by the provider, of the medical history of the donor and of the donor's parents, grandparents, and any siblings.
- (2) The provider must accept any information that is offered by the donor that updates or corrects any of the information about the donor obtained under **subsection (1)**.

45 Providers and Registrar-General must keep information about donors

- (1) A provider must, in accordance with this section, keep all information about a donor obtained or accepted under **section 44** in relation to any donated cell.
- (2) In any case where the use of the donated cell results in the birth of a living donor offspring, the provider must give the information to the Registrar-General on the earlier of the following events:
 - (a) the expiry of 50 years after the date of that birth:
 - (b) the provider ceasing to be a provider in circumstances where there is no successor provider.
- (3) The Registrar-General must keep indefinitely all information given under **subsection (2)**.

- (4) In any case where no living donor offspring is formed from the donated cell, the provider may destroy the information on the occurrence of any of the following events:
- (a) the termination (otherwise than by the birth of a living child) of a pregnancy resulting from the implantation of an embryo formed from the donated cell;
 - (b) the destruction before implantation of an embryo formed from the donated cell;
 - (c) the destruction of the donated cell.

46 Access by donors to information about them kept by providers

If asked to do so by a donor, a provider must—

- (a) give the donor access to any information about the donor that the provider is keeping; and
- (b) tell the donor whether the donor offspring has asked for information about the donor.

47 Access by donor offspring to information about donors kept by providers

- (1) If asked to do so by a donor offspring who is 18 years or older, a provider must tell the donor offspring whether the provider is keeping any information about the donor and, if so, give the donor offspring access to it.
- (2) If asked to do so by a guardian of a donor offspring who is under 18 years, a provider must tell the guardian whether the provider is keeping any information about the donor and, if so, give the guardian access to it.
- (3) A provider may refuse to give a person access to information about a donor if satisfied, on reasonable grounds, that the disclosure is likely to endanger any person.
- (4) **Subsection (3) overrides subsections (1) and (2).**

48 Access by donor offspring to information about donors kept by Registrar-General

- (1) If asked to do so by a donor offspring who is 18 years or older, the Registrar-General must tell the donor offspring whether the Registrar-General is keeping any information about the donor and, if so, give the donor offspring access to it.
- (2) If asked to do so by a guardian of a donor offspring who is under 18 years, the Registrar-General must tell the guardian whether the Registrar-General is keeping any information about the donor and, if so, give the guardian access to it.
- (3) The Registrar-General may refuse to give a person access to information about a donor if satisfied, on reasonable grounds, that the disclosure is likely to endanger any person.
- (4) **Subsection (3) overrides subsections (1) and (2).**

49 Restriction on access to information about donors

A provider or the Registrar-General must not allow any person access to information about a donor unless—

- (a) authorised or required to do so by this Act; or
- (b) required to do so by any other enactment or rule of law; or
- (c) the information is relevant for the purposes of providing medical treatment or medical advice to a person, and is requested by a medical practitioner who produces a certificate signed by 2 medical practitioners that states that access to the information should be obtained for those purposes.

Information about donor offspring

50 Providers must keep track of donor offspring births

A provider must ensure that, at all times, there is in place an efficient system for being notified of, or otherwise becoming aware of, the births of donor offspring.

51 Providers must notify Registrar-General of donor offspring births

A provider who learns of the birth of a donor offspring must promptly—

- (a) take all practicable steps to obtain, from any person who knows of the donor offspring, the following information:
 - (i) the date and place of the donor offspring's birth;
 - (ii) the donor offspring's sex;
 - (iii) the donor offspring's name; and
- (b) give to the Registrar-General, on a form provided by the Registrar-General for the purpose,—
 - (i) the information that the provider has been able to obtain under **paragraph (a)**; and
 - (ii) the names and addresses of the guardians of the donor offspring; and
 - (iii) the donor's name and the date, place, and country of the donor's birth; and
 - (iv) the name of the provider.

52 Providers must give Registrar-General corrected information

If a provider who has given the Registrar-General information under **section 51(b)** receives additional information that updates or corrects any of the information already given, the provider must promptly give the Registrar-General the updated or corrected information.

53 Registrar-General and providers must keep information about donor offspring

- (1) The Registrar-General must keep indefinitely all information given under **section 51 or section 52**.
- (2) A provider must keep all information obtained under **section 51** or accepted under **section 54** until the expiry of the specified period.
- (3) In **subsection (2)**, **specified period** means the period that starts with the date of the birth of the donor offspring concerned and expires on the earlier of the following:
 - (a) the expiry of 50 years after the date of that birth;
 - (b) the provider ceasing to be a provider in circumstances where there is no successor provider.

54 Providers to accept updated and corrected information about donor offspring

- (1) If a donor offspring who is 18 years or older offers to a provider any information that updates or corrects any of the information already given under **section 51(b)** about the donor offspring, the provider must accept the updated or corrected information.
- (2) If a guardian of a donor offspring who is under 18 years offers to a provider any information that updates or corrects any of the information already given under **section 51(b)** about the donor offspring, the provider must accept the updated or corrected information.

55 Access by donor offspring to information about them kept by providers or Registrar-General

- (1) If asked to do so by a donor offspring who is 18 years or older, a provider or the Registrar-General must—
 - (a) give the donor offspring access to any information about the donor offspring kept by the provider or the Registrar-General, as the case requires;
 - (b) tell the donor offspring whether the donor has asked for information about the donor offspring.
- (2) If asked to do so by the guardian of a donor offspring who is under 18 years, a provider or the Registrar-General must—
 - (a) give the guardian access to any information about the donor offspring kept by the provider or the Registrar-General, as the case requires;
 - (b) tell the guardian whether the donor has asked for information about the donor offspring.

56 Donor offspring 18 years or older may consent to disclosure of identifying information to donor

- (1) A donor offspring who is 18 years or older may give a provider or the Registrar-General a written notice—
 - (a) consenting to the disclosure of identifying information about the donor offspring to the donor; or
 - (b) cancelling a notice given to the provider or the Registrar-General by the donor offspring under **paragraph (a)**.
- (2) A provider or the Registrar-General must keep with any information about the donor offspring kept under this Act every notice given by the donor offspring under **subsection (1)**.
- (3) For the purposes of any provision of this Act, a provider or the Registrar-General has the consent of a donor offspring to the disclosure to the donor of identifying information about the donor offspring if, and only if,—
 - (a) the provider or the Registrar-General holds a notice given by the donor offspring under **subsection (1)(a)**; and
 - (b) that notice has not been cancelled under **subsection (1)(b)**.

57 Access by donors to information about donor offspring kept by providers

- (1) At the request of a donor, a provider must tell the donor whether, to the best of the provider's knowledge, there have been born any donor offspring formed from a donated cell given to or through the provider and (if so) the sex of each donor offspring.
- (2) If the provider has the donor offspring's consent to give the donor access to identifying information about the donor offspring, the provider must do so at the donor's request.
- (3) The provider may refuse to disclose to the donor, or give the donor access to, information about the donor offspring if satisfied, on reasonable grounds, that to do so is likely to endanger any person.
- (4) **Subsection (3)** overrides **subsections (1) and (2)**.

58 Access by donors to information about donor offspring kept by Registrar-General

- (1) At the request of a donor, the Registrar-General must tell the donor whether information given to the Registrar-General under **section 51(b)** discloses that there have been any donor offspring born and, if so, the sex of each donor offspring.
- (2) If the Registrar-General has the donor offspring's consent to give the donor access to identifying information about the donor offspring, the Registrar-General must do so at the donor's request.
- (3) The Registrar-General may refuse to disclose to the donor, or give the donor access to, identifying information about the

donor offspring if satisfied, on reasonable grounds, that to do so is likely to endanger any person.

- (4) **Subsection (3)** overrides **subsections (1) and (2)**.

59 Restriction on disclosure of information about donor offspring

A provider or the Registrar-General must not disclose any information about a donor offspring unless—

- (a) authorised or required to do so by this Act; or
(b) required to do so by any other enactment or rule of law.

Court orders deeming certain donor offspring to be 18

60 Family Court may confer certain rights on donor offspring aged 16 or 17

- (1) A donor offspring who is 16 years or older but under 18 years may apply to the Family Court for an order that for the purposes of 1 or more of the provisions stated in **subsection (2)** the donor offspring is to be treated as a donor offspring who is 18 years old.
- (2) The provisions are **sections 47(1), 48(1), 54(1), 55(1), and 56(1)**.
- (3) If satisfied that it is in the best interests of the donor offspring to do so, a Family Court Judge may make an order that requires a named provider or the Registrar-General, or both, to treat, for the purposes of 1 or more of the provisions specified in **subsection (2)**, the donor offspring as a donor offspring who is 18 years old.
- (4) Rules may be made under section 16A of the Family Courts Act 1980 relating to the practice and procedure of Family Courts in proceedings under this Act.

Application of Privacy Act 1993

61 Application of Privacy Act 1993

- (1) Any person may make a complaint to the Privacy Commissioner holding that office under section 12 of the Privacy Act 1993 if—
- (a) the person is dissatisfied with any decision, action, or failure to act by a provider or the Registrar-General in relation to—
- (i) a request under this Act for information or access to information; or
- (ii) a request under this Act to accept updated or corrected information; or
- (b) the person believes that information—
- (i) has been obtained, kept, or disclosed otherwise than in accordance with this Act; or
- (ii) has not been obtained, accepted, kept, or given, as required by this Act.

- (2) Sections 40 and 41 of the Privacy Act 1993, so far as applicable and with any necessary modifications, apply to any request of a kind referred to in **subsection (1)(a)**.
- (3) Parts VIII, IX, and XII of the Privacy Act 1993, so far as applicable and with any necessary modifications, apply to the making of a complaint under **subsection (1)** as if the matter to which the complaint relates were an interference with privacy within the meaning of section 66 of that Act.
- (4) Nothing in this section limits the jurisdiction of the Privacy Commissioner under the Privacy Act 1993 to investigate any complaint made under Part VIII of that Act.

Part V

To omit this Part from page 12.

Part VI

To omit this Part from pages 12 and 13, and substitute the following Part:

Part 6
Enforcement and miscellaneous provisions

Enforcement

62 Matters to be ascertained by authorised persons

An authorised person who believes on reasonable grounds that any assisted reproductive procedure is performed or any human reproductive research is conducted in a place may at any reasonable time exercise any of the powers in **section 63** reasonably necessary to ascertain all or any of the following matters:

- (a) whether any assisted reproductive procedure or any human reproductive research is in fact performed or conducted in the place:
- (b) whether the performance of any assisted reproductive procedure or the conduct of any human reproductive research complies—
 - (i) with **section 7 or section 10 or section 11**:
 - (ii) with any regulations made under **section 70(1)(a)** that regulate any kind of assisted reproductive procedure or human reproductive research:
 - (iii) with the requirement to obtain the approval of an ethics committee for the performance of an assisted reproductive procedure or the conduct of human reproductive research:
 - (iv) with any conditions included in an approval given by an ethics committee.

63 Powers of authorised persons

- (1) The powers referred to in **section 62**, in relation to any place, are the powers to—
 - (a) enter the place:

- (b) inspect—
 - (i) any equipment or device believed on reasonable grounds to be used in the place in relation to any assisted reproductive procedure or human reproductive research:
 - (ii) any document in the place believed on reasonable grounds to relate to any assisted reproductive procedure or human reproductive research:
 - (c) take or make copies of, or copies of extracts from, any document inspected and, for that purpose,—
 - (i) take possession of and remove the document from the place for any reasonable period:
 - (ii) in the case of a document or information stored otherwise than on paper, take any reasonable steps to reproduce, in usable form, any or all of the information in it:
 - (d) search for and seize—
 - (i) any equipment or device referred to in **paragraph (b)(i)**:
 - (ii) a gamete of any kind that is outside the body of a human or an animal:
 - (iii) an embryo or foetus of any kind that is outside the body of a human or an animal:
 - (iv) a document or record (whether in electronic or other form):
 - (e) take photographs, and make drawings or other representations, of any item that may be seized under **paragraph (d)**:
 - (f) mark or identify, by any appropriate means, any item that may be seized under **paragraph (d)**:
 - (g) require any person appearing to be in charge of the place concerned (or any part of it) to ensure that any item that may be seized under **paragraph (d)** is not removed or interfered with:
 - (h) require any person appearing to be in charge of the place concerned (or any part of it) to answer any question the authorised person may reasonably ask for the purpose of exercising the powers of the authorised person.
- (2) An authorised person who enters a place under this section must produce evidence of his or her authorisation—
 - (a) on first entering the place:
 - (b) whenever subsequently reasonably required to do so by a person appearing to be in charge of the place or any part of the place.
 - (3) An authorised person who enters a place under this section may be accompanied by any number of persons (including

any member of the police) reasonably necessary to assist him or her with the exercise of his or her powers under this section.

- (4) A person who accompanies an authorised person under **subsection (3)** may, under the direction of the authorised person, exercise each of the powers described in **subsection (1)(a) to (f)**.
- (5) This section does not limit the privilege against self-incrimination.

64 Entry of dwellinghouses

- (1) An authorised person may not enter a dwellinghouse under **section 63(1)(a)**, except—
 - (a) with the consent of an occupier of the dwellinghouse; or
 - (b) with the authority of a search warrant issued under **subsection (2)**.
- (2) A District Court Judge, a Justice, or a Court Registrar who is not a member of the police, may, on a written application made on oath by an authorised person, issue a search warrant in the form set out in **Schedule 2** in respect of a dwellinghouse if satisfied that there are reasonable grounds to believe that in that house—
 - (a) an offence against this Act has been or is being committed; or
 - (b) there is any gamete, any kind of embryo or foetus, or being that is or may be evidence of the commission of an offence against this Act.
- (3) The search warrant authorises the authorised person to whom it is directed to exercise in respect of the dwellinghouse all or any of the powers described in **section 63**, and the provisions of that section apply to the execution of the warrant.
- (4) The Judge, Justice, or Court Registrar may issue the warrant unconditionally or subject to any conditions that he or she thinks fit.
- (5) The authorised person to whom the search warrant is directed may execute it on 1 occasion within 14 days after the date of its issue.

65 Identification of authorised person

- (1) An authorised person exercising powers under **section 63** in respect of any place,—
 - (a) if a person appearing to be in charge of the place is present on first entering the place, must identify himself or herself to that person; and
 - (b) if asked by the person appearing to be in charge of the place or any part of the place to do so, must produce evidence of his or her identity and evidence of his or her appointment as an authorised person.

- (2) If the authorised person executes a search warrant issued under **section 64**, the authorised person must produce the warrant,—
 - (a) on first entering the place specified in the warrant, to the person appearing to be in charge of the place; and
 - (b) whenever subsequently required to do so by any person appearing to be in charge of the place or any part of that place.

66 Notice requirements when place entered

- (1) If the occupier of the place is not present when an authorised person enters a place under **section 63(1)(a)**, the authorised person must leave in a prominent location at the place a written statement of the time and date of the entry, the name of the person, and the address of the office of the Ministry of Health to which inquiries should be made.
- (2) If anything is seized under **section 63(1)(d)**, the authorised person concerned must leave in a prominent location at the place, or deliver or send to the occupier within 10 working days after the search, a written inventory of all things seized.

67 Disposal of property seized

Section 199 of the Summary Proceedings Act 1957 applies to any property seized by an authorised person under **section 63(1)(d)**, subject to the following provisions:

- (a) an item seized by an authorised person may be retained by the authorised person or the Commissioner of Police pending the trial of the person for the offence in respect of which the item was seized; and
- (b) the item in question must be returned to the person from whom it was seized,—
 - (i) if no proceedings are taken in respect of an offence to which the item relates, within 2 years after its seizure; or
 - (ii) if proceedings are completed in respect of the offence and no order of forfeiture is made in respect of the item; and
- (c) if any person is convicted of an offence to which the item relates, the Court may, if it thinks fit, order that the item be forfeited to the Crown or disposed of as the Court directs at the expense of the convicted person, and may order that the person pay any reasonable costs incurred by the authorised person or the Commissioner of Police in retaining the item.

68 Protection of persons acting under authority of Act

No authorised person, or a person requested to assist an authorised person, who does, or omits to do, an act in pursuance of a function or power conferred on that person by this Act is under civil or criminal liability for that act or omission unless the person acts, or omits to act, in bad faith or without reasonable cause.

69 Offences related to inspections and searches

- (1) Every person commits an offence who—
 - (a) intentionally obstructs, hinders, or resists an authorised person, or any person lawfully assisting an authorised person, in the exercise of the authorised person's powers under this Act; or
 - (b) intentionally refuses or fails to comply with any lawful requirements of an authorised person under this Act.
- (2) A person who commits an offence against **subsection (1)** is liable on summary conviction to a fine not exceeding \$20,000.

*Miscellaneous provisions***70 Regulations**

- (1) The Governor-General may, by Order in Council, make regulations for all or any of the following purposes:
 - (a) regulating the performance of any kind of assisted reproductive procedure or the conduct of any human reproductive research, including, without limitation, providing for the circumstances and the manner in which, and the conditions subject to which, the procedure may be performed or the research may be conducted;
 - (b) prescribing offences in respect of the contravention of, or non-compliance with, any regulations made under **paragraph (a)** and the amounts of fines that may be imposed in respect of those offences, which fines must not exceed \$20,000;
 - (c) prescribing the fees to be paid in relation to the taking of any action under **Part 4** by the Registrar-General;
 - (d) providing for any other matters that are contemplated by, or necessary for giving full effect to, this Act, and for its due administration.
- (2) Regulations under **subsection (1)(a)** may be made only on the recommendation of the Minister after the Minister has consulted the advisory committee and any other person the Minister thinks fit to consult.

71 Liability of employers, principals, and directors

- (1) An act done by a person as the employee (the **employee**) of another person (the **employer**) is, for the purposes of an offence against this Act, to be treated as done by the employer as well as by the employee if—
 - (a) the employer approved of the act; or
 - (b) the employer knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it.
- (2) An act done by a person as the agent (the **agent**) of another person (the **principal**) is, for the purposes of an offence against this Act, to be treated as done by the principal as well as by the agent if—
 - (a) the principal approved of the act; or
 - (b) the principal knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it.
- (3) Whenever a body corporate is convicted of an offence against this Act, a director of the body corporate is to be treated as having committed the same offence if—
 - (a) the director approved of the act that constituted the offence; or
 - (b) the director knew the offence was to be or was being committed and failed to take all reasonable steps to prevent it.
- (4) In **subsection (3)**, **director** includes a person who is concerned in the management of a body corporate.

72 Fees

The Registrar-General may refuse to take any action under this Act for which a fee is prescribed unless the fee has been paid.

73 Provisions to be treated as guidelines in interim period

- (1) In this section, **interim period** means the period that commences on the day after the date on which this Act receives the Royal assent and ends on the third anniversary of that day.
- (2) During the interim period, the Minister may—
 - (a) issue a requirement requiring each ethics committee to treat specified provisions of any document as guidelines issued by the advisory committee for the purposes of this Act; and
 - (b) amend or revoke a requirement of that kind.
- (3) A requirement, or the amendment or revocation of a requirement, comes into force on the 28th day after the day on which it is published in the *Gazette*.

- (4) A requirement and any amendment of a requirement, unless sooner revoked, expires at the end of the interim period.
- (5) Each ethics committee must give effect to the current form of every requirement.
- (6) Every requirement and any amendment or revocation of the requirement must be published in the *Gazette*, and the publication of a requirement or an amendment of a requirement must identify the provisions that are to be treated as guidelines but need not set them out.

74 Availability of provisions treated as guidelines

When, by a requirement under **section 73**, each ethics committee is required to treat any provisions as guidelines, the Director-General of Health must ensure that there are—

- (a) sufficient copies of the provisions available for public inspection, free of charge, at the Head Office of the Ministry of Health during normal office hours; and
- (b) sufficient copies of those provisions available either for distribution free of charge or for purchase at a reasonable price during normal office hours at places designated by the Director-General of Health.

75 Amendment to Medicines Act 1981

- (1) Section 96A of the Medicines Act 1981 is amended by repealing the definitions of **cloned human organism**, **cloning procedure**, **genetically modified embryo**, **genetically modified gamete**, and **germ-cell genetic procedure**.
- (2) Section 96A of the Medicines Act 1981 is amended by repealing the definition of **specified biotechnical procedure**, and substituting the following definition:
“**specified biotechnical procedure** means any xenotransplantation”.
- (3) Any application made, before the commencement of this section, under section 96G of the Medicines Act 1981 for the grant of an authorisation in relation to any germ-cell genetic procedure or any cloning procedure must be treated as if this Act had not been enacted; and an authorisation under section 96C or section 96D of that Act granted in respect of such an application has effect as if this Act had not been enacted.

76 Amendment to Summary Proceedings Act 1957

Part II of the First Schedule of the Summary Proceedings Act 1957 is amended by inserting, after the item relating to the Harbours Act 1950, the following item:

Human Assisted Reproductive Technology Act 2003	7(1)	Taking an action described in Schedule 1
	7(2)	Importing or exporting a gamete, any kind of embryo or foetus, or being formed by an action described in Schedule 1
	7(3)	Possessing a gamete, any kind of embryo or foetus, or being formed by an action described in Schedule 1

First, Second, and Third Schedules

To omit the *First, Second, and Third Schedules* (pages 14 to 19), and substitute the following schedules:

Schedule 1
Prohibited actions

s 7

- 1 Artificially form, for reproductive purposes, a cloned embryo. For the purposes of this item, a cloned embryo is not formed by splitting, on 1 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 or a foetus that has developed from a cloned embryo.
 - 4 Implant into a human being an animal embryo or foetus.
 - 5 Implant into a human being a hybrid embryo or a foetus that has developed from a hybrid embryo.
 - 6 Implant into an animal a human embryo or foetus.
 - 7 Implant into an animal a hybrid embryo or a foetus that has developed from a hybrid embryo.
-

Schedule 2

Form of search warrant

s 64(2)

Warrant under section 64(2) of Human Assisted Reproductive Technology Act 2003 to enter dwellinghouse

To: *[state name of authorised person]*

Being satisfied on written application made on oath by an authorised person that there are reasonable grounds to believe that in the dwellinghouse located at *[state address or other description of location]*—

- (a) an offence against the Human Assisted Reproductive Technology Act 2003 has been or is being committed; or
- (b) there is any gamete, any kind of embryo or foetus, or being that is or may be evidence of the commission of an offence against the Human Assisted Reproductive Technology Act 2003,—

by this warrant I authorise you, on 1 occasion within 14 days of the issue of this warrant, to enter that dwellinghouse and exercise the powers conferred by section 62 of that Act.

Dated at *[state place and date of issue]*.

Conditions (if any) subject to which warrant issued:

.....
District Court Judge (*or Justice or Court Registrar (not being a member of the police)*).

Explanatory note

This Supplementary Order Paper (SOP) amends the Human Assisted Reproductive Technology Bill (the **HART Bill**). The SOP retains the following core features of the HART Bill:

- a regulatory framework for assisted reproductive procedures and human reproductive research in New Zealand;
- principles to guide those operating under the legislation, with the health and well-being of a child born as a result of assisted reproductive procedures being paramount in decisions about the use of such procedures;
- protection against the commercialisation of surrogacy, embryos, and gametes;
- prohibitions relating to particular activities, including reproductive cloning and the implantation of a human embryo in an animal (or vice versa):

- a record-keeping regime, and provisions for access to information about donors and donor offspring.

The SOP updates the HART Bill in light of government policy decisions, changes in New Zealand health sector legislation and regulation, advances in the field of assisted reproductive procedures and human reproductive research, and developments in overseas legislation.

Background

The HART Bill was introduced in 1996 to provide a legislative framework for restrictions and controls on assisted reproductive technology in New Zealand. It was developed in line with existing British, Australian, and Canadian law. The Assisted Human Reproduction Bill was introduced in 1998. Both Bills are before the Health Committee.

Technology and scientific knowledge regarding assisted human reproduction has progressed rapidly since the Bills were developed. In response to these developments, the Government decided to introduce amendments to the HART Bill by way of a Government SOP.

Main changes to HART Bill

The SOP removes the licensing regime for fertility service providers established in the HART Bill.

Part 1AA

Preliminary provisions

The SOP—

- amends the purpose, principles, and interpretation clauses to reflect the changes in the SOP:
- provides that the Governor-General, by Order in Council, can declare any assisted reproductive procedure, treatment, or application an established procedure, on the recommendation of the Minister of Health.

Part 1

Prohibited and regulated activities

The SOP—

- prohibits certain actions and creates offences and penalties relating to these actions:
- provides a mechanism to add actions to the Schedule of prohibited actions:
- requires prior approval from an ethics committee for assisted reproductive procedures that are not established procedures, and for all human reproductive research:
- provides for the Minister of Health to designate 1 or more committees as an ethics committee for the purposes of the Act:

- establishes an advisory committee appointed by the Minister of Health to provide advice, and develop guidelines on assisted human reproductive procedures and human reproductive research that ethics committees have to operate in accordance with:
- provides for a moratorium to be imposed on an activity by the Governor-General in Council on the recommendation of the Minister of Health:
- provides for regulations to be made by the Governor-General in Council on the recommendation of the Minister of Health in relation to any assisted reproductive procedure or human reproductive research:
- removes the prohibitions on germ line genetic modification, sex selection, mandatory genetic screening, the use of eggs from foetuses, and non-reproductive cloning. Instead, it requires a Ministerial advisory committee to provide advice to the Minister of Health on these activities before applications relating to these activities may be considered for ethical approval.

Part 4

Information about donors of donated cells and donor offspring

The SOP sets out in more detail the requirements on fertility service providers to collect, retain, and provide access to information about donors and donor offspring. It also expands the requirements on the Registrar-General of Births, Deaths, and Marriages to retain and provide access to information about donors and donor offspring. This Part is drawn from the Assisted Human Reproduction Bill.

Part 6

Enforcement and miscellaneous provisions

The SOP—

- provides for enforcement of the provisions, regulations, or guidelines made under this Act:
- amends the regulation-making powers to reflect the changes in the SOP.

Schedule 1

Prohibited Actions

Schedule 1 sets out the prohibited actions under the Act relating to—

- the creation, for reproductive purposes, of cloned and hybrid embryos:
- the implantation in humans of a cloned embryo, a hybrid embryo, or animal embryo:
- the implantation in an animal of a human or hybrid embryo.

Schedule 2
Form of search warrant

Schedule 2 sets out the form of a search warrant to enter a dwellinghouse.

