



Western Australia

Human Reproductive Technology Act 1991

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Human Reproductive Technology Act 1991

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Human Reproductive Technology Act 1991

An Act to establish the Western Australian Reproductive Technology Council; to require the compilation of a Code relating to the practice of, the procedures used in, and the ethics governing, human reproductive technology; to make provision with respect to the use of that technology in relation to artificially assisted human conception and for the regulation of certain research; and for related purposes.

Preamble

Whereas:

- A. In enacting this legislation Parliament is seeking to give help and encouragement to those eligible persons who wish to be parents.
- B. Parliament considers that the primary purpose and only justification for the creation of a human embryo in vitro is to assist persons who are unable to conceive children naturally due to medical reasons or whose children are otherwise likely to be affected by a genetic abnormality or a disease, to have children, and this legislation should respect the life created by this process.
- C. Although Parliament recognises that research has enabled the development of current procedures and that certain research procedures and other uses upon a human embryo may be licit, it does not approve the creation of a human embryo for a purpose other than the implantation in the body of a woman.

[Preamble amended by No. 3 of 2002 s. 72; No. 17 of 2004 s. 4.]

The Parliament of Western Australia enacts as follows:

Part 1 — Preliminary

Division 1 — Introduction

1. Short title

This Act may be cited as the *Human Reproductive Technology Act 1991*¹.

2. Commencement

The provisions of this Act shall come into operation on such day as is, or days as are respectively, fixed by proclamation and in any event this Act, or so much of it as has not been proclaimed, shall come into operation 18 months after the date upon which it receives the Royal Assent¹.

3. Terms used and application

(1) In this Act, unless the contrary intention appears —

artificial fertilisation procedure means any —

- (a) artificial insemination procedure; or
- (b) in vitro fertilisation procedure;

artificial insemination procedure means a procedure where human sperm are introduced, by a non-coital method, into the reproductive system of a woman but which is not, and is not an integral part of, an in vitro fertilisation procedure;

authorised officer means —

- (a) the CEO; or
- (b) a person authorised by the CEO, generally or in relation to particular functions, circumstances, or purposes, as may be specified in the relevant certificate issued under section 59(2);
- (c) in relation to the powers referred to in section 44(3)(c) or 49(4)(b), includes a reference to the CEO as defined in section 3 of the *Children and Community Services*

Act 2004 or an officer as defined in that section authorised in writing by that CEO;

- (d) in relation to the powers referred to in section 54, a person on whom the powers are conferred by the CEO under section 53ZQ(4);

biological parent means a person who —

- (a) is the source of a human egg or human sperm used in an artificial fertilisation procedure; and
- (b) is the genetic parent of a human embryo developed, or of a child born, as a consequence of that procedure;

CEO has the meaning given by section 3 of the *Health Legislation Administration Act 1984*;

Chairperson means the member appointed to that office under clause 1(1) of the Schedule, and includes a reference to a person acting in that office;

Code of Practice or **Code** means the Code of Practice compiled under section 14(1)(c), as from time to time amended and in force;

committee means a committee of the Council;

Commonwealth Human Embryo Act means the *Research Involving Human Embryos Act 2002* of the Commonwealth;

condition in relation to a licence or exemption, includes —

- (a) a limitation, restriction or prohibition; and
- (b) any other provision of that licence or exemption affecting its operation or the authorisation conferred,

whether or not it purports to be expressed by way of a condition;

Council means the Western Australian Reproductive Technology Council established by section 8;

counselling services include —

- (a) the screening or assessment of potential participants;
- (b) the provision of information; and

- (c) generally, assisting participants to address personal issues arising from infertility and its treatment;

Deputy Chairperson means the member for the time being appointed or selected to that office under clause 1(3) of the Schedule, and includes a reference to a person acting in that office;

directions means directions given under Division 2 of Part 4;

director, in relation to a body corporate, includes —

- (a) a member of the board or committee of management of the body corporate;
- (b) a person occupying or acting in a position to which paragraph (a) refers, by whatever name the position is called and whether or not validly appointed to occupy or duly authorised to act in the position; and
- (c) any person in accordance with whose directions or instructions directors of the body corporate are accustomed to act;

effective consent is to be construed in accordance with section 22(8);

excess ART embryo has the meaning given to that term in section 53T;

Executive Officer means the person appointed as the Executive Officer of the Council under section 8(2)(b), and includes a reference to a deputy to that person appointed under clause 2(2) of the Schedule when acting in the place of that person;

exemption means —

- (a) an exemption that is applied for and is not refused, or is specifically issued, under section 28; or
- (b) an exemption under section 28A;

fertilisation, for the purposes of this Act, means the process that commences at the moment of inclusion of a sperm head within the plasma membrane of an egg, and is completed when an embryo is formed;

guidelines means, except in section 14(3), the information set out in Part 2 of the Code;

human egg means a live human egg;

human embryo has the meaning given to that term in section 3A;

human gamete means a human egg or a human sperm;

human sperm means live human sperm or spermatids;

in vitro fertilisation procedure means a procedure, not being a storage procedure, which —

- (a) is consequent upon the removal of a human egg from the body of a woman, and carried out for one or more of the following purposes —
 - (i) the fertilisation of that egg, within or outside her body;
 - (ii) the keeping or use of that egg with intent to derive from it a human egg undergoing fertilisation or a human embryo; or
 - (iii) the keeping or use of that human egg undergoing fertilisation or human embryo so derived;
 - (b) is directed at the introduction into the body of a woman of —
 - (i) a human egg;
 - (ii) a human egg undergoing fertilisation or a human embryo, whether or not fertilisation began outside the body into which it is introduced;
- or
- (c) is a procedure in relation to artificially assisted human conception which is prescribed for the purposes of this definition;

Institutional Ethics Committee means a body which is recognised by the Council, as having —

- (a) in relation to ethical matters, the role of overseeing all the aspects of a reproductive technology practice, or of research, carried on by a licensee; and
- (b) functions, and a composition, complying with requirements of the NHMRC relating to ethical oversight of research involving humans;

licence means a licence granted under Part 4;

licence supervisor, in relation to a licence or exemption, means the individual under whose supervision the storage or practice authorised is, or is to be, carried on;

licensee means a person holding a licence under Part 4 and also includes a reference to —

- (aa) a person who holds an exemption under section 28A;
- (a) a person who is authorised under section 30 to carry on the practice of a licensee;
- (b) the licence supervisor, in relation to any licence or exemption;
- (c) a person authorised or permitted, in accordance with section 51, to carry on, supervise or manage a reproductive technology practice or specified activities;
- (d) a registered medical practitioner to whom an exemption under section 28 applies; and
- (e) in relation to the duties of keeping, and maintaining the confidentiality of, any record to which this Act relates, a person who as a licensee has, or at any earlier time had, such a duty under this Act in respect of that record;

medical practitioner has the meaning given to that term in the *Medical Practitioners Act 2008*;

member means member of the Council, and includes a reference to a deputy or other person acting in the place of a member;

NHMRC means the National Health and Medical Research Council established by the *National Health and Medical Research Council Act 1992* of the Commonwealth;

NHMRC licence means a licence granted under —

- (a) section 53ZB; or
- (b) section 21 of the Commonwealth Human Embryo Act;

nominated member means a member of the Council, other than the Executive Officer;

participant, in relation to any artificial fertilisation procedure, means —

- (a) a person who —
 - (i) undergoes that procedure; or
 - (ii) is the donor, or being a woman is the recipient, of human gametes, of a human egg undergoing fertilisation or of a human embryo used in that procedure;

or

- (b) a person from whom, by reason of this Act, a consent to the carrying out of that procedure is required;

person to whom the licence applies is to be construed in accordance with subsection (5);

premises includes any land, any vehicle, vessel or aircraft, and any part of premises;

procedure means any treatment, course of treatment or cycle of treatment involving reproductive technology, but may also include any part of such treatment or any other service or process which is defined in and described by the Code as constituting for the purposes of this Act a procedure of a specified kind;

proprietary company means a proprietary company within the meaning of the *Corporations Act 2001* of the Commonwealth;

Public Health Official means a person designated as such for the purposes of this Act under section 7 of the *Health Legislation Administration Act 1984*;

record means —

- (a) any book, account, document, financial records (within the meaning of the *Corporations Act 2001* of the Commonwealth), paper, return, register or other source of information compiled, recorded or stored in written or encoded form or on microfilm, or by electronic or other means or process;
- (b) the contents, in a printout or other intelligible format, of records that are kept, by computer or otherwise, in a format that is not readily intelligible; and
- (c) any other sources of information prescribed for the purposes of this definition;

related body corporate, in relation to a specified body corporate, means a body corporate that is, within the meaning of the *Corporations Act 2001* of the Commonwealth, related to the specified body corporate;

reproductive technology means that branch of medical science which is concerned with —

- (a) artificial fertilisation procedures;
- (b) the keeping or use of human gametes intended for use in an artificial fertilisation procedure, human eggs undergoing fertilisation or human embryos; or
- (c) other procedures or matters incidental thereto;

research means systematic investigations carried out for the primary purpose of adding to general knowledge but includes the carrying out of an experiment, and **project of research** shall be construed accordingly;

Rules means the rules contained in Part 1 of the Code;

storage procedure shall be construed in accordance with subsection (4);

subsidiary legislation includes the Rules and any direction having legislative effect;

summary conviction penalty, in relation to a crime, has the same meaning as that term has in section 5 of *The Criminal Code*;

this Act includes a reference to —

- (a) the regulations;
- (b) the Rules and the guidelines; and
- (c) such directions as are published in the *Gazette*;

treatment includes medical, surgical and obstetric services;

woman means any female human.

- (2) This Act, other than Part 4A or 4B so far as it relates to the keeping or use of, or any offence relating to, a human egg undergoing fertilisation or a human embryo applies —
 - (a) only to such keeping or use as takes place outside the body of a woman; and
 - (b) only if the egg or the embryo has been or is developed in consequence of an in vitro fertilisation procedure.
- (3) In this Act, a reference —
 - [(a) *deleted*]
 - (b) to a human egg, except where the context otherwise indicates, does not include a reference to a human egg undergoing fertilisation;
 - (c) to a **reproductive technology practice** or **practice** includes all activities authorised under a licence issued or exemption granted under this Act, including storage, unless the context otherwise requires; and
 - (d) to the keeping of human sperm, does not include keeping for purposes other than for use in an artificial fertilisation procedure.

- (4) In relation to human gametes, a human egg undergoing fertilisation or a human embryo a reference in this Act —
- (a) to keeping, includes storing, whether by cryo-preservation or in any other way, in such a state as temporarily arrests or suspends metabolic function; and
 - (b) to any human gametes which are or a human egg or embryo which is, **stored**, means kept in such a state, and **store** and **storage** shall be construed accordingly.
- (5) References in this Act to a “person to whom the licence applies” are to —
- (a) the licensee;
 - (b) the licence supervisor;
 - (c) any person designated in a notice given to the CEO by the licensee or the licence supervisor, as a person to whom the licence applies; and
 - (d) any person acting under the direction of the licensee, the licence supervisor or of the person so designated.
- (6) In this Act a reference to what is “proper” or “suitable” shall be construed having regard to any relevant provision of the Code.
- (7) A requirement in this Act to provide or produce a record includes, where the record is not written or not written in the English language, a requirement that any person having the power to do so provide or produce a statement written in the English language supported by details of any encoding involved, setting forth such of the particulars in the record as are not written or are not written in the English language in such a manner as to allow for verification.
- (8) Where directions are published in the *Gazette* those directions are to be taken to be subsidiary legislation to which the *Interpretation Act 1984* applies, but not to be regulations within the meaning or for the purposes of section 42 of that Act.

- (9) For the purposes of this Act, a person occupies a position of authority in a body if that person —
- (a) where the body is a body corporate, is a director;
 - (b) exercises or exerts, or is in a position to exercise or exert, control or substantial influence over the body in the conduct of its affairs; or
 - (c) manages, or is deemed to manage, the business of the practice to be carried on under a licence,

or, where a body corporate is a proprietary company, if that person is a shareholder in that proprietary company.

- (9a) Nothing in this Act, or in a licence, authorisation or approval under this Act, authorises or permits the use of a human embryo for technical or commercial purposes in the testing, creation or manufacture of cosmetic products such as lipstick, mascara, face moisturising creams and other like beauty products.
- (10) This Act binds the Crown.

[Section 3 amended by No. 57 of 1997 s. 75; No. 10 of 2001 s. 108; No. 17 of 2004 s. 5; No. 18 of 2004 s. 4; No. 34 of 2004 Sch. 2 cl. 14; No. 55 of 2004 s. 522 and 540; No. 28 of 2006 s. 266 and 270(1); No. 22 of 2008 Sch. 3 cl. 28.]

3A. Term used: human embryo

- (1) In this Act —
- human embryo*** means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.
- (2) For the purposes of the definition of ***human embryo*** in subsection (1), in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

[Section 3A inserted by No. 17 of 2004 s. 6.]

4. The objects of this Act

- (1) Generally, the objects of this Act are —
- (a) to regulate, and to provide guidance in, the use of reproductive technology by —
 - (i) the establishment of the Council, with the functions referred to in section 14;
 - (ii) the compilation and implementation of a Code of Practice;
 - (iii) the imposition of licensing requirements; and
 - (iv) the enforcement of this Act;
 - (b) to ensure adherence to standards in the practice of reproductive technology that are proper and suitable;
 - (c) to allow beneficial developments in reproductive technology, but to discourage, and if required to prohibit, developments or procedures that are not both proper and suitable;
 - (d) to ensure —
 - (i) that artificial fertilisation procedures may only be carried out for the benefit of persons who, in accordance with this Act, are eligible to be so treated;
 - (ii) that the participants are adequately assessed medically as to the need for any procedure, and counselled and informed as to its implications;
 - (iii) that the welfare of participants is properly promoted; and
 - (iv) that the prospective welfare of any child to be born consequent upon a procedure to which this Act relates is properly taken into consideration;
 - (e) to require that equity, welfare and general standards prevailing in the community are taken into account in the practice of reproductive technology; and

- (f) to provide a forum whereby —
 - (i) debate by the community on reproductive technology issues may be conducted;
 - (ii) proper standards to evaluate and monitor reproductive technology can be determined, established and maintained; and
 - (iii) policy decisions may be made about reproductive technology,
on an informed basis.
- (1a) The particular objects of Part 4A are set out in section 53A.
- (2) The particular objects of Part 4B are set out in section 53S.
[Section 4 amended by No. 17 of 2004 s. 7; No. 18 of 2004 s. 5.]

5. Administration of this Act

- (1) Subject to the Minister, the administration of this Act is vested in the CEO who —
 - (a) shall be responsible for the implementation of the licensing system set out in Part 4; and
 - (b) may give directions to licensees.
- (2) The Western Australian Reproductive Technology Council established under section 8 shall —
 - (a) compile the Code of Practice;
 - (b) advise the Minister, generally; and
 - (c) advise the CEO on licensing and disciplinary matters,but shall give effect to instructions given by the Minister under section 12(3) and, if the CEO is empowered under section 13 to discharge functions of the Council, shall assist the CEO in so doing.
- (3) The Code of Practice shall be compiled and implemented in accordance with Part 3.

- (4) Regulations made under this Act shall have effect notwithstanding any inconsistency with the Code of Practice, but the Minister shall not recommend the making of regulations in relation to any matter in respect of which a Rule is, or could be, made under the Code unless, in the opinion of the Minister —
- (a) the making of the regulation is necessary to ensure the coming into operation of a provision which is required to have effect sooner than the procedure set out in section 16 would permit; or
 - (b) the regulation is required for the purposes of section 13(2).
- (5) Directions given by the CEO shall have effect, except to the extent of any inconsistency with the regulations or the Code, in accordance with section 31.
- (6) A report on the use of human reproductive technology in the State during the preceding financial year shall be furnished annually by the Council to the CEO who shall thereafter submit the annual report required by clause 11 of the Schedule to the Minister who shall, within 14 sitting days after the submission of that report, cause copies of it to be laid before each House of Parliament.
- (7) For parliamentary purposes, and for the conduct of the public business of the Minister, the Minister is entitled —
- (a) to be furnished by the CEO and the Council with —
 - (i) any report concerning the activities or proceedings of the CEO, the Council or the committees of the Council; and
 - (ii) all information in their respective possession, as the Minister may from time to time require; and
 - (b) to have, and to retain copies of, any record required to be kept, or kept, under this Act, or under any order or

resolution of either House of Parliament in relation to this Act,

but the Minister shall ensure that the confidentiality of any record or other information to which this Act applies is not thereby prejudiced.

- (8) For the purposes of subsection (7), the Minister may —
- (a) request the CEO or the Council to furnish, or to give the Minister access to, information, and to supply records; and
 - (b) make use of the services of any staff of the CEO or of the Council, or of any other person engaged in the administration or enforcement of this Act, for the purposes of obtaining access to information or copies of records,

and the Executive Officer is authorised to ensure compliance with any requirement of the Minister made under this section.

- (9) In this section —

information means —

- (a) any record relating to the functions of the CEO or the Council;
- (b) any other document or information which relates to the CEO or the Council or to reproductive technology which is in the custody or control of the CEO or of the Council and is specified, or of a description specified, by the Minister;

parliamentary purposes means the purpose of —

- (a) answering a question asked in a House of Parliament; or
- (b) complying with a written law, or an order or resolution of a House of Parliament, that requires information to be furnished to a House of Parliament;

record includes any data that is compiled, recorded, encoded or stored, and any film, tape, disc or other device or medium on which it can or may be found.

[Section 5 amended by No. 28 of 2006 s. 270.]

Division 2 — Specific offences

5A. Application

This Division does not apply in relation to an excess ART embryo except in relation to a use of such an embryo that is an exempt use as defined in section 53W(2).

[Section 5A inserted by No. 17 of 2004 s. 8.]

6. Unlicensed practices

- (1) No person shall cause or permit —
 - (a) any procedure to be carried out related to the storage of —
 - (i) a human egg intended for use in an in vitro fertilisation procedure;
 - (ii) a human egg undergoing fertilisation; or
 - (iii) a human embryo;
 - (b) human sperm, having been obtained from different men, to be kept;
 - (c) an artificial fertilisation procedure, other than an artificial insemination to which section 28(3) applies, to be carried out; or
 - (d) any other use, outside the body of a woman, of a human embryo, if the use is not for a purpose relating to the reproductive technology treatment of the woman,

except pursuant to a licence or exemption by which it is authorised under this Act.

- (2) A person who contravenes subsection (1) commits a crime and is liable to imprisonment for 5 years.

Summary conviction penalty: Imprisonment for one year.

[(3) deleted]

- (4) If an offence referred to in subsection (1) is shown to have been committed after the service upon the alleged offender of a notice in the prescribed form signed by the CEO drawing attention to a continuing state of affairs alleged in that notice to contravene subsection (1), the offender is liable to a penalty of \$10 000, in addition to the penalty specified in subsection (2) or (3), in respect of each day on which that offence is continued after the service of that notice.
- (5) It shall not be a defence to proceedings for an offence against this section to allege that the accused believed that what was done was —
- (a) authorised by a licence or exemption under this Act; or
 - (b) done at the request of, or with the consent of, a participant.

[Section 6 amended by No. 17 of 2004 s. 9; No. 84 of 2004 s. 82; No. 28 of 2006 s. 270(1).]

7. Offences relating to reproductive technology

- (1) A person, whether or not a licensee, must not cause or permit —
- (a) research to be conducted upon or with a human egg undergoing fertilisation, or any embryo, not being research in respect of which the Council has already granted relevant approval or all requisite specific prior approvals have been sought and obtained under section 20; or
 - (b) a diagnostic procedure to be carried out upon or with a human egg undergoing fertilisation, or any embryo, not being a procedure which is —
 - (i) authorised by the Code; or

(ii) specifically approved by the Council.

(2) A person who contravenes subsection (1) commits a crime and is liable to imprisonment for 5 years.

Summary conviction penalty: Imprisonment for one year.

[(3), (4) deleted]

(5) A person who —

- (a) being a licensee, keeps or uses human gametes, a human egg undergoing fertilisation or a human embryo in contravention of this Act; or
- (b) being a person to whom a licence applies or applied, fails to comply with a direction given for the purpose of section 30(4)(a),

commits an offence.

Penalty: 2 years imprisonment.

[Section 7 amended by No. 17 of 2004 s. 10.]

Part 2 — The Council

8. Establishment of Council

- (1) As soon as is practicable after the coming into operation of this Part, there shall be established a body of persons, to be known as the Western Australian Reproductive Technology Council, which shall have the functions conferred under this Act.
- (2) The Council shall consist of —
 - (a) 10 nominated members, to be appointed by the Governor on the recommendation of the Minister, of whom —
 - (i) 7 shall be individuals respectively selected from panels comprising the names of not less than 2 individuals submitted in accordance with section 9(1) by each of —
 - (A) the Royal Australian College of Obstetricians and Gynaecologists;
 - (B) the Australian Medical Association;
 - (C) the Law Society of Western Australia;
 - (D) 3 other bodies, being bodies having interests relevant to this Act; and
 - (E) the Minister charged with the administration of the *Children and Community Services Act 2004*;
 - and
 - (ii) 3 shall be individuals selected by the Minister having regard to section 9(2);
 - and
 - (b) an ex officio member appointed by the Minister, subject to subsection (3), as the Executive Officer of the Council.

- (3) The person appointed as the Executive Officer —
 - (a) shall be an individual who is an officer of, or who carries out duties in, the department of the Public Service of the State principally assisting the Minister in the administration of the *Health Act 1911*; and
 - (b) shall not be eligible to be appointed or selected to hold or act in the office of Chairperson or Deputy Chairperson.
- (4) Appointment as a member under subsection (2) does not render the provisions of Part 3 of the *Public Sector Management Act 1994* or of any other Act applying to persons as officers of the Public Service of the State applicable to the person so appointed, or affect or prejudice the application of those provisions if they applied immediately before the appointment.
- (5) The Minister shall cause each appointment under subsection (2) to be notified in the *Gazette*.
- (6) The Schedule has effect with respect to the membership and proceedings of the Council.

[Section 8 amended by No. 32 of 1994 s. 19; No. 1 of 1996 s. 4; No. 34 of 2004 Sch. 2 cl. 14.]

9. Nominations, and recommendations, for membership

- (1) A panel of nominees to be submitted under section 8(2) shall —
 - (a) be so compiled, if practicable having regard also to the requirement that the Council should comprise individuals who have special knowledge and experience in the areas that the Council is required to deal with under this Act but should still be reasonably representative of the general community, as to include both a man and a woman; and

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- (b) be submitted to the Minister within such time, after the receipt of a notice from the Minister that the submission of the nominations is required, as is specified in that notice,

but if any requisite panel of names is not submitted within the specified time the Minister may nominate instead an individual to represent the relevant interest and a nomination so made shall be deemed to have been submitted under paragraph (b).

- (2) In recommending persons for membership of the Council the Minister shall endeavour to ensure that —
 - (a) the Council has available to it from its own membership —
 - (i) adequate representation of the interests of women, of parents, of the children born of reproductive technology, and of participants in reproductive technology;
 - (ii) expertise in reproductive technology;
 - (iii) relevant experience in public health matters; and
 - (iv) relevant ethical guidance,and also that any other appropriate discipline, experience or background is adequately reflected in so far as is practicable;
 - (b) the Council is constituted of equal numbers of men and women;
 - (c) no one person is the sole representative of disparate interests; and
 - (d) no more than one member of the Council at any time —
 - (i) is a licensee; or
 - (ii) is a person who has a pecuniary or other beneficial interest, other than an interest of a prescribed kind, in the practice of a licensee.

10. Committees

- (1) The Council may from time to time appoint committees of such members, or such members and other persons, as it thinks fit and may discharge, continue, reconstitute or alter any committee so appointed.
- (2) The Minister or the CEO may request the Council to furnish the advice of an appropriate committee on any matter related to the provisions or operation of this Act and, unless the Council otherwise requires, the committee may consider the matter and give to the Minister or the CEO directly a written report as to that advice.
- (3) The Council may instruct a committee with respect to its constitution, membership, terms of reference and proceedings, and incidental and related matters.
- (4) Instructions given by the Council under subsection (3) which relate to —
 - (a) the constitution or terms of reference of a committee; or
 - (b) the conditions of appointment to a committee of persons other than members, and the grounds on which such a person may be removed from office,shall not be given otherwise than as approved by the Minister, either generally or for a particular case.

[Section 10 amended by No. 28 of 2006 s. 270.]

11. Delegation by the Council

- (1) The Council may by resolution, either generally or as otherwise provided in the resolution, delegate to —
 - (a) a member;
 - (b) a committee;
 - (c) the CEO;

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- (d) a public authority who or which —
 - (i) under any written law carries out any duty or administration or exercises any power in the State in relation to a function appropriate to the requirements of the Council; and
 - (ii) is approved by the Minister to act in that capacity on behalf of the Council,or, subject to subsection (2)(a), a member or officer of that public authority; or
- (e) subject to the approval of the Minister, some other person engaged in the administration or enforcement of this Act,

any function vested in the Council, other than the function of advising the CEO on disciplinary matters.

- (2) Where a delegation under subsection (1) is given otherwise than to a member or a committee, the powers delegated shall not be exercisable until —
 - (a) where the delegation is to a member or officer of a public authority, the Council has satisfied the CEO that the delegate has sufficient knowledge and experience to give effect to the objects of this Act; and
 - (b) a notice, giving sufficient particulars to describe the function delegated and to identify the person who is to be the delegate, has been published in the *Gazette*.
- (3) A resolution delegating a function of the Council may, if the Minister approves, authorise the delegate to further delegate to any other person any function, or any power or duty, referred to in the resolution, and the provisions of section 59 of the *Interpretation Act 1984* shall apply to and in relation to any such further delegation as they apply to a delegation.
- (4) Where a person is authorised under subsection (1) or subsection (3) to perform a function of the Council as a

delegate, the performance of that function by the delegate is deemed to be performance of the function by the Council.

[Section 11 amended by No. 28 of 2006 s. 270.]

12. Relationship of the Council to the Minister

- (1) The Council shall, as soon as is practicable after being requested to do so, furnish to the Minister such advice relating to reproductive technology matters or this Act as the Minister may seek.
- (2) The Council shall —
 - (a) consider any proposal made by the Minister in relation to the affairs of the Council;
 - (b) if so required by the CEO, consult the Minister before continuing with a proposed course of action that in the opinion of the CEO amounts to a major initiative; and
 - (c) if so requested, report to the Minister on any proposal, whether made by the Minister, the CEO or the Council, or on any existing or prior proceedings or function.
- (3) The Minister, having regard to the objects of this Act, may give instructions in writing to the Council in relation to any function of the Council, either generally or with respect to a particular matter (but not in relation to dealings with, or the licensing of, any particular person), and the Council shall —
 - (a) subject to subsection (4), give effect to any such instruction; and
 - (b) include in the annual report to be furnished under section 5(6) the text of any such instruction.
- (4) Where, in the opinion of the Council, an instruction given by the Minister fails to give due regard to one or more of the objects of this Act the Council shall so advise the Minister, giving such particularity as the Minister may require, and thereupon if the terms of the instruction given are not agreed, or agreed as amended by the Minister, after consultation between the

Minister and the Council, the Council may cause a report on the disagreement to be laid before each House of Parliament.

[Section 12 amended by No. 28 of 2006 s. 270.]

13. Powers, and relationship to the Council, of the CEO

- (1) The CEO may at any time require the Council to advise on reproductive technology matters, on the evaluation or monitoring of licensee compliance with the regulations, any directions, and the Code of Practice, on public education, on the compilation of the reports to be furnished under this Act, or on the administration or enforcement of this Act, and the Council shall, as soon as is practicable, furnish that advice.
- (2) Where —
 - (a) a decision relevant to a function of the Council is, in the opinion of the CEO having regard to the objects of this Act, required to be taken in the interests of public health;
 - (b) that decision has not been, and in the opinion of the CEO is not likely promptly to be, taken by the Council and the CEO has so informed the Minister;
 - (c) the CEO has, by instrument in writing signed personally by the Minister, been required to consider and if appropriate to take that decision;
 - (d) the CEO has thereafter made known to the Council the decision which the CEO has taken and any requirements made of the Council as to the discharge of the function in question; and
 - (e) the function is not thereafter, in the opinion of the Minister, properly discharged by the Council,

the CEO may, if so instructed by the Minister, thereafter discharge that function as though a delegate of the Council specifically authorised to do so, and any reference in this Act to a function of the Council may for the purposes of this subsection be construed as including a reference to the CEO so acting as delegate.

- (3) Any question arising between the Council, or any committee or member, and the CEO as to the operation of this section, or as to a conflict between instructions given by the Minister and requirements made known by the CEO respectively, shall be addressed to, and having regard to the objects of this Act may be determined by, the Minister.
- (4) Subject to subsection (5), the CEO may, by an instrument in writing signed personally, delegate to a person who is an officer of, or who carries out duties in, the Department as defined in section 3 of the *Health Legislation Administration Act 1984*, either generally or as otherwise provided by that instrument, any function in the administration of this Act vested in or required to be discharged by the CEO.
- (5) Subsection (4) does not apply to or in relation to —
- (a) the power to take a decision required under subsection (2)(c);
 - (b) the power to license;
 - (c) any disciplinary function referred to in section 37 or 38; or
 - (d) any other function in relation to which the Minister otherwise directs.
- (6) Where —
- (a) a requirement under this section is made known by the CEO to the Council; or
 - (b) the CEO has been required to exercise any power under subsection (2)(c),

the CEO shall include in the annual report to be submitted to the Minister the text of that requirement, particulars as to the function to which the requirement related and as to the manner in which the power under subsection (2)(c) and any function thereby effected was discharged or purported to have been discharged, and any reason given to the Council for the requirement or for the discharge of the function, and shall

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include in relation to such matters such information as the Council may request that is contained in the report required to be furnished by the Council.

- (7) Subject to sections 31 and 32, the CEO may impose conditions and give directions in relation to any licence or exemption.
- (8) In the discharge of any function, or in imposing any condition, and in giving any direction under this Act the CEO shall, where practicable and requested, afford to an applicant or licensee reasons for any determination which may be made in relation to that person and a reasonable opportunity to show cause why the determination should not be given effect.

[Section 13 amended by No. 28 of 2006 s. 267 and 270.]

14. Functions of the Council

- (1) Subject to section 13(2), the functions of the Council are —
 - (a) to advise the Minister —
 - (i) on reproductive technology and any matter that is connected with, or incidental to, reproductive technology; and
 - (ii) generally, as to the administration and enforcement of this Act;
 - (b) to advise the CEO —
 - (i) on matters relating to licensing under this Act, including but not limited to the suitability of any applicant for a licence or of any licensee to carry out particular procedures or approved research and as to the conditions that should be imposed on any licence; and
 - (ii) generally as to the administration and enforcement of this Act and particularly on disciplinary matters;
 - (c) after consultation with bodies representing persons having relevant expertise or sections of the public

having appropriate interests, to compile and to cause to be published, to review, and to amend, a Code of Practice which —

- (i) sets out Rules, guidelines and relevant information;
- (ii) establishes the ethical standards required of licensees, and gives effect to the principles specified in, and the requirements of, this Act; and
- (iii) provides for such other matters as may be instructed by the Minister, or as the Council may determine,

regulating the proper conduct of any reproductive technology practice, and of any procedure, required to be licensed and the proper discharge of the functions of the licence supervisor and other persons to whom a licence applies, having due regard to this Act;

- (d) subject to paragraph (e), to encourage and facilitate, research —
 - (i) into the cause, prevention and treatment of all types of human infertility, adequate attention being given both to female and to male infertility; and
 - (ii) as to the social and public health implications of reproductive technology;
- (e) to ensure that no project of research is carried out by or on behalf of a licensee upon or with —
 - (i) any human egg collected in the course of an in vitro fertilisation procedure;
 - (ii) human gametes intended for subsequent use in an artificial fertilisation procedure;
 - (iii) any human egg undergoing fertilisation;
 - (iv) any human embryo; or

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- (v) any participant,
otherwise than in accordance with this Act and pursuant to a general or specific prior approval given by the Council;
 - (f) to consider applications for, and where proper grant, approval to carry out research to which paragraph (e) applies;
 - (g) to promote informed public debate, and to consult with bodies representing the public or sections of the public, on the ethical, social, economic and public health issues that arise from reproductive technology;
 - (h) to communicate and collaborate with other bodies having similar functions, in Australia and elsewhere,
and, generally, to give effect or to cause effect to be given to the objects of this Act.
- (2) Subsection (1)(e)(iv) does not apply in relation to an excess ART embryo except in relation to the use of such an embryo that is an exempt use as defined in section 53W(2).
- (2a) The Council must not grant approval to any research being conducted upon or with a human embryo unless —
- (a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is satisfied, on the basis of existing scientific and medical knowledge, that the research is unlikely to leave the embryo unfit to be implanted in the body of a woman; or
 - (b) the research consists of a use referred to in section 53W(2)(b) or (f).
- (2b) The Council must not grant approval to any diagnostic procedure to be carried out upon or with a human embryo unless —
- (a) the embryo is intended for use in the reproductive technology treatment of a woman and the Council is

satisfied, on the basis of existing scientific and medical knowledge, that —

- (i) the diagnostic procedure is unlikely to leave the embryo unfit to be implanted in the body of a woman; and
- (ii) where the diagnostic procedure is for the genetic testing of the embryo, there is a significant risk of a serious genetic abnormality or disease being present in the embryo;

or

- (b) the diagnostic procedure consists of a use referred to in section 53W(2)(d) or (f).

(3) Where a person contravenes —

- (a) any provision of, or requirement under, this Act, not being a direction; or
- (b) any direction given by the CEO, being a direction which is consistent with the Code or is not inconsistent with —
 - (i) ethical guidelines laid down by the NHMRC, as for the time being prescribed;
 - (ii) criteria established by a body referred to in section 29(5)(a)(i) or (ii), as for the time being prescribed; or
 - (iii) a provision of, or any principle set out in, or requirement under, this Act, as from time to time amended,

the Council shall endeavour to ensure that effect is given to that provision, requirement or direction.

[Section 14 amended by No. 17 of 2004 s. 11; No. 55 of 2004 s. 523; No. 28 of 2006 s. 270.]

Part 3 — The Code of Practice

Division 1 — Compilation of the Code

15. The concept of the Code of Practice

- (1) The Code of Practice shall be divided into Parts, as follows —
- (a) Part 1 — which shall set out the Rules which, subject to section 16, are to have effect as subsidiary legislation and may also set out or refer to conditions that may be imposed on a licence —
 - (i) generally, by regulations or by directions published under section 35(1); or
 - (ii) specifically, by reference to the appropriate Rule in, or in a subsequent direction relating to or endorsement on, that particular licence;
 - (b) Part 2 — containing guidelines, either specifically published by the Council or referred to in accordance with section 60, which —
 - (i) set out the ethics and relevant professional information as to the practices that should govern, and the procedures to be used in and the services to be provided in relation to, the conduct of reproductive technology; and
 - (ii) set out specific terms which are there defined or identified as intended to describe the medical detail or circumstances applicable to a condition or direction that may be imposed in respect of a practice, procedure or licence of a particular kind;
- and
- (c) Part 3 — containing notices and other ancillary information that the Council authorises for circulation.

- (2) In so far as is practicable, a Rule shall be expressed in terms likely to be understandable by persons not medically qualified but may, where it is necessary to explain or enlarge upon those terms, contain or refer to medical or other detail either explicitly, by a reference complying with section 60(3), or by reference to —
- (a) appropriate terms specifically defined in the guidelines contained in Part 2 of the Code; or
 - (b) a description, text or requirement included or referred to in those guidelines.
- (3) The Rules may provide that where a person is convicted of a specified offence under this Act the licence of that person, or any exemption held by that person, shall, with immediate mandatory effect and notwithstanding any appeal that may be lodged, be thereby deemed to be —
- (a) cancelled; or
 - (b) otherwise affected in a manner specified in the Rules;
- and effect shall be given to any such Rule but without prejudice to the conduct of any disciplinary action that may be brought under section 38 in relation to the facts disclosed at the proceedings for that offence.
- (4) In any proceedings under this Act —
- (a) the Code, and any particular provision of the Code, shall be an admissible document; and
 - (b) where it is alleged that a person has contravened this Act —
 - (i) a failure to comply with the Rules may be relied on as establishing liability;
 - (ii) a failure to have regard to the guidelines under the Code may be relied on as tending to establish liability; and

- (iii) proof of compliance with the guidelines may be relied on as tending to negative liability,

but, notwithstanding that the failure on the part of a person to comply with the Code may not be the subject of any such proceedings, the CEO in considering any application may, at discretion, take into account any alleged tendency on the part of the applicant not to have regard to the guidelines.

[Section 15 amended by No. 55 of 2004 s. 540; No. 28 of 2006 s. 270(1).]

16. The implementation of the Code of Practice

- (1) A provision of Part 1 of the Code of Practice, whether in the original text or as from time to time amended, shall not have legislative effect, and shall not be taken into account in considering any application or in any disciplinary proceedings under this Act, unless —
- (a) the provision has been promulgated as a proposed Rule, or being a condition is referred to in a proposed Rule;
 - (b) that proposed Rule has been published in the *Gazette*; and
 - (c) that proposed Rule has, in accordance with subsection (2), been laid before each House of Parliament, within 6 sitting days of such House next following that publication and thereafter has come into operation,
- unless the regulations specifically otherwise provide.
- (2) A proposed Rule required by subsection (1) to be laid before each House of Parliament —
- (a) shall be accompanied by a copy, certified by the Executive Officer as correct, of the relevant excerpt from any condition, text or requirement (within the meaning of section 60(4)) approved or adopted, or

- referred to in or by the guidelines, for the purposes of that Rule;
- (b) may not be amended, or have its provisions substituted, by resolution of the House;
 - (c) shall be so laid, for 14 sitting days of that House, whether in the same session or during the same Parliament or otherwise; and
 - (d) shall come into operation on a date to be published after the expiry of that period of 14 sitting days in each House, by notice in the *Gazette*, unless subsection (3A) or (3B) otherwise provides.
- (3A) Where notice of motion to disallow any proposed Rule is given in either House the proposed Rule shall not be given effect unless and until —
- (a) the motion has been defeated or the notice or the motion withdrawn; or
 - (b) if the motion or notice of it has lapsed by prorogation or dissolution, notice of a motion to disallow the Rule has not been given within 14 sitting days of the commencement of sitting of Parliament next after such prorogation or dissolution; or
 - (c) such further motion has been dealt with in accordance with paragraph (a) or (b).
- (3B) Where a resolution disallowing any proposed Rule has been passed by either House that Rule shall be deemed revoked and shall not be given effect.
- (4) Where a resolution disallowing a proposed Rule has been passed under subsection (3A), notice of that resolution shall be published in the *Gazette* within 21 days thereafter.
- (5) The Executive Officer shall —
- (a) ensure that a compiled text of the Code is available from the Council, together with any relevant excerpt from a

text or requirement which is referred to in the Code but which was not published originally by the Council; and

- (b) endeavour to ensure that —
 - (i) on any Rule coming into operation; and
 - (ii) on any change to the guidelines being introduced,

notice is brought to the attention of licensees likely to be thereby affected,

as soon as is practicable.

[Section 16 amended by No. 19 of 2010 s. 51.]

17. Matters which shall be dealt with by the Code, subject to exception by way of regulations

As a matter of principle but without limiting the generality of section 14(1)(c), in the compilation of the Code of Practice the Council shall prohibit the mixing in the same artificial fertilisation procedure of multiple sources of —

- (a) human gametes;
- (b) human eggs undergoing fertilisation; or
- (c) human embryos,

in such a manner as may create confusion as to the biological parentage of any child born as a result of the procedure.

[Section 17 amended by No. 17 of 2004 s. 12.]

18. Matters which may be dealt with in the Code

- (1) The Code may make provision, and may impose conditions or prohibitions, in relation to the following matters —
 - (a) ovarian stimulation undertaken by a licensee;
 - (b) artificial fertilisation procedures likely to lead to multiple pregnancies;

- (ca) an artificial fertilisation procedure for implementing a surrogacy arrangement as defined in the *Surrogacy Act 2008* section 3;
 - (c) the treatment of any human gametes intended for use in an artificial fertilisation procedure;
 - (d) the circumstances in which, the periods and purposes for which, and the methods by which, a human embryo may be kept and maintained outside a human body, or human gametes, a human egg undergoing fertilisation or a human embryo may be stored;
 - (e) any treatment or other services to which this Act applies that may be provided by licensees;
 - (f) the donation, use, supply, export from the State, posthumous use, or other dealing in or disposal of, human gametes, human eggs undergoing fertilisation or human embryos by licensees;
 - (g) the privacy of patients, and the conduct of authorised officers, during the carrying out of any inspection or investigation; and
 - (h) the giving or withdrawal of recognition to Institutional Ethics Committees by the Council for the purposes of this Act.
- (2) Subject to the requirements of this Part, the regulations or the Code may —
- (a) establish criteria as to the consent required of participants in prescribed circumstances, as to the qualifications of counsellors and the adequacy of the services provided for counselling, and as to the particular circumstances when counselling should be offered, ensuring that any question as to a consent required or given is decided on a basis of adequate and relevant information, as regards —
 - (i) procedures of different kinds;

- (ii) the outcome of procedures, with particular reference to the control, possession and disposal of human gametes, a human egg undergoing fertilisation or a human embryo; and
 - (iii) the type and quality of the treatment or other services, or of any assistance, provided or to be provided, or not likely to be provided, and as to the nature and extent of the information to be supplied; and
- (b) provide for —
- (i) the obtaining and recording of an effective consent on the part of particular participants; and
 - (ii) the effect of any consent given.

[Section 18 amended by No. 17 of 2004 s. 13; No. 47 of 2008 s. 66.]

19. Principles to be embodied in the Code

- (1) The Council in compiling the Code of Practice shall have regard to the principles set out in section 17 and sections 22, 23, 24, 25 and 26.
- (2) Until the principles referred to in subsection (1) are embodied in the Code —
 - (a) where any of those principles is specifically referred to in directions given for the purposes of this Act, a failure to give effect to it on the part of a licensee may for the purposes of sections 14(3), 29(5)(a) and 39(2)(b) be taken to be a contravention of a requirement under this Act; and
 - (b) otherwise, in so far as any of those principles is relevant to the conduct of a practice or any procedure —
 - (i) effect shall be given to the principle by all persons to whom this Act applies; and
 - (ii) on any application or in disciplinary proceedings, the manner of observance of any such principle

is a matter which the CEO and the State
Administrative Tribunal may take into account.

*[Section 19 amended by No. 55 of 2004 s. 524; No. 28 of 2006
s. 270(1).]*

20. Principles applicable to projects of research

- (1) A licence shall not be capable of authorising any research contravening the condition referred to in subsection (3).
- (2) No licensee shall carry out, or authorise or facilitate or become involved in the carrying out of, any project of research —
 - (a) upon or with —
 - (i) human gametes obtained in the course of an in vitro fertilisation procedure or intended for use in an artificial fertilisation procedure; or
 - (ii) a human egg undergoing fertilisation or a human embryo whether or not live;
 - or
 - (b) involving any person who is a participant in an artificial fertilisation procedure,

unless general or specific approval relevant to that project has already been granted by the Council, or unless specific prior approval from the Council for that particular project of research is sought for in such manner as may be required by the Code or directions, and if the Council so requires is also sought from a specific Institutional Ethics Committee recognised by the Council, and is obtained.

- (2a) Subsection (2)(a)(ii) does not apply in relation to an excess ART embryo except in relation to a use of such an embryo that is an exempt use as defined in section 53W(2).
- (3) Every licence is subject at all times to the condition that any project of research shall be carried out in accordance with the terms of, and any conditions applicable to, the approval given and not otherwise.

- (4) The Council, subject to subsection (5), may under the Code grant general approval to the carrying on by any licensee of a project of research of a kind or in relation to matters specified in the Code, but may impose conditions as to the manner in which the research is to be carried on.
- (5) The Rules or directions may make provision as to —
- (a) the requirements with which a licensee proposing to carry out any research must comply in seeking approval to the proposal, for the manner of submitting that proposal to an Institutional Ethics Committee or to the Council, and for the furnishing by the licensee of a report on that proposal from such a Committee to the Council or the CEO;
 - (b) any requirement for —
 - (i) counselling;
 - (ii) the obtaining from any person of an effective consent,
for the purposes of the research;
 - (c) generally, the ethics and standards that should apply to the carrying out of projects of research by or involving licensees.
- (6) In considering whether to grant approval to a project of research, the Council shall have regard to any decision or report which may have been made by an Institutional Ethics Committee and may adopt a decision or report so made as sufficient grounds for the grant of approval by the Council.

[Section 20 amended by No. 17 of 2004 s. 14; No. 28 of 2006 s. 270(2).]

21. The Code and directions, generally

Without limiting the generality of section 14(1)(c), the Code, or directions, may make provision as to —

- (a) the criteria by which the appropriateness of a proposed artificial fertilisation procedure is to be assessed;
- (b) the means of determining and evaluating the considerations which should or may be taken into account before an artificial fertilisation procedure is commenced, including the diagnostic procedures involved;
- (c) the method by which, and the extent to which, donors or prospective donors of human gametes, human eggs undergoing fertilisation or human embryos are to be assessed or selected;
- (d) the practice and procedures to be carried out in relation to the collection, keeping, use and disposal of human gametes, human eggs undergoing fertilisation or human embryos, or for securing that such eggs or embryos are in a suitable condition for implantation;
- (e) the responsibilities of persons carrying out any procedures to which this Act applies;
- (f) the establishment of a basis for determining questions as to the control of, and the power to deal with or dispose of, human gametes, human eggs undergoing fertilisation or human embryos;
- (g) the means of disposal, or prohibitions or restrictions in respect of the disposal, of human gametes, human eggs undergoing fertilisation or human embryos;
- (h) limitations to be placed on the use of human gametes, human eggs undergoing fertilisation or human embryos which may be donated by any one individual donor;
- (i) the means of identifying, for the purposes of sections 24 and 26, the person or persons on behalf of whom any human gametes, human eggs undergoing fertilisation or human embryos are stored, kept for implantation or developed which, in accordance with consents given, may be —

- (i) a woman or man; or
- (ii) a couple who are married, or in a de facto relationship with each other whether they are different sexes or both female;
- (j) the circumstances in which any human egg undergoing fertilisation or human embryo derived from the use of reproductive technology shall be allowed to succumb;
- (k) what, for the purposes of this Act, may constitute an authorised diagnostic procedure in relation to any human egg undergoing fertilisation or human embryo or an approved project of research, or may be carried out or performed in any particular kind of research, and what shall not;
- (m) the assessment of applications seeking approval to carry out any project of research;
- (n) the requirement that prior approval of an Institutional Ethics Committee specified in, or ascertainable by reference to, those Rules, be a condition applicable to any particular practice, kind of practice or procedure or kind of procedure;
- (o) the making, retention and confidentiality of records; and
- (p) such other matters relating to the practice of reproductive technology as may be specified in, or are required by or to be carried out or determined in accordance with, the regulations.

[Section 21 amended by No. 3 of 2002 s. 73; No. 17 of 2004 s. 15.]

Division 2 — Consents

22. Consents, generally

- (1) For the purposes of the licence condition referred to in section 33(2)(e) —

- (a) the gametes of a person shall not be used, or for such a use be received by a licensee or participant, unless —
 - (i) there is an effective consent, by that person, to the gametes being so used; and
 - (ii) the gametes are used in accordance with that consent;
- (b) the gametes of a person shall not be kept in storage unless —
 - (i) there is an effective consent, by that person, to the storage; and
 - (ii) the gametes are stored in accordance with that consent;
- (c) the gametes of a person shall not be used in an in vitro fertilisation procedure unless there is an effective consent, by that person, to any human egg undergoing fertilisation or human embryo thereby derived being used for a consequential purpose authorised by this Act;
- (d) where the development of an egg undergoing fertilisation or a human embryo was brought about by an in vitro fertilisation procedure it shall not be kept in storage unless —
 - (i) there is an effective consent, by each person from whose gametes the egg or embryo was derived, to the storage; and
 - (ii) the egg or embryo is stored in accordance with that consent;
- (e) where the development of a human egg undergoing fertilisation or a human embryo was brought about by an in vitro fertilisation procedure, it shall not be used for any purpose, or for such a purpose be received by a licensee or participant, unless —
 - (i) there is an effective consent, by each person from whose gametes the egg or embryo was derived, to the use for that purpose;

- (ia) in the case of a use outside the body of a woman, there is an effective consent to the use for that purpose by the woman on whose behalf it is being developed and her spouse or de facto partner, if any;
- (ib) in the case of implantation in the body of a woman, there is an effective consent to the implantation by the woman and her spouse or de facto partner, if any;
- (ii) the purpose is authorised by this Act; and
- (iii) that egg or embryo is used in accordance with that consent,

and the Code may make further provision in relation to such, or related, matters.

- (2) Where a consent is given in general terms to the use or storage of human gametes separately, whether human eggs or human sperm, that consent shall be taken to relate to the use or storage of any of those eggs or sperm, and also to any human egg undergoing fertilisation or human embryo derived from the use of the human gametes, for any purpose, save that —
- (a) any such consent may be given subject to specific conditions in its terms; and
 - (b) notwithstanding subsection (4) or that a human egg undergoing fertilisation or a human embryo, may have developed which is derived from the use of human gametes the subject of any particular consent, in so far as it relates to any human egg or human sperm that has not been used that consent may be varied or withdrawn,

but where a human egg in the process of fertilisation, or a human embryo, has been developed from any human gametes the consent thereafter to be required is not a consent to the use of those human gametes but a specific consent relating to that particular egg undergoing fertilisation or embryo only.

- (3) The terms of any effective consent may from time to time be varied or the consent withdrawn, unless subsection (4) applies, by notice given by the person who gave the consent to the person keeping the human gametes, human eggs undergoing fertilisation or human embryos to which the consent is relevant.
- (4) The terms of any effective consent to the use of any human gametes, a human egg undergoing fertilisation or a human embryo can not be varied, and such a consent can not be withdrawn, once the gametes have, or that egg or embryo has, been used.
- (5) A consent to the use of a human egg undergoing fertilisation or a human embryo must specify the purposes for which the egg or embryo may be used and may specify conditions subject to which the egg or embryo shall or shall not be used.
- (6) A consent to the keeping of any human gametes, a human egg undergoing fertilisation or a human embryo must —
- (a) specify the maximum period of storage, if that is to be less than such limit as may be prescribed or may be determined in accordance with section 24(1)(b); and
 - (b) give instructions as to what is, subject to this Act, to be done with the gametes, the egg or the embryo if the person who gave the consent is unable by reason of incapacity or otherwise to vary the terms of the consent or to withdraw it,
- and may specify conditions subject to which the gametes, or the egg or embryo, shall or shall not remain in storage.
- (7) Before a licensee gives effect to a consent given for the purposes of this Act the licensee shall ensure that each participant has been provided with a suitable opportunity to receive —
- (a) proper counselling about the implications of the proposed procedures; and

- (b) such other relevant and suitable information as is proper or as may be specifically required by the Code or directions,

including an explanation of the effect of subsection (3) and subsection (4).

- (8) For the purposes of this Act a consent to the use or keeping of any human gametes, a human egg undergoing fertilisation or a human embryo shall not be taken to be effective unless —
 - (a) it is given in writing;
 - (b) any condition to which it is subject is met;
 - (c) it has not been withdrawn; and
 - (d) those gametes are, or that egg or embryo is, kept and used in accordance with the consent.
- (9) Where a consent required by or under this Act is not given, or is not effective, or is not complied with that matter may be a cause for disciplinary action or proceedings for an offence but does not necessarily affect the rights of any person.

[Section 22 amended by No. 17 of 2004 s. 16.]

23. When procedures may be carried out

- (1) An in vitro fertilisation procedure may be carried out where —
 - (a) it would be likely to benefit —
 - (i) persons who, as a couple, are unable to conceive a child due to medical reasons; or
 - (ia) a woman who is unable to conceive a child due to medical reasons; or
 - (ii) a couple or a woman whose child would otherwise be likely to be affected by a genetic abnormality or a disease; or

- (iii) a woman who is unable to give birth to a child due to medical reasons and is a party to a surrogacy arrangement (as defined in the *Surrogacy Act 2008* section 3) that is lawful;
and
 - (b) each of the participants required to do so has given an effective consent; and
 - (c) any persons seeking to be regarded, in applying paragraph (a), as members of a couple are —
 - (i) married to each other; or
 - (ii) in a de facto relationship with each other and are of the opposite sex to each other;and
 - (d) the reason for infertility is not age or some other cause prescribed for the purpose of this paragraph; and
 - (e) consideration has been given to the welfare and interests of —
 - (i) the participants; and
 - (ii) any child likely to be born as a result of the procedure,and in the opinion of the licensee that consideration does not show any cause why the procedure should not be carried out,
- but not otherwise.
- (2) Subsection (1) does not require that the benefit likely to result from the procedure involve the pregnancy of a member of the couple who are, or the woman who is, likely to benefit.

[Section 23 amended by No. 3 of 2002 s. 74; No. 17 of 2004 s. 17; No. 47 of 2008 s. 67.]

24. Storage

- (1) In relation to the storage of any human gametes, human egg undergoing fertilisation or human embryo —
- (a) the primary purpose stated in any consent to the storage of a human embryo must relate to the probable future implantation of that embryo or its probable future use under an NHMRC licence; and
 - (b) the Code may make provision as to what, in particular circumstances, constitutes an excessive time for the storage of —
 - (i) human gametes;
 - (ii) a human egg undergoing fertilisation; or
 - (iii) a human embryo,

but no human egg undergoing fertilisation or human embryo shall be stored for a period in excess of 10 years except with the approval of the Council under subsection (1a).

- (1a) The Council may, on an application by an eligible person, approve in writing a longer storage period for a human egg undergoing fertilisation or a human embryo if it considers that there are special reasons for doing so in a particular case.
- (1b) An approval under subsection (1a) may be subject to conditions and is to specify the date on which the longer storage period ends.
- (1c) An approval under subsection (1a) can only be given before the end of 10 years, or if a longer storage period has previously been approved under subsection (1a), before the end of that period.
- (1d) The Council is to inform the Minister of each approval given under subsection (1a), but in such a manner that the identity of the biological parents cannot be ascertained from the approval.

- (2) In subsection (1a) —
- eligible person***, in relation to a human egg undergoing fertilisation or a human embryo, means —
- (a) a person who is or is to be a participant in an artificial fertilisation procedure in which the egg or embryo is to be used;
 - (b) a person for whom the egg or embryo was developed; or
 - (c) in the case of an excess ART embryo, except in relation to the use of such an embryo referred to in section 10(2)(e) of the Commonwealth Human Embryo Act, the licensee.
- (3) Three months before the end of a period of storage permitted under this section the licensee must take reasonable steps to notify each person for whom the human egg undergoing fertilisation or human embryo is being stored.
- (4) If a period of storage permitted under this section comes to an end and no application has been made for the extension of the storage period, the licensee may, if the licensee has complied with subsection (3), allow the human egg undergoing fertilisation or the human embryo to succumb and will not be liable to anyone for so doing.

[Section 24 amended by No. 1 of 1996 s. 5 and 6; No. 3 of 2002 s. 75; No. 17 of 2004 s. 18.]

Division 3 — Rights of control, etc.

25. Rights in relation to gametes

In relation to any rights in, or power to deal with or dispose of, human gametes —

- (a) in respect of both human eggs and human sperm, all rights remain vested in the respective gamete providers, unless and until otherwise dealt with, as though personal property subject to section 53Q;

- (b) where human gametes are donated with effective consent to a licensee, all rights in those gametes vest in the licensee subject to the limitation that, in accordance with that consent, the gametes may be used —
 - (i) for the purpose of initiating an in vitro fertilisation procedure intended to develop a human egg undergoing fertilisation or a human embryo for implantation into a recipient named in, or to be selected in accordance with circumstances specified, in that consent;
 - (ii) for artificial insemination purposes;
 - (iii) in, or in connection with, an approved project of research; or
 - (iv) for the purposes of diagnostic procedures, and not otherwise, but if the gametes are not so used they shall, subject to section 26(1)(c) and (d), be allowed to succumb; and
- (c) in respect to human gametes donated subject to a consent which is conditional and which are not used, if a condition to which the consent was made subject is not observed, the rights, subject to section 22(6) and any instructions to which effect can then be given, revert to the donor and in default vest in the CEO.

[Section 25 amended by No. 17 of 2004 s. 19; No. 18 of 2004 s. 6; No. 28 of 2006 s. 270(1).]

26. Control, dealing and disposal in relation to an egg in the process of fertilisation or an embryo

- (1a) This section does not apply in relation to an excess ART embryo except in relation to the use of such an embryo that is an exempt use as defined in section 53W(2).
- (1) Subject to section 24(4), in relation to rights to the control of, or power to deal with or dispose of, any human egg undergoing

fertilisation or human embryo that is outside the body of a woman —

- (a) each person on whose behalf it is developed or is being or is to be, kept has, subject to section 53Q, the right to decide how a human egg undergoing fertilisation or a human embryo is to be dealt with or disposed of, so that —
 - (i) such a person shall have, while storage continues, the right to review the decision to store from time to time and may withdraw consent or vary the terms of any consent; and
 - (ii) any question as to the nature or extent of the respective rights or powers may, subject to subsection (2), be referred to a court of competent jurisdiction;
- (b) in the event of the death of one member of a couple in whom the rights are vested, those rights vest solely in the survivor;
- (c) where from any human gametes, a human egg undergoing fertilisation or a human embryo is developed, whether or not with effective consent, the individual rights of a human gamete provider or person to whom the human gametes were provided and of a licensee cease at the moment fertilisation begins and the rights thereafter vest jointly in the couple on whose behalf that egg or embryo was developed, or vest in the woman on whose behalf that egg or embryo was developed;
- (d) where a human egg undergoing fertilisation or a human embryo has been developed on behalf of a couple or a woman and is no longer required for that purpose, the egg may be used if all the participants in a proposed procedure give an effective consent; and

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- (e) on the commencement of an implantation procedure the rights in a human egg undergoing fertilisation or a human embryo vest in the woman receiving it, whether or not —
 - (i) that recipient was eligible to undergo the procedure; or
 - (ii) any consent required was given or, if given, was effective.
- (2) Where rights in relation to a human egg undergoing fertilisation or a human embryo are vested in a couple and the couple disagree about its use or continued storage, the CEO shall, on application by a member of that couple, direct the licensee storing the egg or embryo to ensure that the storage is maintained subject to —
 - (a) payment of the proper charges of the licensee for the storage;
 - (b) any limitation as to the time of storage prescribed or determined in accordance with section 24(1)(b); and
 - (c) any order made by a court of competent jurisdiction which otherwise requires.

[Section 26 amended by No. 3 of 2002 s. 76; No. 17 of 2004 s. 20; No. 18 of 2004 s. 7; No. 28 of 2006 s. 270(1).]

Part 4 — Licensing, etc.

Division 1 — Licensing

27. Licences, and the person responsible

- (1) On application under section 29 the CEO, having referred the matter to and had regard to any advice received from the Council, may grant —
 - (a) a storage licence;
 - (b) a practice licence;
 - (c) both a storage licence and a practice licence; or
 - (d) an exemption under section 28 or 28A,to a person, or to a body of persons (whether or not incorporated) who practise together.
- (2) In accordance with its terms a storage licence may authorise the licensee to carry out any procedure related to —
 - (a) the storage of —
 - (i) any human egg intended for use in an in vitro fertilisation procedure;
 - (ii) any human embryo; or
 - (iii) any human egg undergoing fertilisation;
 - (b) the keeping of human sperm, having been obtained from different men; and
 - (c) any project of research related to such storage and approved under section 20.
- (3) In accordance with its terms a practice licence may authorise the licensee to carry out any artificial fertilisation procedure, not being a storage procedure, and any project of research approved under section 20.

(4) A licence —

(a) shall be granted in a form approved by the CEO specifying —

(i) the kind or kinds of licence granted;

(ii) any particular condition imposed specifically on that licence or the respective licences, or in substitution for a condition which would otherwise apply;

(iii) the conditions set out in the Code which apply to a licence of that kind, and any particular modifications to the text of those conditions which are to apply to that licence;

(iv) such other terms or matters as may be set out in the Rules or directions and are to apply;

(v) the licence supervisor; and

(vi) the premises to which the licence relates;

(b) continues in force, unless the operation of that licence is suspended or the licence is cancelled, for a period of 5 years or such shorter period as may be specified in that licence; and

(c) may be varied, in accordance with this Act, as to its terms and conditions during that period,

but is not capable of being transferred by or on behalf of the licensee.

[Section 27 amended by No. 17 of 2004 s. 21; No. 28 of 2006 s. 270.]

28. Exemptions relating to artificial insemination

(1) Subject to subsection (2), an exemption shall be deemed to have been issued, and a licence under this Part is not required, in respect of an artificial insemination procedure where —

(a) the procedure is carried out by a medical practitioner who has —

(i) applied for exemption from the licensing requirement in the prescribed manner, notifying the CEO of the kind of procedures that will be carried out by that practitioner; and

(ii) lodged with the CEO a written undertaking in the prescribed form to observe and comply with the Code of Practice and any directions;

and

(b) in relation to that medical practitioner, and to a procedure of that kind, that application is not refused or the exemption is not subsequently revoked,

but where the CEO notifies the medical practitioner in writing that conditions are to be imposed in relation to any practice or procedure and issues to that practitioner a certificate of exemption in the prescribed form applicable to that practice or procedure, the exemption conferred by this subsection in relation to that practice or a procedure of that kind shall be taken to be subject to the conditions that are set out in that certificate.

(2) A person who holds an exemption deemed to have been or specifically issued under subsection (1) is —

(a) subject to the like disciplinary procedures in relation to that exemption as would have been applicable had the exemption been a licence under this Part; and

(b) shall be deemed in respect of the practice or procedure thereby authorised to be the licence supervisor under that licence.

- (3) A licence or an exemption under this Part is not required in respect of artificial insemination where the artificial insemination is carried out by prescribed persons in prescribed circumstances.

[Section 28 amended by No. 17 of 2004 s. 22; No. 28 of 2006 s. 270(2).]

28A. Exemptions relating to storage of certain embryos

- (1) The CEO may, on an application by a person who holds an NHMRC licence grant an exemption from the requirement to hold a licence under this Part to store excess ART embryos to which the NHMRC licence applies.
- (2) A person who holds an exemption under subsection (1) is not required to hold a licence under this Part to store the excess ART embryos.
- (3) A person who holds an exemption under subsection (1) is subject to the disciplinary procedures in relation to that exemption as if the exemption were a licence under this Part and the person were the licence supervisor in relation to that licence.

[Section 28A inserted by No. 17 of 2004 s. 23; amended by No. 28 of 2006 s. 270(1).]

29. Applications, generally

- (1) An application for a licence or exemption shall be —
- (a) made in the first instance to the CEO, in writing, and, if a form or manner of making an application of that kind is prescribed, as prescribed;
 - (b) accompanied by the prescribed fee, if any; and
 - (c) supported by such further or other information as the CEO may in a particular case require.
- (2) The CEO, or a person authorised by the CEO, may cause an investigation or inquiry to be made into the background and antecedents of an applicant, or of any person who occupies a position of authority in a body which is an applicant, or who

- would become a person to whom the licence applies, or who may be directly materially interested in the reproductive technology practice to be carried on under the proposed licence or exemption.
- (3) Where the CEO is of the opinion that the information provided in relation to the application is insufficient to enable him or her to determine the application, the CEO need not consider the application until the applicant has provided such further information as the CEO requires.
- (4) The CEO shall not grant a licence or issue an exemption to a person, or to a body corporate of which a person who occupies a position of authority in that body is a person, or to a body of persons where a member of that body is a person, who —
- (a) is, according to the *Interpretation Act 1984* section 13D, a bankrupt or a person whose affairs are under insolvency laws; or
 - (b) being a body corporate, is under receivership or official management or is in liquidation; or
 - (c) is disqualified from holding a licence, or holds a licence which is suspended.
- (5) A licence shall not be granted to an applicant, and a licence shall not be renewed in favour of an existing holder, unless the CEO is satisfied —
- (a) that every person who would become a person to whom the licence applies is, for the purposes of this Act, a fit and proper person;
 - (aa) that the applicant is accredited to carry out reproductive technology by —
 - (i) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or
 - (ii) if the regulations prescribe another body or other bodies in addition to, or instead of, the body

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- mentioned in paragraph (a), that other body or any of those other bodies, as the case requires;
- (b) that adequate and appropriate premises, equipment, staff, supervision, support services and facilities are available, and are likely to remain available, for the purposes to which the licence relates; and
 - (c) that the licence is needed to fulfil a genuine social need.
- (6) In relation to any application for the grant or renewal of a licence the applicant —
- (a) may be required to satisfy the CEO —
 - (i) if the applicant is a body of persons or a body corporate, that any person who occupies a position of authority in that body is for the purpose of this Act a fit and proper person to occupy that position;
 - (ii) that any person who has a material interest in the reproductive technology practice to be carried on under the licence is a fit and proper person to have that interest;
 - (iii) if the application is made on behalf of a body of persons associated together, as to the nature of their common interest;
- and
- (b) shall be required to satisfy the CEO as to —
 - (i) the character, qualifications and experience of the individual who is to be the licence supervisor;
 - (ii) the manner in which any person who would under the proposed licence be a person to whom the Act applies has in the past observed the requirements of this Act;

- (iii) matters relating to the counselling of participants and the obtaining of an informed and effective consent; and
 - (iv) the compilation, safe keeping, retention, storage and confidentiality of records.
- (7) An application —
- (a) may be refused, even if the applicant meets all the requirements of this Act; or
 - (b) may be granted, if there is evidence of substantial compliance with this Act, even if the application does not comply entirely with the requirements of this Act,
- and shall be dealt with on its merits, after such inquiry as the CEO thinks fit, in a manner that the CEO considers to be in the public interest.
- (8) Where the CEO waives or modifies any requirement for formal compliance with any procedure relating to an application, conditions may be imposed in relation to that waiver or modification.

[Section 29 amended by No. 17 of 2004 s. 24; No. 55 of 2004 s. 525 and 540; No. 28 of 2006 s. 270; No. 8 of 2009 s. 76; No. 18 of 2009 s. 44(2).]

30. Interim authorisations and transitional directions

- (1) Where a person who claims to be entitled to carry on the activities carried on, or formerly carried on, by a particular licensee but who would not otherwise be authorised under this Act —
- (a) applies to the CEO for approval so to carry on; and
 - (b) the CEO is satisfied that —
 - (i) by reason of death, insolvency or other sufficient cause the licensee is unable or unwilling to carry on those activities, and the person has a claim or

an entitlement to an interest in the licensed activities; and

- (ii) there is nothing that would have precluded the grant of a licence of the same kind to that person,

the CEO may cause the name of that person to be endorsed on the licence, if that person then proposes to apply for a licence to carry on thereafter those activities or any of them.

- (2) The endorsement of the name of a person on a licence under subsection (1) authorises that person to carry on the activities to which the licence relates until —
 - (a) an application for a licence made by that person in respect of those activities has been determined;
 - (b) by notice in writing given by the CEO to that person, the authorisation conferred by the endorsement is cancelled; or
 - (c) the expiry of a period of 12 months,whichever first occurs.
- (3) Where a licensee dies, or being a body corporate ceases to carry on licensed activities, and an individual who is a person to whom the licence applied does any act which that individual would have been authorised to do if the licensee had continued to carry on those activities that act shall be treated as authorised by the licence, until directions terminating the authorisation take effect.
- (4) Where a licence has been varied or has ceased to have effect, or is to be varied or cease to have effect, directions may be given for the purpose of securing the continued discharge of the functions of the licence supervisor under that licence and, in particular, may —
 - (a) require any human gametes, a human egg undergoing fertilisation or a human embryo or other thing kept or record held under that licence, or information available

to a person to whom that licence applied, to be transferred to the CEO or any other person; or

- (b) provide for the discharge of the duties in question by any other person, and authorise the carrying on of the practice licensed and the exercise of powers by or under the supervision of any other person, if that other person consents.
- (5) For the purposes of the giving under this section of any direction to “a person to whom the licence applies”, a licence which is varied or ceases to have effect shall be deemed to continue to be applicable to the person to whom the direction is given.

[Section 30 amended by No. 17 of 2004 s. 25; No. 55 of 2004 s. 540; No. 28 of 2006 s. 270.]

Division 2 — Directions and conditions

31. Directions, generally

- (1) The CEO may from time to time give directions, or directions varying or revoking such directions, in relation to any matter for which —
 - (a) directions are expressly authorised to be given under this Act; or
 - (b) a provision of the Code has been, or could be, made,giving due regard to the principles set out in the Act.
- (2) Where in relation to any matter a relevant regulation or Rule applies or any direction is inconsistent with any other provision of the Code which has been specifically applied, the regulation, Rule or other provision of the Code prevails.
- (3) Directions may be given to any person to whom a licence applies, and a person to whom any requirement contained in directions is applicable shall comply with the requirement.

- (4) Anything done by a person pursuant to directions is to be treated for the purposes of this Act as done pursuant to a licence.

[Section 31 amended by No. 28 of 2006 s. 270(1).]

32. Terms, conditions and directions specifically applicable

- (1) Without derogating from the generality of the discretion conferred on the CEO, the CEO may impose terms, conditions or directions which it considers desirable in order to —
- (a) ensure that the safety, health or welfare of persons is not at risk;
 - (b) regulate the kind of practice and procedure, or any project of research, authorised and the manner in which it shall be carried out;
 - (c) limit the authority conferred under a licence or exemption;
 - (d) require action therein specified to be undertaken by the holder —
 - (i) within a time or at times therein specified; or
 - (ii) on occasions or in circumstances therein specified,in relation to the premises to which the licence or exemption relates, the conduct of the reproductive technology practice carried on, or otherwise in the public interest;
 - (e) prevent improper arrangements or practices; or
 - (f) ensure compliance with the requirements of, or with terms fixed, conditions imposed or directions given, under this Act.
- (2) A term or condition applicable to a licence or exemption, other than a term or condition imposed specifically by Part 3, this Part or the regulations, may be varied or cancelled, or may be imposed subsequent to the grant of the licence or the issue of the exemption, at discretion by the CEO if evidenced —

- (a) by a notice in writing setting out particulars of the term or condition concerned (which may be a reference to the Rules or directions) and served on the licensee; or
- (b) by being endorsed on the licence or exemption or being included, or so referred to, in a revised version,

as the CEO may require, but no such term or condition shall have effect in so far as it may be inconsistent with the Rules for the time being.

- (3) The CEO at any time may, on the application of the licensee or the licence supervisor, vary the terms of, or revoke, a licence or any condition other than a condition imposed by section 33.

[Section 32 amended by No. 17 of 2004 s. 26; No. 55 of 2004 s. 526 and 540; No. 28 of 2006 s. 270.]

33. Conditions applicable to all licences and exemptions

- (1) Every licence and every exemption shall at all times be subject to the general condition that the ethics and practices that should govern, and the procedures to be used in, the conduct of reproductive technology in so far as they —
 - (a) are for the time being set out in —
 - (i) the Code; or
 - (ii) where no relevant Rule has been brought into operation, directions;and
 - (b) are applicable to —
 - (i) every licence or exemption;
 - (ii) a licence or exemption of that kind; or
 - (iii) that licence or exemption, specifically,

are to be observed by the licensee in relation to the reproductive technology practice carried on by the licensee.

- (2) Every licence granted or exemption issued under this Part is subject to the conditions —
- (a) that the practice authorised thereby shall be carried on —
 - (i) under the supervision of the licence supervisor;
 - (ii) only on the premises to which the licence or exemption relates; and
 - (iii) in accordance with this Act and the terms, conditions and directions applicable,but in no other manner;
 - (b) that any authorised officer, on production if so required of the certificate issued under section 59 or other identification as such, shall be permitted to enter the premises to which the licence or exemption relates and inspect them, including any equipment or records, to observe any procedure and to take account of any human gametes, a human egg undergoing fertilisation or a human embryo, there;
 - (c) that every participant to be treated has been given a suitable opportunity to receive proper counselling about the implications of the treatment and has been provided with such relevant information as is proper;
 - (d) that the requirements of this Act as to the obtaining and recording of effective consents be complied with;
 - (e) that section 22(1) is complied with;
 - (ea) that the licensee maintains the accreditation required by section 29(5)(a);
 - (f) that proper records in relation to the practice, procedures and participants be maintained, in such manner and form and including such information about such matters as this Act or the terms or conditions of the licence or exemption may require or the CEO may by directions specify;

- (g) that, where any human gametes, a human egg undergoing fertilisation or a human embryo is supplied to a person to whom another licence applies, that person shall be provided with such information additional to that otherwise required as the CEO may by directions specify;
 - (h) that the CEO shall be provided, in such form and at such times as directions may specify, with such copies of or extracts from records to which this Act relates, or other information for the purposes of this Act, as the CEO may by directions specify; and
 - (j) that no information shall be removed from any records maintained under the licence or exemption before the expiry of such period as may be prescribed for records of that kind, except with the written approval of the CEO.
- (3) Every storage licence is subject to the conditions —
- (a) that human gametes, a human egg undergoing fertilisation or a human embryo shall be stored only if received or acquired from —
 - (i) a person to whom a licence applies; or
 - (ii) a person who satisfies the licensee that they can give an effective consent to that storage;
 - (b) that a human egg undergoing fertilisation or a human embryo the development of which was brought about by an in vitro fertilisation procedure, otherwise than under the authorisation conferred by a practice licence held by the same licensee, shall be stored only if received or acquired from —
 - (i) another person to whom a licence applies; or
 - (ii) a person who satisfies the licensee that they can give an effective consent to that storage;
 - (c) that human gametes, human eggs undergoing fertilisation or human embryos which are or have been

stored shall not be supplied to a person unless that person is a person to whom a licence or an exemption applies, or the supply has been otherwise authorised under this Act; and

- (d) that no human gametes, human egg undergoing fertilisation or human embryo shall be stored for longer than this Act authorises.

[Section 33 amended by No. 17 of 2004 s. 27; No. 55 of 2004 s. 527; No. 28 of 2006 s. 270(2).]

34. Contravention of a condition or direction

A contravention of a condition or a direction applicable to a licence or exemption, whether —

- (a) applicable generally under this Act;
- (b) applicable to licences or exemptions of a particular kind or in particular circumstances; or
- (c) specifically imposed on or given in relation to that licence or exemption or a particular matter,

shall not be taken to be an offence, unless the regulations specifically otherwise provide, but any such contravention may constitute grounds for disciplinary action and may be taken into account in considering any application.

35. Notice and coming into operation of directions and conditions

- (1) A notice relating to a term or condition for the purposes of section 32(2) or a notice giving directions generally —
 - (a) shall be signed by the CEO;
 - (b) may be published, and if not published shall be brought to the attention of the persons to whom it is applicable in such a way as, in the opinion of the CEO, is likely to be effective;

- (c) when published in the *Gazette*, is to be (whether or not subject to specified exceptions) of general application, or to apply generally to licences or exemptions of the kind specified in that notice, and is not required to refer to the particular licence or exemption to which it relates; and
 - (d) shall be served on each licensee.
- (2) Where directions are to be applicable only to a particular person, or in particular circumstances, the directions shall in so far as is practicable be given by serving notice in writing of these directions on the person in relation to whom they are to have effect, but may be given by a notice under subsection (1).
- (3) A condition which is imposed or varied after the grant of the licence or the issue of the exemption to which it relates, or a direction given, takes effect on the date specified —
- (a) in the notice served on the licensee setting out the particulars;
 - (b) in the endorsement made on, or revised version of, the licence or exemption; or
 - (c) in the *Gazette* notice,
- as the case may be.

[Section 35 amended by No. 55 of 2004 s. 540; No. 28 of 2006 s. 270(1).]

Division 3 — Suspension or cancellation, and disciplinary action

36. Suspension or cancellation of a licence or exemption, other than on disciplinary grounds

- (1) The CEO, on application made by the licensee, may suspend the operation of any licence or exemption.

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- (2) The CEO may suspend the operation of any licence or exemption, or cancel any licence or revoke an exemption, by notice given to the licensee or delivered to any premises to which the licence or exemption relates with effect from a date not earlier than 3 months after service of that notice, where in the opinion of the CEO the licensee has failed to carry on a reproductive technology practice, or to carry out the procedures authorised by the licence or exemption, in the manner required by the public interest, but a licensee thereby affected may apply for a review of the decision under section 42.
- (2a) The CEO may by notice suspend the operation of any licence or exemption with immediate effect, by reason of any requirement of public health, where in the opinion of the CEO imminent risk of serious harm to a person may occur.
- (2b) A notice under subsection (2a) is to state that the CEO will refer the matter to the State Administrative Tribunal within 14 days of giving the notice.
- (2c) The CEO may, by notice given to the person to whom the notice made under subsection (2a) was given, revoke or vary a notice made under subsection (2a) at any time before referring the matter to the State Administrative Tribunal under section 36A.
- (3) Where a suspension has been imposed with immediate effect pursuant to subsection (2a) and the matter has been referred to the State Administrative Tribunal under section 36A then, unless the Tribunal otherwise orders, which order may be upon terms including terms as to undertakings by the CEO as to damages, such suspension shall lapse or be rescinded at the expiration of 21 days from the commencement of such referral.

[Section 36 amended by No. 55 of 2004 s. 528; No. 28 of 2006 s. 270(1).]

36A. Referring to State Administrative Tribunal a matter leading to a section 36(2a) notice

Within 14 days of giving a notice under section 36(2a), if that notice is not revoked under section 36(2c), the CEO shall refer the matter in respect of which the notice was made to the State Administrative Tribunal.

[Section 36A inserted by No. 55 of 2004 s. 529; amended by No. 28 of 2006 s. 270(1).]

37. Summary determinations

- (1) If it appears to the CEO that a licensee or a person to whom section 40(2) applies may, by reason of a matter of a kind referred to in section 39, be liable to a penalty and that a penalty appropriate to the case is provided by section 40(1)(a) to (f), the CEO may, on making a summary determination to that effect, issue a written warning or impose a penalty of that kind summarily.
 - (1a) The CEO shall seek the advice of the Council before making a summary determination under subsection (1).
 - (2) Notice of a summary determination made under subsection (1) and of any warning or penalty proposed to be so imposed shall be given in writing by the CEO —
 - (a) to the person to be warned or liable to the penalty; or
 - (b) if that is not practicable, by publication in the *Gazette*, setting out short particulars of the reason and giving that person a reasonable opportunity, within a period specified in that notice, to show cause to the CEO why effect should not be given to that determination.
 - (3) If within the period specified in the notice given under subsection (2), the person to be warned or liable for the penalty summarily imposed —
 - (a) consents to the summary determination; or

- (b) endeavours to show cause why effect should not be given to the summary determination, but otherwise submits to the discretion of the CEO and does not request that any matter alleged be brought before the State Administrative Tribunal under section 38,

effect may, by notice in writing to that person, be given to the summary determination and thereupon the warning or penalty proposed, or such lesser penalty as the CEO may think appropriate and specify instead in that notice, shall, as from the date specified in that notice, be thereby imposed.

[Section 37 amended by No. 55 of 2004 s. 530; No. 28 of 2006 s. 268 and 270.]

38. Disciplinary action

- (1) Where —
 - (a) the licensee or other person liable to a warning or penalty does not consent to a summary determination or submit to the discretion of the CEO under section 37; or
 - (b) it appears to the CEO that a penalty provided by section 40(1)(a) to (f) may not be appropriate or that effect has not been given under section 37(3) to the summary penalty imposed,

the CEO may make an allegation to the State Administrative Tribunal in respect of the matter.

- (1a) If the CEO makes an allegation to the State Administrative Tribunal under subsection (1)(a), the CEO shall advise the Council that the allegation has been made.
- (1b) If the CEO proposes to make an allegation to the State Administrative Tribunal under subsection (1)(b), the CEO shall first consult the Council.

[Section 38 inserted by No. 55 of 2004 s. 531; amended by No. 28 of 2006 s. 270.]

39. Matters that may be the subject of disciplinary action

[(1) deleted]

- (2) It may be a cause for disciplinary action if —
- (a) any reproductive technology practice, or any procedure authorised under a licence or exemption, is not properly conducted or carried out in accordance with the licence or that exemption;
 - (b) a person to whom the licence applies has contravened a requirement of this Act, a term or condition of that licence or any direction;
 - (c) a licensee has contravened a term or condition applicable to an exemption;
 - (d) a person to whom the licence applies has been convicted of —
 - (i) an offence under this Act;
 - (ii) an offence under the *Health Act 1911* in relation to the conduct of the reproductive technology practice or premises to which the licence or exemption relates; or
 - (iii) an offence in the State or elsewhere that implies that the person is unfit to be a licensee;
 - (e) a licensee at a material time employed or engaged, in relation to the practice carried on under the licence or exemption, a person who in the course of that practice committed any offence of a kind to which paragraph (d) refers and of which that person was convicted;
 - (f) the person to whom the licence applies, or any person holding a position of authority in a body that holds a licence or who has a material interest in a reproductive technology practice, is or becomes not a fit and proper person to hold that position or to be so interested;
 - (g) activities conducted under the licence or on the premises to which this licence relates are jeopardizing public

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health, and the continuation of the licence or exemption would not be in the public interest;

- (h) the premises to which the licence relates, or other circumstances material to the conduct of the practice authorised, are no longer suitable for the research or procedures authorised under the licence or exemption;
- (j) information given for the purposes of this Act by or on behalf of the licensee was in any material respect false or misleading;
- (k) information which this Act requires to be kept confidential is not so kept;
- (m) the safety, health or welfare of persons who resort to a reproductive technology practice as participants or prospective participants is endangered by an act or neglect of the licensee; or
- (n) an order made under section 40 in respect of a determination previously made under section 37 or by the State Administrative Tribunal in proceedings commenced under section 38 has been contravened.

[Section 39 amended by No. 55 of 2004 s. 532.]

40. Penalties

- (1) The CEO may, in relation to any disciplinary action in respect of which a determination has been made under section 37, by order impose any one or more of the following penalties —
 - (a) a reprimand;
 - (b) the imposition of a condition to which a licence or exemption is to be subject, limiting the authority conferred by the licence or exemption;
 - (c) the variation or cancellation of a term or condition to which a licence or exemption is subject;
 - (d) a requirement that a person to whom the licence applies or who is interested in the licence or exemption enter

into a written undertaking or a bond, or give a prescribed security, for future conduct;

- (e) a requirement as to the conduct of the reproductive technology practice under the licence or exemption, contravention of which may result in its mandatory suspension;
- (f) a requirement that specified action be taken by the licence supervisor within a specified period, contravention of which may result in mandatory suspension of the licence or exemption,

and may make such other ancillary order, including an order for the payment of costs not exceeding the prescribed amount, as the CEO thinks fit.

- (1a) If in a proceeding commenced by a referral under section 36A or an allegation under section 38(1), the State Administrative Tribunal is of the opinion that cause exists for disciplinary action, the Tribunal may impose any one or more of the following penalties —
 - (a) a reprimand;
 - (b) the imposition of a condition to which a licence or exemption is to be subject, limiting the authority conferred by the licence or exemption;
 - (c) the variation or cancellation of a term or condition to which a licence or exemption is subject;
 - (d) a requirement that a person to whom the licence applies or who is interested in the licence or exemption enter into a written undertaking or a bond, or give a prescribed security, for future conduct;
 - (e) a requirement as to the conduct of the reproductive technology practice under the licence or exemption, contravention of which may result in its mandatory suspension;

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- (f) a requirement that specified action be taken by the person responsible within a specified period, contravention of which may result in mandatory suspension of the licence or exemption;
 - (g) the suspension of the operation of a licence or exemption —
 - (i) until further order; or
 - (ii) for a specified period;
 - (h) the suspension of the operation of the licence or exemption for so long as a person to whom subsection (2) applies is —
 - (i) the holder of a position of authority in a body that holds a licence; or
 - (ii) directly or indirectly materially interested in a reproductive technology practice carried on under a licence or exemption,subject to subsection (3);
 - (i) the cancellation of a licence, or the revocation of an exemption;
 - (j) the disqualification, for such period as the Tribunal thinks fit, of a licensee from holding a licence or exemption; or
 - (k) an order that the person to whom the licence applies pay to the Crown a monetary penalty not exceeding the prescribed amount.
- (2) Where the CEO finds that a proper cause for disciplinary action exists in relation to a licence or an exemption held by a proprietary company, any penalty that by subsection (1)(d) or (e) might have been imposed in relation to the licence or exemption, whether or not a penalty is imposed on the licensee, may be imposed on or in relation to any person who occupies a position of authority in that company or any related body corporate, subject to subsection (3).

- (2a) Where the State Administrative Tribunal finds that a proper cause for disciplinary action exists in relation to a licence or an exemption held by a proprietary company, any penalty that by subsection (1)(d), (e) or (j) might have been imposed in relation to the licence or exemption, whether or not a penalty is imposed on the licensee, may be imposed on or in relation to any person who occupies a position of authority in that company or any related body corporate, subject to subsection (3).
- (3) The CEO and the State Administrative Tribunal shall not impose a penalty under subsection (1a)(i), (2) or (2a) where it is proved that the person concerned —
- (a) did not know of, and could not reasonably have been aware of or have prevented, the matter upon which the ground of complaint was made out; or
 - (b) had taken reasonable steps to prevent the occurrence of a matter of the kind to which the complaint related.

[Section 40 amended by No. 17 of 2004 s. 28; No. 55 of 2004 s. 533 and 540; No. 28 of 2006 s. 270.]

41. Effect on pending procedures

- (1) The suspension of the operation of a licence or exemption, the cancellation of a licence, the revocation of an exemption or a change in the terms and conditions imposed in relation to a licence or exemption does not, unless the CEO otherwise directs, relieve the licensee or former licensee of any obligation in relation to the completion of any artificial fertilisation procedure then being undergone by a participant.
- (2) Where a licence or exemption under which a procedure was commenced, or was purportedly commenced, ceases to have effect the CEO, if that would be in the best interests of a participant, may give directions to the licence supervisor requiring that the procedure, or specified matters relating to the procedure, be carried out and completed by —
- (a) a person specified in the direction; or

- (b) some other person authorised to do so under this Act, and may require that to be done at the expense of the licensee, and may take such steps as are necessary to ensure that the expense is met.
- (3) Where any human egg undergoing fertilisation or human embryo is, or human gametes are, kept by a licensee and the licence or exemption under which the keeping took place ceases to have effect the CEO may require that such egg, embryo or gametes be stored in accordance with this Act thereafter in a manner and by a person approved by the CEO.

[Section 41 amended by No. 17 of 2004 s. 29; No. 28 of 2006 s. 270.]

Division 4 — State Administrative Tribunal powers

[Heading amended by No. 55 of 2004 s. 534.]

42. Reviews

- (1) Where the CEO —
- (a) refuses an application for —
 - (i) the grant, variation or renewal of a licence;
 - (ii) an exemption under section 28; or
 - (iii) an authorisation under section 30;
 - (b) decides to impose or vary any condition in respect of a licence or exemption; or
 - (c) suspends the operation of a licence or exemption, cancels a licence or revokes an exemption conferred under section 28 —
 - (i) under section 36(2); or
 - (ii) as a consequence of a contravention of an order made under section 43,

notice shall be given in writing by the CEO to the applicant or the licensee of that decision, setting out short particulars of the

reason, and giving that person a reasonable opportunity, within a period specified in that notice, to make representations or show cause to the CEO as to why the decision should be varied or should not have effect or continuing effect.

- (2) An applicant or licensee may apply to the State Administrative Tribunal for a review of a decision of the kind to which subsection (1) refers to which effect is given.
- (3) Any person liable to a penalty thereunder or to be adversely affected thereby, may apply to the State Administrative Tribunal for a review of any decision made by the CEO by way of a summary determination in respect of a disciplinary matter.

[Section 42 amended by No. 55 of 2004 s. 535 and 540; No. 28 of 2006 s. 270.]

43. Restraint of continuing contravention

- (1) Where the State Administrative Tribunal is satisfied on application made by the CEO that a licensee is by any act committing, or permitting the commission of, a continuing contravention of any term, condition or direction applicable to a licence or exemption the Tribunal may —
 - (a) by order restrain the continuance of that act; and
 - (b) make a further order that —
 - (i) the operation of the licence or exemption may be suspended for a specified period; or
 - (ii) the licence may be cancelled or the exemption revoked with immediate effect,by the CEO if the CEO is satisfied that the restraint order has been contravened.
- (2) The continued existence of anything in a state, or the intermittent repetition of any act, contrary to a term or condition of a licence or exemption or to any direction may be deemed for the purposes of subsection (1) to constitute a continuing contravention.

- (3) Proceedings under this section shall not prejudice any disciplinary action under this Act that may be taken in relation to the same or a similar contravention.

[Section 43 amended by No. 55 of 2004 s. 536; No. 28 of 2006 s. 270(1).]

Division 5 — Information

44. Records of procedures

- (1) A licensee shall make, maintain, keep and retain a proper record —
- (a) showing in relation to human gametes, human eggs undergoing fertilisation or human embryos kept or used by that licensee —
 - (i) if human gametes, the identity and consent of the donor from whom, and the date when, received;
 - (ii) if human eggs undergoing fertilisation or human embryos, their biological parentage and the date fertilisation commenced;
 - (iii) the place, period and method of collection and of keeping; and
 - (iv) the identity of any person to whom human gametes, human eggs undergoing fertilisation or human embryos were supplied, of every person for whom the gametes, eggs undergoing fertilisation or embryos were used in an artificial fertilisation procedure, and, if known, the ultimate recipient;
 - (b) in relation to all artificial fertilisation procedures carried out by or on behalf of the licensee showing —
 - (i) the identity of, and full particulars as to the consent given by, each participant;

- (ii) the reasons why each participant was assessed as being an eligible person in respect of that procedure;
- (iii) the nature of the procedure;
- (iv) the identity of the individual who carried out that procedure; and
- (v) where known —
 - (A) the outcome of the procedure;
 - (B) whether any children were born that appear to the licence supervisor to have been born as a result of the procedure; and
 - (C) sufficient particulars to identify each such child;
- (c) of all research relating to reproductive technology conducted, authorised or facilitated by or on behalf of that licensee; and
- (d) any other information, procedure or matter of which a record is required under this Act or any other written law,

in such a manner as to comply with the terms of, and any condition imposed on, the licence or any approval or direction relating to that licence and any requirement under this Act, unless the CEO, in writing, otherwise directs.

- (2) Subsection (1) does not apply to the holder of an exemption conferred under section 28 or 28A, except in so far as the CEO —
 - (a) by a condition imposed on that exemption, requires; or
 - (b) in writing, otherwise directs.

- (3) A person required by subsection (1) to make a record of a matter shall —
- (a) make up the record as soon as is practicable after the occurrence to which it relates;
 - (b) keep and retain a proper record, in such a manner as to keep secure the confidential nature of the information contained in that record, in a place in the State approved by the CEO for the purpose, for the prescribed number of years after the date on which it was compiled; and
 - (c) make the record available for inspection by an authorised officer,

and no information shall be removed from any such record before the expiry of such period as may be specified in the Rules or by directions for information of that kind.

- (4) A licensee shall, if so required by the CEO, furnish in a form acceptable to the CEO any record to which subsection (1) applies and reports containing such further or other information as the CEO may reasonably require —
- (a) in respect of any research;
 - (b) concerning —
 - (i) any artificial fertilisation procedure using; or
 - (ii) the keeping, or any facility or procedure relating to the keeping, of,
any human gametes, a human egg undergoing fertilisation or a human embryo; or
 - (c) relating to any other matter, specified by the CEO as being relevant to the administration of this Act, whether in relation to that licence or exemption or otherwise,

in respect of such period, or in relation to such circumstances, at and within such times, and verified in such manner and by such a person, as the CEO may direct.

- (5) Where a person ceases to be a licensee, any record required to have been kept under this section by that person shall be retained, in a manner and at a place approved by the CEO for that purpose, by or on behalf of that person or may be lodged with the CEO.
- (6) A person who, being a person to whom the relevant licence applies or applied, fails —
- (a) to make, maintain, keep or retain a record or report, as required by this section;
 - (b) to keep secure the confidential information contained in such a record; or
 - (c) to make such a record available for inspection by an authorised officer,

commits an offence.

Penalty: \$5 000.

[Section 44 amended by No. 17 of 2004 s. 30; No. 28 of 2006 s. 270.]

45. Registers of identity

- (1) The CEO shall cause to be kept, in a place and manner approved by the Minister, registers —
- (a) containing current information supplied by, or otherwise obtained from, licensees in respect of —
 - (i) the identity of participants;
 - (ii) the outcome of procedures, showing the genetic origin of the human gametes, human egg undergoing fertilisation or human embryo used;
 - (iii) the identity of children born as a result of an artificial fertilisation procedure, including the identity of each biological parent; and

- (iv) such relevant demographic and clinical information,
as may have been required to be supplied under this Act;
 - (b) showing the prescribed current information relating to —
 - (i) licences, licensees other than persons to whom subparagraph (ii) applies, and persons approved as managers; and
 - (ii) persons to whom an exemption under section 28 applies, the conditions subject to which, and the procedures in relation to which, the exemption applies and whether the exemption is affected by a suspension;
 - (c) information which has been so supplied or obtained under paragraph (a) or entered pursuant to paragraph (b), but is no longer current;
 - (d) setting out a record, complying with the prescribed requirements, of disciplinary proceedings under this Act;
 - (da) any information obtained from the NHMRC Licensing Committee established under section 13 of the Commonwealth Human Embryo Act in relation to any NHMRC licences held or applied for in this State; and
 - (e) in relation to such other matters as may be prescribed.
- (2) A register kept for the purposes of subsection (1) shall be compiled in a manner which enables such information as a person is entitled to under this Act, or any other written law, to be made readily available but keeps secure the confidential nature of the remainder of the register.

[Section 45 amended by No. 17 of 2004 s. 31; No. 28 of 2006 s. 270(1).]

46. Access to information

- (1) Nothing in this Act shall be construed as preventing a person who is or was a participant in relation to any procedure from obtaining access to information being kept by a licensee about that person in respect of that procedure under this Act, and a licensee shall facilitate any such access requested.
- (2) A person, on payment of the prescribed fee, shall be entitled to be furnished with information in a register kept under section 45(1)(a), (b) or (c) if the information supplied related to that person in their capacity as a participant in an artificial fertilisation procedure.
- (3) A person may, on payment of the prescribed fee, be furnished with information in a register kept under section 45 if —
 - (a) it does not identify, but relates to —
 - (i) a biological parent of that person; or
 - (ii) a child of which that person is a biological parent;
 - (b) it is sought by a person so authorised by the CEO;
 - (c) it discloses only the social or public health connotations of reproductive technology; or
 - (d) a written law so provides,but not otherwise, unless subsection (2) applies.
- (4) Nothing in this Act prohibits access to information in the register being given to —
 - (a) an authorised officer, for the purposes of the administration of this Act or a prescribed written law; or
 - (b) a licensee or a person authorised by that licensee, in relation to information previously supplied by that licensee but not otherwise, in order to carry out an artificial fertilisation procedure or to conduct research.

[Section 46 amended by No. 28 of 2006 s. 270(1).]

47. Annual returns etc.

- (1) A licensee, or a person who during the period to which the requirement relates was a licensee, shall furnish to the CEO, in the prescribed manner, an annual return and explanatory documents, which may be required to include participant identifying information, showing such information as may be required by —
- (a) the Rules;
 - (b) the regulations; or
 - (c) the CEO, by direction in writing.
- (2) A person who fails to comply with a requirement made under subsection (1) commits an offence.

Penalty: \$5 000.

[Section 47 amended by No. 28 of 2006 s. 270(1).]

48. Exchange of information

The CEO may disclose, or authorise the disclosure of, information gained in the course of the administration of this Act to —

- (a) authorities vested with the administration of laws relating to reproductive technology or surrogacy in other States and Territories of the Commonwealth; or
- (b) any other bodies that may require the information for the purpose of discharging duties of a public nature,

respecting the affairs of any person or the administration of this Act, but not in such a manner as to disclose the identity of any person who is, or was, a donor of human gametes or a human embryo, a participant, or a child conceived through artificial fertilisation, unless authorised by that person or by any other written law.

[Section 48 amended by No. 17 of 2004 s. 32; No. 28 of 2006 s. 270(1).]

49. Confidentiality

(1) A person shall not divulge, or communicate to any other person, any information disclosed or obtained by reason of this Act respecting the identity of —

- (a) a donor of human gametes, a human egg undergoing fertilisation or a human embryo;
- (b) a participant in any procedure involving reproductive technology; or
- (c) a child born as a result of any artificial fertilisation procedure,

unless subsection (2) applies.

(2) Information to which subsection (1) applies may be divulged or communicated —

- (a) for a purpose necessary to the carrying out of any procedure, or the conduct of any research, to which this Act applies;
- (b) for the purposes of and in the course of the administration of this Act, or pursuant to a request of the Minister made for the purposes of section 5;
- (c) as may be authorised or required by the Code or the regulations;
- (d) subject to subsections (2a) to (2c), with the consent of each donor, participant or child in question or other person whose identity may be disclosed in so far as it does not identify any person who was a participant in the relevant procedure and who has not given such consent; or
- (e) under an authorisation conferred by another written law.

(2a) Information that would identify a child born as a result of the relevant procedure who has not reached 16 years of age cannot be divulged or communicated under paragraph (d) of subsection (2) unless each person who has given consent for the

purposes of that paragraph has completed approved counselling before giving that consent.

- (2b) Except as provided in subsection (2c), a child who has not reached 16 years of age cannot consent for the purposes of paragraph (d) of subsection (2).
- (2c) A person who has parental responsibility (as defined in section 68 of the *Family Court Act 1997*) for the child may, after completing approved counselling, consent for the purposes of paragraph (d) of subsection (2) on behalf of that child and in that case the child is to be taken to have consented for the purposes of that paragraph.
- (2d) Subject to subsection (2e), information to which subsection (1)(a) applies may be divulged or communicated to a child resulting from the donation who has reached 16 years of age and who has completed approved counselling.
- (2e) Information cannot be divulged or communicated under subsection (2d) unless —
- (a) the donation was made on or after the day on which the *Human Reproductive Technology Amendment Act 2004* came into operation (the **commencement day**); or
 - (b) the donation was made before the commencement day and —
 - (i) was used with the effective consent of the donor given on or after the commencement day; or
 - (ii) the CEO is satisfied that the donor was, before the donation, adequately informed that future changes in legislation might enable the information to be divulged or communicated to the child without the donor's consent.
- (2f) In subsections (2a), (2c) and (2d) —
approved counselling means counselling approved by the CEO in relation to the divulging or communication of information to which subsection (1) applies.

(3) A person shall not produce in any court or to any other person, or permit any other person to have access to, a record that is, in the course of the administration of this Act or for purposes authorised by this Act, in the custody of that person and discloses, or may disclose, the identity of —

- (a) a donor of human gametes, a human egg undergoing fertilisation or a human embryo;
- (b) a participant in any procedure involving reproductive technology; or
- (c) a child born as a result of any artificial fertilisation procedure,

unless subsection (4) applies.

(4) Subsection (3) shall not apply where the production or access —

- (a) has been approved by the CEO, or a person to whom the function of approving it is delegated, and is required for the purposes of any proceedings —
 - (i) of the Council;
 - (ii) of the State Administrative Tribunal; or
 - (iii) in respect of an offence under this Act;
- (b) is required by an authorised officer for the purpose of carrying into effect the provisions of this Act; or
- (c) is authorised under any other written law,

but in any such case so far as is practicable the information which is necessary in respect of any particular matter shall be provided in a manner that will not identify the individual to whom it refers.

(5) A person who contravenes subsection (1) or subsection (3) commits an offence.

Penalty: \$5 000, or imprisonment for 12 months.

[Section 49 amended by No. 17 of 2004 s. 33; No. 55 of 2004 s. 537; No. 28 of 2006 s. 270(1).]

50. False or misleading statements and records

- (1) A person who in, or in relation to, any —
- (a) application, disciplinary proceedings or matter to be determined by the CEO; or
 - (b) return or other record required, made, maintained, kept or produced under or for the purposes of this Act,

makes a statement that —

- (c) is false or misleading in a material particular; or
- (d) has omitted from it a matter or thing the omission of which renders the information misleading in a material respect,

commits an offence.

Penalty: \$5 000.

- (2) It is a defence to a prosecution of a person for an offence under subsection (1) if that person proves that when the statement was made the person —
- (a) believed on reasonable grounds that the false matter was true;
 - (b) believed on reasonable grounds that the misleading matter was not misleading;
 - (c) in the case of an omission, believed on reasonable grounds —
 - (i) that no material had been omitted, being material matter the omission of which would make the statement false or misleading; or
 - (ii) that the omitted matter was not material.

- (3) A person who, by an act intended to falsify or destroy the record, alters or destroys any record required, made, maintained, kept or produced under this Act commits an offence.

Penalty: \$5 000.

[Section 50 amended by No. 55 of 2004 s. 540; No. 28 of 2006 s. 270(1).]

Division 6 — Supervision, etc.

51. Supervision

- (1) A licence or exemption can not —
 - (a) authorise any practice to be carried on except under the supervision of one individual as the licence supervisor; or
 - (b) apply in relation to premises other than such as are specified in the licence.
- (2) It shall be the duty of the licence supervisor to secure —
 - (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the practice authorised by the licence;
 - (b) that proper equipment is used;
 - (c) that proper arrangements are made for the keeping of human gametes, human eggs undergoing fertilisation and human embryos and for the disposal of any such gametes, eggs or embryos that succumb;
 - (d) that suitable procedures are used in the course of treatment; and
 - (e) that any terms, conditions or directions applicable to the licence are observed and complied with.
- (3) Where a person is permitted by a licensee to conduct, supervise or manage any reproductive technology practice, or any storage, for which a licence is required under this Act, that person may, for the purposes of any disciplinary proceedings or proceedings for an offence under this Act, be deemed to have been the licence supervisor in relation to that practice.
- (4) It may be made a condition of a licence or exemption that a reproductive technology practice, or specified activities of the practice, shall not be carried on in the absence of a specified person.

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- (5) Except where the CEO has given prior approval to the temporary absence of the licence supervisor, if for any reason the licence supervisor in relation to any licence or exemption is not to carry out that function, the licensee shall forthwith give notice to that effect to the CEO.
- (6) Where the person specified in the licence or exemption as the licence supervisor ceases, or is to cease, to carry out that function and the licensee proposes to appoint or employ some other individual to carry out that function the licensee shall give notice to that effect to the CEO who may, within 7 days after receiving the notice of the proposed appointment or employment of any individual as the licence supervisor in relation to any licence or exemption, notify the licensee that the individual proposed does not have the approval of the CEO, and on receiving such a notice from the CEO the licensee shall terminate any such appointment or employment with effect from a date not later than 21 days after the date of the notice.
- (7) Where —
- (a) a requirement is made of a licensee under this Act; or
 - (b) an element of a contravention of this Act is an act or omission on the part of a licensee,
- the licence supervisor in relation to the licence or exemption in question is, subject to section 53(1)(b), liable accordingly.
- (8) Where a person appointed or employed as, or deemed to be, the licence supervisor in relation to any practice resigns or for any other reason ceases so to act, the licensee remains, and —
- (a) in the case of a licensee which is a company, the directors;
 - (b) in the case of a licensee which is a body corporate other than a company, the committee of management; and

(c) in any other case, such persons as occupy a position of authority in the affairs of the licensee, jointly and severally remain, liable for the conduct of the practice.

[Section 51 amended by No. 17 of 2004 s. 34; No. 55 of 2004 s. 540; No. 28 of 2006 s. 270.]

52. Licensee liable for act of employee etc.

- (1) Where an employee or agent of the licensee, or a person acting, or purporting to act, on behalf of the licensee, commits in relation to the conduct of a reproductive technology practice a contravention of this Act for which the licensee would have been responsible or liable had it been committed by the licensee, the licensee may be deemed also to be liable to disciplinary action or, in the case of an offence, the same penalty.
- (2) A licensee may be proceeded against under subsection (1) notwithstanding that the employee or agent has not been made the subject of disciplinary proceedings or convicted under this Act.
- (3) It is a defence in disciplinary proceedings or to a charge of an offence against subsection (1) to show that the licensee —
 - (a) did not know of and could not reasonably have been aware of or have prevented; or
 - (b) had taken reasonable steps to prevent,the contravention committed by the employee or agent.

[Section 52 amended by No. 84 of 2004 s. 80.]

53. Offences by bodies corporate and partnerships

- (1) Where a body corporate is convicted of an offence under this Act, which in this subsection is referred to as the principal offence, then —
- (a) where a person is or at a material time was —
 - (i) an officer of, or a person occupying a position of authority in, that body corporate; or
 - (ii) a person purporting to act in any such capacity, and that person was in any way, by act or omission, directly or indirectly, knowingly concerned in or party to the commission of the principal offence, that person as well as the body corporate shall be deemed to have committed the principal offence; and
 - (b) unless it is proved that —
 - (i) such direction had been given; and
 - (ii) such supervision had been exercised or caused to be exercised,as were reasonably necessary to ensure that the principal offence was not committed, a person who is or is deemed to be the licence supervisor in relation to any practice in respect of which that offence was committed shall be deemed to have committed the offence as well,
- and each shall be liable to the penalty that is prescribed for the principal offence.
- (2) For the purposes of this section, in relation to a body corporate, a person shall be taken to be an officer of the body corporate if the person would be an officer within the meaning of the definition of that term contained in section 9 of the *Corporations Act 2001* of the Commonwealth.
- (3) Where the affairs of a body corporate are managed by its members, subsection (1) applies in relation to the acts and defaults of a member in connection with functions of

management as if the member were a director of the body corporate.

- (4) Where proceedings for an offence under this Act are taken against a body corporate a person who by virtue of this section would be liable to a penalty as well as the body corporate may, on the request of the CEO, be convicted on the proceedings on which the body corporate is convicted if the court is satisfied that the person had reasonable notice that the CEO intended to make that request.
- (5) Where this Act provides that a licensee commits an offence in specified circumstances the reference to the licensee shall be construed as a reference to each person who holds the licence or exemption.

[Section 53 amended by No. 10 of 2001 s. 109; No. 17 of 2004 s. 35; No. 28 of 2006 s. 270(1).]

Part 4A — Prohibited practices

[Heading inserted by No. 18 of 2004 s. 8.]

Division 1 — General

[Heading inserted by No. 18 of 2004 s. 8.]

53A. Object of this Part

- (1) The object of this Part is —
 - (a) to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos by prohibiting certain practices; and
 - (b) to adopt in this State a uniform Australian approach to the prohibitions.
- (2) For that purpose, this Part creates a number of offences that are similar to offences under the *Prohibition of Human Cloning Act 2002* of the Commonwealth.

[Section 53A inserted by No. 18 of 2004 s. 8.]

53B. Terms used

- (1) In this Part —

animal does not include a human;

chimeric embryo means —

 - (a) a human embryo into which a cell, or any component part of a cell, of an animal has been introduced; or
 - (b) a thing declared by regulations under the *Prohibition of Human Cloning Act 2002* of the Commonwealth to be a chimeric embryo;

human embryo clone means a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm;

hybrid embryo means —

- (a) an embryo created by the fertilisation of a human egg by animal sperm;
- (b) an embryo created by the fertilisation of an animal egg by human sperm;
- (c) a human egg into which the nucleus of an animal cell has been introduced;
- (d) an animal egg into which the nucleus of a human cell has been introduced; or
- (e) a thing declared by regulations under the *Prohibition of Human Cloning Act 2002* of the Commonwealth to be a hybrid embryo;

precursor cell means a cell that has the potential to develop into a human egg or human sperm.

- (2) For the purposes of establishing that a human embryo clone is a genetic copy of a living or dead human —
 - (a) it is sufficient to establish that the set of genes in the nuclei of the cells of the living or dead human has been copied; and
 - (b) it is not necessary to establish that the copy is an identical genetic copy.
- (3) For the purposes of the definition of **human embryo clone** in subsection (1), a human embryo that results from the technological process known as embryo splitting is taken not to be created by a process of fertilisation of a human egg by human sperm.
- (4) A reference in this Part to a number of penalty units is a reference to the amount calculated in accordance with the following formula —

$$A \times B$$

where —

A is that number of penalty units; and

B is the amount (in dollars) that is for the time being a penalty unit under section 4AA of the *Crimes Act 1914* of the Commonwealth.

[Section 53B inserted by No. 18 of 2004 s. 8.]

Division 2 — Human cloning

[Heading inserted by No. 18 of 2004 s. 8.]

53C. Offence — creating a human embryo clone

A person commits a crime if the person creates a human embryo clone.

Penalty: A fine of 900 penalty units or imprisonment for 15 years or both.

[Section 53C inserted by No. 18 of 2004 s. 8.]

53D. Offence — placing a human embryo clone in the human body or the body of an animal

A person commits a crime if the person places a human embryo clone in the body of a human or the body of an animal.

Penalty: A fine of 900 penalty units or imprisonment for 15 years or both.

[Section 53D inserted by No. 18 of 2004 s. 8.]

53E. Offence — importing or exporting a human embryo clone

(1) A person commits a crime if the person imports a human embryo clone into the State from a place outside Australia.

Penalty: A fine of 900 penalty units or imprisonment for 15 years or both.

(2) A person commits a crime if the person exports a human embryo clone from the State to a place outside Australia.

Penalty: A fine of 900 penalty units or imprisonment for 15 years or both.

[Section 53E inserted by No. 18 of 2004 s. 8.]

53F. No defence that human embryo clone could not survive

It is not a defence to an offence under section 53C, 53D or 53E that the human embryo clone did not survive or could not have survived.

[Section 53F inserted by No. 18 of 2004 s. 8.]

Division 3 — Other prohibited practices

[Heading inserted by No. 18 of 2004 s. 8.]

53G. Offence — creating a human embryo other than by fertilisation, or developing such an embryo

A person commits a crime if the person creates a human embryo by a process other than the fertilisation of a human egg by human sperm, or develops a human embryo so created.

Penalty: A fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

[Section 53G inserted by No. 18 of 2004 s. 8.]

53H. Offence — creating a human embryo for a purpose other than achieving pregnancy in a woman

- (1) A person commits a crime if the person creates a human embryo outside the body of a woman, unless the person's intention in creating the embryo is to attempt to achieve pregnancy in a particular woman.

Penalty: A fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

- (2) An accused does not bear an evidential burden in relation to the exception provided by subsection (1).

[Section 53H inserted by No. 18 of 2004 s. 8; amended by No. 2 of 2008 s. 63.]

53I. Offence — creating or developing a human embryo containing genetic material provided by more than 2 persons

A person commits a crime if the person creates or develops a human embryo containing genetic material provided by more than 2 persons.

Penalty: A fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

[Section 53I inserted by No. 18 of 2004 s. 8.]

53J. Offence — developing a human embryo outside the body of a woman for more than 14 days

A person commits a crime if the person develops a human embryo outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended.

Penalty: A fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years.

[Section 53J inserted by No. 18 of 2004 s. 8.]

53K. Offence — using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo

A person commits a crime if the person uses precursor cells taken from a human embryo or a human fetus, intending to create a human embryo, or develops an embryo so created.

Penalty: A fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

[Section 53K inserted by No. 18 of 2004 s. 8.]

53L. Offence — heritable alterations to genome

- (1) A person commits a crime if —
- (a) the person alters the genome of a human cell in such a way that the alteration is heritable by descendants of the human whose cell was altered; and
 - (b) in altering the genome, the person intended the alteration to be heritable by descendants of the human whose cell was altered.

Penalty: A fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

- (2) In this section —

human cell includes a human embryonal cell, a human fetal cell, human sperm or a human egg.

[Section 53L inserted by No. 18 of 2004 s. 8.]

53M. Offence — collecting a viable human embryo from the body of a woman

A person commits a crime if the person removes a human embryo from the body of a woman, intending to collect a viable human embryo.

Penalty: A fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

[Section 53M inserted by No. 18 of 2004 s. 8.]

53N. Offence — creating a chimeric or hybrid embryo

- (1) A person commits a crime if the person creates a chimeric embryo.

- (2) A person commits a crime if the person creates a hybrid embryo.
- (3) A person who commits an offence against this section is liable to a fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

[Section 53N inserted by No. 18 of 2004 s. 8.]

53O. Offence — placing of an embryo

- (1) A person commits a crime if the person places a human embryo in an animal.
- (2) A person commits a crime if the person places a human embryo in the body of a human, other than in a woman's reproductive tract.
- (3) A person commits a crime if the person places an animal embryo in the body of a human for any period of gestation.
- (4) A person who commits an offence against this section is liable to a fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

[Section 53O inserted by No. 18 of 2004 s. 8.]

53P. Offence — importing, exporting or placing a prohibited embryo

- (1) A person commits a crime if the person imports a prohibited embryo into the State from a place outside Australia.
- (2) A person commits a crime if the person exports a prohibited embryo from the State to a place outside Australia.

- (3) A person commits a crime if the person places a prohibited embryo in the body of a woman.
- (4) A person who commits an offence against this section is liable to a fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

- (5) In this section —

prohibited embryo means —

- (a) a human embryo created by a process other than the fertilisation of a human egg by human sperm;
- (b) a human embryo created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman;
- (c) a human embryo that contains genetic material provided by more than 2 persons;
- (d) a human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended;
- (e) a human embryo created using precursor cells taken from a human embryo or a human fetus;
- (f) a human embryo that contains a human cell (as defined in section 53L(2)) whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered;
- (g) a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or
- (h) a chimeric embryo or a hybrid embryo.

[Section 53P inserted by No. 18 of 2004 s. 8.]

53Q. Offence — commercial trading in human eggs, human sperm or human embryos

- (1) A person commits a crime if the person gives or offers valuable consideration to another person for the supply of a human egg, human sperm or a human embryo.
- (2) A person commits a crime if the person receives, or offers to receive, valuable consideration from another person for the supply of a human egg, human sperm or a human embryo.
- (3) A person who commits an offence against this section is liable to a fine of 600 penalty units or imprisonment for 10 years or both.

Summary conviction penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

- (4) In this section —

reasonable expenses —

- (a) in relation to the supply of a human egg or human sperm includes, but is not limited to, expenses relating to the collection, storage or transport of the egg or sperm; and
- (b) in relation to the supply of a human embryo —
 - (i) does not include any expenses incurred by a person before the time when the embryo became an excess ART embryo; and
 - (ii) includes, but is not limited to, expenses relating to the storage or transport of the embryo;

valuable consideration, in relation to the supply of a human egg, human sperm or a human embryo by a person, includes any inducement, discount or priority in the provision of a service to the person, but does not include the payment of reasonable expenses incurred by the person in connection with the supply.

[Section 53Q inserted by No. 18 of 2004 s. 8.]

Division 4 — Review of Part

[Heading inserted by No. 18 of 2004 s. 8.]

53R. Review of Part

- (1) The Minister must cause a review of the operation of this Part to be undertaken as soon as possible after 19 December 2004.
- (2) The review must take into account —
 - (a) developments in technology in relation to assisted reproductive technology;
 - (b) developments in medical research and scientific research and the potential therapeutic applications of such research;
 - (c) community standards; and
 - (d) the applicability of establishing a national stem cell bank.
- (3) The review of this Part may be undertaken as part of the review of the *Prohibition of Human Cloning Act 2002* of the Commonwealth mentioned in section 25 of that Act.
- (4) The Minister is to prepare a report based on the review made under subsection (1) and cause the report to be laid before each House of Parliament not later than 12 months from the date on which the review is first commenced.
- (5) The Minister must cause a copy of the report based on the review conducted under section 25 of the *Prohibition of Human Cloning Act 2003* of the Commonwealth to be laid before each House of Parliament not later than 6 sitting days from the date of receipt of the report.

[Section 53R inserted by No. 18 of 2004 s. 8.]

**Part 4B — Regulation of certain uses involving excess
ART embryos**

[Heading inserted by No. 17 of 2004 s. 36.]

Division 1 — General

[Heading inserted by No. 17 of 2004 s. 36.]

53S. Object of this Part

- (1) The object of this Part is —
 - (a) to address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos by regulating activities that involve the use of certain human embryos created by assisted reproductive technology; and
 - (b) to adopt in this State a uniform Australian approach to the regulation of activities that involve the use of certain human embryos created by assisted reproductive technology.
- (2) For that purpose, this Part contains a number of provisions that are similar to provisions in the Commonwealth Human Embryo Act.
- (3) Nothing in this Part or in a licence under this Part authorises or permits the use of an excess ART embryo if that use is not a therapeutic use.
- (4) In subsection (3) —

therapeutic use, in relation to an excess ART embryo, means —

 - (a) its use in, or in connection with —
 - (i) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons;
 - (ii) influencing, inhibiting or modifying a physiological process in persons;

- (iii) testing the susceptibility of persons to a disease or ailment;
 - (iv) influencing, controlling or preventing conception in persons;
 - (v) testing for pregnancy in persons; or
 - (vi) the replacement or modification of parts of the anatomy of persons;
- (b) a use of it that is prescribed in the regulations and is not inconsistent with a use referred to in paragraph (a); or
- (c) its use in training or research for the purposes of a use referred to in paragraph (a) or (b).

[Section 53S inserted by No. 17 of 2004 s. 36.]

53T. Terms used

- (1) In this Part, unless the contrary intention appears —
- AHEC** means the Australian Health Ethics Committee established by the *National Health and Medical Research Council Act 1992* of the Commonwealth;
- Commonwealth Human Embryo regulations** means the regulations in force under the Commonwealth Human Embryo Act;
- confer** includes to impose;
- confidential commercial information** means information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed;
- corresponding law** means —
- (a) the Commonwealth Human Embryo Act; or
 - (b) an Act of another State that is a corresponding State law as defined in the Commonwealth Human Embryo Act;
- disclose**, in relation to information, means give or communicate in any way;

excess ART embryo means a human embryo that —

- (a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and
- (b) is excess to the needs of —
 - (i) the woman for whom it was created; and
 - (ii) her spouse or de facto partner (if any) at the time the embryo was created;

HREC means a Human Research Ethics Committee;

inspector means a person appointed as an inspector under section 53ZN(1);

licence means a licence issued under section 53ZB;

licensed ART centre means a person licensed under Part 4;

NHMRC Licensing Committee means the Committee of that name established under section 13 of the Commonwealth Human Embryo Act;

proper consent, in relation to the use of an excess ART embryo, means —

- (a) consent obtained in accordance with the *Ethical Guidelines on Assisted Reproductive Technology* (1996) issued by the NHMRC;
- (b) if other guidelines are issued by the NHMRC under the *National Health and Medical Research Council Act 1992* of the Commonwealth and prescribed by the Commonwealth Human Embryo regulations for the purposes of paragraph (b) of the definition of **proper consent** in section 8 of the Commonwealth Human Embryo Act — consent obtained in accordance with those other guidelines, rather than the guidelines mentioned in paragraph (a); or
- (c) where an intended use is to provide a human embryonic stem cell line, the uses to which the human embryonic

stem cell line may be put must have been disclosed and explained;

responsible person, in relation to an excess ART embryo, means —

- (a) each person who provided the egg or sperm from which the embryo was created;
- (b) the woman for whom the embryo was created, for the purpose of achieving her pregnancy;
- (c) any person who was the spouse or de facto partner of a person mentioned in paragraph (a) at the time the egg or sperm mentioned in that paragraph was provided; and
- (d) any person who was the spouse or de facto partner of the woman mentioned in paragraph (b) at the time the embryo was created;

State includes the Australian Capital Territory and the Northern Territory.

- (2) For the purposes of paragraph (b) of the definition of **excess ART embryo**, a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if —
 - (a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or
 - (b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.
- (3) A reference in this Part to a number of penalty units is a reference to the amount calculated in accordance with the following formula —

$$A \times B$$

where —

A is that number of penalty units; and

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Division 2 Performance of functions

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B is the amount (in dollars) that is for the time being a penalty unit under section 4AA of the *Crimes Act 1914* of the Commonwealth.

- (4) In this Part, a reference to a Commonwealth Act includes a reference to —
- (a) that Commonwealth Act, as amended and in force for the time being; and
 - (b) an Act enacted in substitution for that Act and, if it is amended, as amended and in force for the time being.

[Section 53T inserted by No. 17 of 2004 s. 36.]

Division 2 — Performance of functions

[Heading inserted by No. 17 of 2004 s. 36.]

53U. Functions not affected by State laws

The NHMRC Licensing Committee or an officer of the Commonwealth is not precluded by any law of the State from performing a function conferred by this Part.

[Section 53U inserted by No. 17 of 2004 s. 36.]

53V. Extent to which functions are conferred

- (1) This Part does not purport to impose any duty on the NHMRC Licensing Committee or an officer of the Commonwealth to perform a function if the imposition of the duty would be beyond the legislative power of the Parliament of the State.
- (2) This section does not limit the operation of section 7 of the *Interpretation Act 1984*.

[Section 53V inserted by No. 17 of 2004 s. 36.]

Division 3 — Offences

[Heading inserted by No. 17 of 2004 s. 36.]

53W. Offence — use of excess ART embryo

- (1) A person commits a crime if the person uses an excess ART embryo, unless —
- (a) the use by the person is authorised by a licence; or
 - (b) the use by the person is an exempt use as defined in subsection (2).

Penalty: A fine of 300 penalty units or imprisonment for 5 years or both.

Summary conviction penalty: A fine of 60 penalty units or imprisonment for 12 months or both.

- (2) A use of an excess ART embryo by a person is an *exempt use* for the purposes of subsection (1) if —
- (a) the use consists only of —
 - (i) storage of the excess ART embryo;
 - (ii) removal of the excess ART embryo from storage; or
 - (iii) transport of the excess ART embryo;or
 - (b) the use consists only of observation of the excess ART embryo;
 - (c) the use consists only of allowing the excess ART embryo to succumb;
 - (d) the use is carried out by a licensed ART centre, and —
 - (i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and

- (ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created;
 - (e) the use is carried out by a licensed ART centre and is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; or
 - (f) the use is of a kind prescribed by the Commonwealth Human Embryo regulations for the purposes of section 10(2)(f) of the Commonwealth Human Embryo Act.
- (3) An accused does not bear an evidential burden in relation to any matter in subsection (1).
- (4) In subsection (2) —

diagnostic investigation, in relation to an excess ART embryo, means any procedure undertaken on embryos for the sole purpose of diagnostic investigations for the direct benefit of the woman for whom it was created;

observation, in relation to an excess ART embryo, includes taking a photograph of the embryo, or taking a recording of the embryo from which a visual image can be produced.

[Section 53W inserted by No. 17 of 2004 s. 36; amended by No. 84 of 2004 s. 82.]

53X. Offence — breaching a licence condition

- (1) A person commits a crime if the person engages in conduct that contravenes a condition of a licence that applies to the person.
Penalty: A fine of 300 penalty units or imprisonment for 5 years or both.
Summary conviction penalty: A fine of 60 penalty units or imprisonment for 12 months or both.
- (2) In this section —

engage in conduct means —

- (a) do an act; or
- (b) omit to perform an act.

[Section 53X inserted by No. 17 of 2004 s. 36.]

Division 4 — Embryo Research Licensing Committee of the NHMRC

[Heading inserted by No. 17 of 2004 s. 36.]

53Y. Functions of Committee

The functions of the NHMRC Licensing Committee are —

- (a) to perform functions in relation to licences under Division 5;
- (b) to perform functions in relation to databases under Division 6; and
- (c) to perform such other functions as are conferred on it by this Part or any other law.

[Section 53Y inserted by No. 17 of 2004 s. 36.]

53Z. Powers of Committee

The NHMRC Licensing Committee has power to do all things necessary or convenient to be done for or in connection with the performance of its functions.

[Section 53Z inserted by No. 17 of 2004 s. 36.]

Division 5 — Licensing system

[Heading inserted by No. 17 of 2004 s. 36.]

53ZA. Person may apply for licence

- (1) A person may apply to the NHMRC Licensing Committee for a licence authorising use of excess ART embryos.
- (2) An application under subsection (1) —

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- (a) must be made in accordance with the requirements (if any) specified in writing by the NHMRC Licensing Committee; and
- (b) must be accompanied by a fee that is equal to the fee (if any) prescribed by the Commonwealth Human Embryo regulations for the purposes of section 20(2)(b) of the Commonwealth Human Embryo Act.

[Section 53ZA inserted by No. 17 of 2004 s. 36.]

53ZB. Determination of application by Committee

- (1) This section applies if a person has made an application under section 53ZA for a licence.
- (2) The NHMRC Licensing Committee must decide, in accordance with this section, whether or not to issue the licence.
- (3) The NHMRC Licensing Committee must not issue the licence unless it is satisfied of the following —
 - (a) that appropriate protocols are in place —
 - (i) to enable proper consent to be obtained before an excess ART embryo is used under the licence (see section 53ZE(1)(a)); and
 - (ii) to enable compliance with any restrictions on such consent;
 - [(b) expired 5 Apr 2005 (see s. 53ZV)]*
 - (c) that the activity or project proposed in the application has been assessed and approved by a HREC that is constituted in accordance with, and acting in compliance with, the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (1999), as in force from time to time.

- (4) In deciding whether to issue the licence, the NHMRC Licensing Committee must have regard to the following —
- (a) restricting the number of excess ART embryos to that likely to be necessary to achieve the goals of the activity or project proposed in the application;
 - (b) the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos proposed in the application, which could not reasonably be achieved by other means;
 - (c) any relevant guidelines, or relevant parts of guidelines, issued by the NHMRC under the *National Health and Medical Research Council Act 1992* of the Commonwealth and prescribed by the Commonwealth Human Embryo regulations for the purposes of section 21(4)(c) of the Commonwealth Human Embryo Act;
 - (d) the HREC assessment of the application mentioned in subsection (3)(c);
 - (e) such additional matters (if any) as are prescribed by the Commonwealth Human Embryo regulations for the purposes of section 21(4)(e) of the Commonwealth Human Embryo Act.

[Section 53ZB inserted by No. 17 of 2004 s. 36.]

53ZC. Notification of decision

- (1) The NHMRC Licensing Committee must notify its decision on an application for a licence under section 53ZA to the following —
- (a) the applicant;
 - (b) the HREC that assessed and approved the activity or project proposed in the application as mentioned in section 53ZB(3)(c);
 - (c) the CEO.

- (2) If the NHMRC Licensing Committee decides to issue the licence, it must, in addition to issuing the licence to the applicant, give a copy of the licence to the bodies mentioned in subsection (1)(b) and (c).

[Section 53ZC inserted by No. 17 of 2004 s. 36; amended by No. 28 of 2006 s. 269.]

53ZD. Period of licence

- (1) A licence —
- (a) comes into force on the day specified in the licence, or if no day is specified, on the day on which it is issued; and
 - (b) remains in force until the day specified in the licence, unless it is suspended, revoked or surrendered before that day.
- (2) A licence is not in force throughout any period of suspension.

[Section 53ZD inserted by No. 17 of 2004 s. 36.]

53ZE. Licence is subject to conditions

- (1) A licence is subject to the condition that before an excess ART embryo is used as authorised by the licence —
- (a) each responsible person in relation to the excess ART embryo must have given proper consent to that use;
 - (b) the licence holder must have reported in writing to the NHMRC Licensing Committee that such consent has been obtained, and any restrictions to which the consent is subject; and

[(c) expired 5 Apr 2005 (see s. 53ZV)]

- (2) A licence is subject to the condition that the use of an excess ART embryo must be in accordance with any restrictions to which the proper consent under subsection (1) is subject.

[(3) expired 5 Apr 2005 (see s. 53ZV)]

- (4) A licence is subject to such other conditions as are specified in the licence.
- (5) The conditions specified in the licence may include, but are not limited to, conditions relating to the following —
 - (a) the persons authorised by the licence to use excess ART embryos;
 - (b) the number of excess ART embryos in respect of which use is authorised by the licence;
 - (c) reporting;
 - (d) monitoring;
 - (e) information to be given by the licence holder to persons authorised by the licence to use excess ART embryos.
- (6) The licence conditions set out in subsections (1), (2) and (3) apply to all persons who are authorised by the licence to use excess ART embryos.
- (7) Licence conditions specified in the licence apply to —
 - (a) the licence holder; and
 - (b) such other persons authorised by the licence to use excess ART embryos as are specified in the licence.

[Section 53ZE inserted by No. 17 of 2004 s. 36.]

53ZF. Variation of licence

- (1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, vary a licence if the Committee believes on reasonable grounds that it is necessary or desirable to do so.
- (2) The NHMRC Licensing Committee may vary a licence under subsection (1) on its own initiative or on application by the licence holder.

- (3) Without limiting subsection (1), the NHMRC Licensing Committee may vary the licence by specifying additional conditions or varying existing conditions.
- (4) The NHMRC Licensing Committee must not vary a licence in such a way that, had a person applied under section 53ZA for the licence as varied, the Committee would not have been permitted by this Part to issue the licence.

[Section 53ZF inserted by No. 17 of 2004 s. 36.]

53ZG. Suspension or revocation of licence

- (1) The NHMRC Licensing Committee may, by notice in writing given to the licence holder, suspend or revoke a licence if the Committee believes on reasonable grounds that a condition of the licence has been breached.
- (2) If a licence holder is convicted of an offence under this Division, a corresponding law, Part 4A or the *Prohibition of Human Cloning Act 2002* of the Commonwealth, the NHMRC Licensing Committee must, by notice in writing given to the licence holder, revoke each licence held by the licence holder.

[Section 53ZG inserted by No. 17 of 2004 s. 36; amended by No. 18 of 2004 s. 9.]

53ZH. Surrender of licence

A licence holder may surrender a licence by written notice given to the NHMRC Licensing Committee.

[Section 53ZH inserted by No. 17 of 2004 s. 36.]

53ZI. Notification of variation, suspension, revocation or surrender of licence

If the NHMRC Licensing Committee varies, suspends or revokes a licence, or a licence is surrendered, the Committee must notify —

- (a) the licence holder;

- (b) the HREC to which the NHMRC Licensing Committee notified its decision on the application for the licence under section 53ZC; and
- (c) the CEO.

[Section 53ZI inserted by No. 17 of 2004 s. 36; amended by No. 28 of 2006 s. 269.]

Division 6 — Reporting and confidentiality

[Heading inserted by No. 17 of 2004 s. 36.]

53ZJ. NHMRC Licensing Committee to make certain information publicly available

- (1) The NHMRC Licensing Committee must maintain a database containing the following information in relation to each licence (including a licence as varied) —
 - (a) the name of the person to whom the licence was issued;
 - (b) a short statement about the nature of the uses of excess ART embryos that are authorised by the licence;
 - (c) any conditions to which the licence is subject;
 - (d) the number of excess ART embryos in respect of which use is authorised by the licence;
 - (e) the date on which the licence was issued;
 - (f) the period throughout which the licence is to remain in force.
- (2) The database is to be made publicly available.
- (3) The database may be kept and made publicly available in electronic form.
- (4) Information mentioned in subsection (1) must not be such as to disclose confidential commercial information.

[Section 53ZJ inserted by No. 17 of 2004 s. 36.]

53ZK. Confidential commercial information may only be disclosed in certain circumstances

- (1) A person commits an offence if —
- (a) the person discloses confidential commercial information that the person has only because of performing duties or functions under this Part or under a corresponding law;
 - (b) the person knows that the information is confidential commercial information; and
 - (c) the disclosure is not —
 - (i) to the Commonwealth, a Commonwealth authority or a State agency in the course of carrying out duties or functions under this Part or under a corresponding law;
 - (ii) by order of a court; or
 - (iii) with the consent of each person to whom the information has a commercial or other value.

Penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

- (2) A person commits an offence if —
- (a) the person discloses confidential commercial information that the person has only because of a disclosure permitted under subsection (1) or this subsection;
 - (b) the person knows that the information is confidential commercial information; and
 - (c) the disclosure is not —
 - (i) to the Commonwealth, a Commonwealth authority or a State agency in the course of carrying out duties or functions under this Part or under a corresponding law;
 - (ii) by order of a court; or

- (iii) with the consent of each person to whom the information has a commercial or other value.

Penalty: A fine of 120 penalty units or imprisonment for 2 years or both.

- (3) In this section —

Commonwealth authority means —

- (a) a body corporate established for a public purpose by or under an Act of the Commonwealth; or
- (b) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together —
 - (i) the Commonwealth;
 - (ii) a body covered by paragraph (a);
 - (iii) a body covered by subparagraph (i) or (ii);

court includes a tribunal, authority or person having power to require the production of documents or the answering of questions;

State agency means —

- (a) the Crown in right of a State;
- (b) a Minister of a State;
- (c) a department of the Government of a State;
- (d) an instrumentality of a State, including a body corporate established for a public purpose by or under a law of a State; or
- (e) a company in which a controlling interest is held by any one of the following persons, or by 2 or more of the following persons together —
 - (i) the Crown in right of a State;
 - (ii) a person or body covered by paragraph (b) or (d);

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- (iii) a person or body covered by subparagraph (i) or (ii).

[Section 53ZK inserted by No. 17 of 2004 s. 36.]

53ZKA. Annual reports

- (1) The NHMRC Licensing Committee must furnish to the Minister a copy of any report prepared under section 19(3) of the *Research Involving Human Embryos Act 2002* of the Commonwealth (insofar as the report is relevant to the operation of this Act).
- (2) The Minister must, within 12 sitting days after receipt of a report under subsection (1), cause copies of the report to be laid before each House of Parliament.

[Section 53ZKA inserted by No. 17 of 2004 s. 36.]

Division 7 — Review provisions

[Heading inserted by No. 17 of 2004 s. 36.]

53ZL. Terms used

In this Division —

decision has the same meaning as in the *Administrative Appeals Tribunal Act 1975* of the Commonwealth;

eligible person, in relation to a decision of the NHMRC Licensing Committee, means —

- (a) in relation to a decision under section 53ZB not to issue a licence — the applicant for the licence;
- (b) in relation to a decision in respect of the period throughout which the licence is to be in force under section 53ZD — the licence holder;
- (c) in relation to a decision to specify a licence condition under section 53ZE(4) — the licence holder;
- (d) in relation to a decision to vary or refuse to vary a licence under section 53ZF — the licence holder; or

- (e) in relation to a decision to suspend or revoke a licence under section 53ZG — the person who was the licence holder immediately before the suspension or revocation.

[Section 53ZL inserted by No. 17 of 2004 s. 36.]

53ZM. Review of decisions

- (1) An eligible person may apply to the Administrative Appeals Tribunal for review of the following decisions of the NHMRC Licensing Committee —
 - (a) a decision under section 53ZB not to issue a licence;
 - (b) a decision in respect of the period throughout which the licence is to be in force under section 53ZD;
 - (c) a decision to specify a licence condition under section 53ZE(4);
 - (d) a decision to vary or refuse to vary a licence under section 53ZF;
 - (e) a decision to suspend or revoke a licence under section 53ZG.
- (2) This section has effect subject to the *Administrative Appeals Tribunal Act 1975* of the Commonwealth and section 43 of the Commonwealth Human Embryo Act.

[Section 53ZM inserted by No. 17 of 2004 s. 36.]

Division 8 — Monitoring powers

[Heading inserted by No. 17 of 2004 s. 36.]

53ZN. Appointment of inspectors

- (1) The Chairperson of the NHMRC Licensing Committee may, by instrument in writing, appoint any of the following persons as inspectors —
 - (a) an officer of the Commonwealth;
 - (b) a person who is appointed or employed by the State.

- (2) In exercising powers or performing functions as an inspector, an inspector must comply with any directions of the Chairperson of the NHMRC Licensing Committee.
- (3) The Chairperson of the NHMRC Licensing Committee must not appoint a person as an inspector under subsection (1) unless he or she is satisfied that the person has appropriate skills and experience.

[Section 53ZN inserted by No. 17 of 2004 s. 36.]

53ZO. Identity card

- (1) The Chairperson of the NHMRC Licensing Committee must issue an identity card to an inspector.
- (2) The identity card —
 - (a) must be in the form prescribed by the Commonwealth Human Embryo regulations for the purposes of section 34(2)(a) of the Commonwealth Human Embryo Act; and
 - (b) must contain a recent photograph of the inspector.
- (3) If a person to whom an identity card has been issued ceases to be an inspector, the person must return the identity card to the Chairperson of the NHMRC Licensing Committee as soon as practicable.

Penalty: One penalty unit.

- (4) An inspector must carry his or her identity card at all times when exercising powers or performing functions as an inspector.

[Section 53ZO inserted by No. 17 of 2004 s. 36.]

53ZP. Powers available to inspectors for monitoring compliance

- (1) For the purpose of finding out whether this Part or Part 4A has been complied with, an inspector may —
 - (a) enter any premises; and

- (b) exercise the monitoring powers set out in section 53ZQ.
- (2) An inspector is not authorised to enter premises under subsection (1) unless —
- (a) the occupier of the premises has consented to the entry;
or
 - (b) the premises are premises at which the occupier of the premises is carrying out activities authorised by a licence issued under section 53ZB, and the entry is at a reasonable time.

[Section 53ZP inserted by No. 17 of 2004 s. 36; amended by No. 18 of 2004 s. 10.]

53ZQ. Monitoring powers

- (1) The monitoring powers that an inspector may exercise under section 53ZP(1)(b) are as follows —
- (a) to search the premises and any thing on the premises;
 - (b) to inspect, examine, take measurements of, conduct tests on, or take samples of, any human embryo or thing on the premises that relates to this Part or Part 4A;
 - (c) to take photographs, make video or audio recordings or make sketches of the premises or any thing on the premises;
 - (d) to inspect any book, record or document on the premises;
 - (e) to take extracts from or make copies of any such book, record or document;
 - (f) to take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises.
- (2) For the purposes of this Division, monitoring powers include the power to operate equipment at premises to see whether —
- (a) the equipment; or

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- (b) a disk, tape or other storage device that —
 - (i) is at the premises; and
 - (ii) can be used with the equipment or is associated with it,

contains information that is relevant to determining whether there has been compliance with this Part or Part 4A.

- (3) If the inspector, after operating equipment at the premises, finds that the equipment, or that a tape, disk or other storage device at the premises, contains information mentioned in subsection (2), the inspector may —
 - (a) operate equipment or facilities at the premises to put the information in documentary form and copy the document so produced; or
 - (b) if the information can be transferred to a tape, disk or other storage device that —
 - (i) is brought to the premises; or
 - (ii) is at the premises and the use of which has been agreed to in writing by the occupier of the premises,operate the equipment or other facilities to copy the information to the storage device, and remove the storage device from the premises.
- (4) In addition, the CEO may confer on an inspector the powers set out in section 54.

[Section 53ZQ inserted by No. 17 of 2004 s. 36; amended by No. 18 of 2004 s. 10; No. 28 of 2006 s. 270(1).]

53ZR. Power to secure

If an inspector, during a search of premises, believes on reasonable grounds that there is at the premises a human embryo or a thing that may afford evidence of the commission of an offence against this Part or Part 4A, the monitoring powers include securing the embryo or thing pending the

obtaining of a warrant (whether by the inspector or by another person) to seize it.

[Section 53ZR inserted by No. 17 of 2004 s. 36; amended by No. 18 of 2004 s. 10.]

53ZS. Inspector must produce identity card on request

An inspector is not entitled to exercise any powers under this Division in relation to premises if —

- (a) the occupier of the premises has required the inspector to produce his or her identity card for inspection by the occupier; and
- (b) the inspector fails to comply with the requirement.

[Section 53ZS inserted by No. 17 of 2004 s. 36.]

53ZT. Consent

- (1) Before obtaining the consent of a person for the purposes of section 53ZP(2)(a), the inspector must inform the person that he or she may refuse consent.
- (2) An entry of an inspector by virtue of the consent of a person is not lawful unless the person voluntarily consented to the entry.

[Section 53ZT inserted by No. 17 of 2004 s. 36.]

53ZU. Compensation for damage

- (1) The owner of equipment or other facilities is entitled to compensation for damage to the equipment or other facilities if —
 - (a) the damage was caused to the equipment or other facilities as a result of it being operated by an inspector as mentioned in this Division; and
 - (b) the damage was caused as a result of insufficient care being exercised by the inspector operating the equipment or other facilities.

- (2) An application for compensation is to be made to the NHMRC Licensing Committee.
- (3) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and his or her employees and agents, if they were available at the time, had provided any warning or guidance as to the operation of the equipment or other facilities that was appropriate in the circumstances.

[Section 53ZU inserted by No. 17 of 2004 s. 36.]

Division 9 — Expiry

[Heading inserted by No. 17 of 2004 s. 36.]

53ZV. Expiry of certain provisions

- (1) Sections 53ZB(3)(b) and 53ZE(1)(c) and (3) expire on 5 April 2005.
- (2) Subsection (1) may be repealed by resolution passed by both Houses of Parliament.

[Section 53ZV inserted by No. 17 of 2004 s. 36.]

Division 10 — Conscientious objection to use of excess ART embryos

[Heading inserted by No. 17 of 2004 s. 36.]

53ZVA. Conscientious objection to use of excess ART embryos

Despite any requirement under a contract or a written law, a person is not required to use, or assist another person in using, an excess ART embryo under this Part if the person has a conscientious objection to doing so.

[Section 53ZVA inserted by No. 17 of 2004 s. 36.]

Division 11 — Review of Part

[Heading inserted by No. 17 of 2004 s. 36.]

53ZW. Review of Part

- (1) The Minister must cause a review of the operation of this Part to be undertaken as soon as possible after 19 December 2004.
- (2) The review must take into account —
 - (a) developments in technology in relation to assisted reproductive technology;
 - (b) developments in medical research and scientific research and the potential therapeutic applications of such research;
 - (c) community standards; and
 - (d) the applicability of establishing a National Stem Cell Bank.
- (3) The review of this Part may be undertaken as part of the review of the Commonwealth Human Embryo Act mentioned in section 47 of that Act.
- (4) The Minister is to prepare a report based on the review made under subsection (1) and cause the report to be laid before each House of Parliament not later than 12 months from the date on which the review is first commenced.
- (5) The Minister must cause a copy of the report based on the review conducted under section 47 of the Commonwealth Human Embryo Act to be laid before each House of Parliament not later than 6 sitting days from the date of receipt of the report.

[Section 53ZW inserted by No. 17 of 2004 s. 36.]

Part 5 — Enforcement

Division 1 — Powers of authorised officers

54. Powers of authorised officers

- (1) An authorised officer, at any time, may —
- (a) enter and inspect any premises on which that person has reasonable cause to believe —
 - (i) any human egg undergoing fertilisation or human embryo is kept;
 - (ii) any human gametes intended for use in an artificial fertilisation procedure, not being sperm derived from only one man, are kept;
 - (iii) any artificial fertilisation procedure is being, has been or is likely to be carried out;
 - (iv) any research is being, has been or is likely to be conducted, upon or with human gametes or participants or any human egg undergoing fertilisation or human embryo; or
 - (v) an offence under this Act has been, is being or is likely to be, committed,and inspect any equipment, examine any records, and take possession or an account of any human gametes, human egg undergoing fertilisation or human embryo, there;
 - (b) require any licensee, or any person who is apparently in a position to do so, to —
 - (i) provide any record or other information, or any assistance, reasonably required by the authorised officer relating to any matter with respect to activities to which this Act may apply carried on at any such premises; and

- (ii) answer any question put to that person by the authorised officer on such a matter;
 - and
 - (c) require any person having possession of records relevant to a reproductive technology practice conducted under a licence or pursuant to an exemption, or to transactions involving the possession or use of human gametes, a human egg undergoing fertilisation or a human embryo, to produce those records for inspection.
- (2) An authorised officer may —
- (a) examine any record found or produced under this section;
 - (b) in the case of any record kept otherwise than in a readily intelligible format, require a person having the power to do so to produce the record in a legible form;
 - (c) make copies of, or take extracts from, any such record; and
 - (d) take possession of and retain any such record for such reasonable period as may be necessary for the purposes of this Act,
- but shall endeavour to ensure that, so far as is practicable, the confidentiality of the record or any other record to which this Act applies is not thereby prejudiced.
- (3) An authorised officer entering and inspecting premises to which subsection (1) relates may —
- (a) take possession of anything which that officer has reasonable grounds to believe may be required —
 - (i) for the purpose of the functions of the CEO relating to the grant, variation and suspension of licences; or

- (ii) for the purpose of being used in evidence in any disciplinary proceedings or proceedings for an offence under this Act,
and retain it for so long as it may be required for that purpose; and
 - (b) for that purpose, take such steps as appear to be necessary for preserving any such thing or preventing interference with it, including requiring any person having the power to do so to give such assistance as may reasonably be required.
- (4) A person is not excused from complying with a requirement under this section to answer any question or producing any thing on the ground that the answer to a question put to the person or the production of that thing might incriminate the person or render the person liable to a penalty, but an answer given by a person pursuant to a requirement under this section is not admissible in evidence against the person in any civil proceedings or in any proceedings for an offence other than —
 - (a) under this Act;
 - (b) perjury; or
 - (c) an offence arising out of the false or misleading nature of that answer.
- (5) A person who discloses to an authorised person under this section information that would otherwise be confidential shall not be taken to have committed thereby any breach of a principle of professional ethics.
- (6) Notwithstanding anything in this section to the contrary, the powers conferred hereunder shall only be exercised at reasonable times and at reasonable intervals unless the authorised officer has good grounds or a reasonable belief for doing otherwise and has prior to exercising the powers other than at reasonable times and intervals recorded his grounds or beliefs in writing and signed that record and had his signature witnessed in writing, noting the date and time of signature. The

authorised officer shall place his record of grounds upon a register kept by the CEO for that purpose as soon as practicable.

- (7) A person who —
- (a) hinders an authorised officer in the exercise of powers conferred by this section;
 - (b) fails, without reasonable excuse, to comply with a requirement of an authorised officer under this section;
 - (c) fails, without reasonable excuse, to answer, to the best of the knowledge, information and belief of that person, a question put to that person by an authorised officer; or
 - (d) impersonates an authorised officer,

commits an offence.

Penalty: \$5 000.

[Section 54 amended by No. 17 of 2004 s. 37; No. 55 of 2004 s. 538 and 540; No. 28 of 2006 s. 270(1).]

55. Entry, search and seizure, by warrant

- (1) Where a justice is satisfied, upon an application supported by evidence on oath, that there is reason to suspect that an offence is, or is likely to be, committed under this Act at any premises, the justice may, by warrant in the prescribed form stating the proposed purpose, empower any authorised officer or member of the Police Force to enter, with such other persons as may be necessary to assist, upon those premises using such force as may be necessary and any such warrant continues to have effect until the purpose for which it was granted is satisfied.
- (2) A warrant under subsection (1) authorises the holder and such other persons as are necessary to assist —
- (a) to arrest any person suspected of being concerned in an offence under this Act and found on the premises to which the warrant relates;

- (b) to seize all records or other things which there are reasonable grounds for believing may be required as evidence for the purposes of disciplinary proceedings or as an offence under this Act; and
- (c) to search —
 - (i) the premises; and
 - (ii) all persons found at or in the immediate vicinity of the premises and suspected of being concerned in an offence under this Act.

[Section 55 amended by No. 84 of 2004 s. 80.]

Division 2 — Proceedings

56. Complaints for a simple offence

- (1) All proceedings for a simple offence under this Act shall be —
 - (a) instituted in the name of the CEO; and
 - (b) dealt with by a court constituted by a magistrate.
- (2) A prosecution for an offence under this Act may be commenced until 5 years have elapsed since the date on which the offence was allegedly committed, but not thereafter.

[Section 56 amended by No. 17 of 2004 s. 38; No. 84 of 2004 s. 80; No. 28 of 2006 s. 270(1).]

57. Averments, and other evidentiary matters

- (1) In disciplinary proceedings under this Act or proceedings for an offence under this Act, an allegation in the prosecution notice —
 - (a) that a substance referred to in the prosecution notice was or contained human gametes, a human egg undergoing fertilisation or a human embryo as may be there specified;

- (b) that a person named in the prosecution notice is (or is not), or was (or was not) on a specified date —
 - (i) licensed;
 - (ii) licensed in respect of any specified procedure or practice;
 - (iii) approved as the licence supervisor in relation to a specified practice;
 - (iv) an employee or agent of a specified licensee; or
 - (v) the holder of a specified exemption;
- (c) that any premises named in the prosecution notice are (or are not), or were (or were not) on a specified date, premises to which a specified licence or specified exemption relates;
- (d) that a licence or exemption referred to in the prosecution notice is, or was on a specified date, subject to specified conditions or not so subject, or was of a specified class, or suspended;
- (e) that a person named in the prosecution notice is, or was on a specified date, an authorised officer or otherwise authorised by the CEO;
- (f) that a person named in the prosecution notice has, or had on a specified date, a specified function by virtue of a delegation under this Act; or
- (g) that a delegation under this Act is, or was on a specified date, subject to specified conditions,

shall be accepted as proved in the absence of proof to the contrary.

- (2) In subsection (1) —

prosecution notice shall be construed as including a reference to an allegation upon which any disciplinary action under this Act is founded; and

specified means specified in the prosecution notice.

- (3) In proceedings under this Act against a person named in a licence or certificate of exemption as the holder of that licence or exemption, the person shall be taken to be the holder of that licence or exemption in the absence of proof to the contrary.
- (4) In any legal proceedings, a document apparently certified by the CEO to be a licence, notice or other document issued under this Act, or to be a copy of a licence, notice or other document issued under this Act, or to be a document or a copy of a document furnished to the CEO, shall be —
 - (a) accepted as such in the absence of proof to the contrary; and
 - (b) for all purposes, without producing the original, sufficient evidence as to what matter was contained in the document.
- (5) In all proceedings in which the giving of any notice to a party to the proceedings by the CEO, or of any other document required or authorised under this Act, has to be proved, the party is deemed to have received notice to produce that document, and, until the contrary is shown, the giving of the notice or the due service of the document may be sufficiently proved by the production of what purports to be a copy, bearing what purports to be a certificate signed by the person giving that notice or authorised to issue the original document, or the CEO, as the case may be, that the copy is a true copy of the original and that the original notice was given or document served on the date specified in the certificate.
- (6) The validity of any notice or other document or of its service is not affected by any error, misdescription, or irregularity which is not calculated to mislead, or which in fact does not mislead.
- (7) In all courts and before all persons authorised to receive evidence —
 - (a) a signature purporting to be that of the Minister, or of the CEO or any other authorised officer, shall be taken

to be the signature of the person whose signature it purports to be in the absence of proof to the contrary;

- (b) a certificate purporting to be signed by the CEO —
 - (i) that a notice or other document of the description mentioned in the certificate has or has not been given to or served on a person under this Act; or
 - (ii) as to the date of and the contents of any notice so given or any document so served,

is evidence of those matters as specified in the certificate.

- (8) Where proceedings are taken in the name of the CEO by an authorised officer no proof shall be required of the appointment of that officer or of the authority of that officer to take those proceedings, and the averment in the prosecution notice that the officer is so authorised shall be deemed to be proof of the fact, in the absence of proof to the contrary.
- (9) A certificate, purporting to be signed by the CEO, certifying that on a day specified in the certificate a person named in the certificate was a delegate of the CEO under section 13(4) to whom such functions of the CEO as are specified in the certificate had been delegated on terms, if any, so specified shall be admissible in evidence in any proceedings and, in the absence of proof to the contrary, shall be proof of the matters stated in the certificate.
- (10) In any proceedings against a person for failing or neglecting duly to furnish the CEO with any information required by the licensing authority a certificate, purporting to be signed by the CEO, certifying —
 - (a) that the accused was so required to furnish the licensing authority with the information of the nature specified in the certificate; and

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Part 5 Enforcement

Division 2 Proceedings

s. 57

- (b) that the licensing authority has not been furnished with the information so required,

shall be admissible in evidence in those proceedings and, in the absence of proof to the contrary, shall be proof of the matters so stated therein.

[Section 57 amended by No. 17 of 2004 s. 39; No. 55 of 2004 s. 539 and 540; No. 84 of 2004 s. 80 and 82; No. 28 of 2006 s. 270.]

Part 6 — Administration

Division 1 — Staff

58. Use of staff and facilities of departments, agencies and instrumentalities, and engagement of consultants, etc.

- (1) The Council may, by arrangement made between it and the Minister concerned, and on such terms and conditions as may be mutually arranged by it with that Minister and with the relevant employing authority within the meaning of the *Public Sector Management Act 1994*, make use, either full-time or part-time, of —
 - (a) the services of any officer or employee employed in the Public Service of the State or in a State agency or instrumentality or otherwise in the service of the Crown in right of the State; or
 - (b) any facilities of a department of the Public Service of the State or of a State agency or instrumentality.
- (2) The Council may, with the prior approval of the Minister, engage under contracts for services such consultants and professional or technical or other assistance as it considers necessary to enable the Council to exercise and perform its functions.
- (3) Subsections (1) and (2) shall not be taken to prejudice the operation of the *Health Legislation Administration Act 1984* in so far as that Act may apply to this Act.
- (4) Where the services of a person are for the time being utilized by the Council under this Act, it does not prejudice the existing or accruing rights of that person under the *Public Sector Management Act 1994* or any other written law, and service rendered on behalf of the Council pursuant to this Act shall be regarded as not constituting a break in the service in which the person would otherwise have been employed.

[Section 58 amended by No. 32 of 1994 s. 19.]

59. Staff

(1) Subject to this section —

(a) officers required to —

(i) ensure that licensees, and their procedures and practices, conform to the requirements of this Act; and

(ii) examine records relating to reproductive technology;

and

(b) such other officers as may be required,

shall be appointed under, and shall hold office subject to and in accordance with, Part 3 of the *Public Sector Management Act 1994*, to assist the CEO in the administration of this Act.

(2) The CEO shall issue to —

(a) a person appointed pursuant to subsection (1)(a);

(b) a Public Health Official required to exercise power as an authorised officer;

(c) a person to whom a function is delegated pursuant to section 13(4); or

(d) a person on whom a power is conferred under section 53ZQ(4),

a certificate of identity in the prescribed form, and that certificate shall specify the particular functions or circumstances in relation to which, and the purposes for which, the person may exercise powers conferred by this Act or may be expressed to operate as a general authorisation for the purposes of this Act.

(3) A person shall not be eligible for appointment under this section unless, in relation to the functions which they are to carry out, that person has such qualifications or training as may be required by this Act in relation to an appointment of that kind.

(4) A person shall not be appointed or permitted to assist the CEO in the administration of this Act in so far as that may involve

access to information identifying participants in any artificial fertilisation procedure unless that person is specifically authorised by the CEO to carry out that function.

[Section 59 amended by No. 32 of 1994 s. 19; No. 17 of 2004 s. 40; No. 28 of 2006 s. 270.]

Division 2 — Subsidiary legislation

60. Regulations, and subsidiary legislation generally

- (1) The Governor, on the recommendation of the Minister, may make regulations prescribing all matters that are required or permitted by this Act to be dealt with by the Code or to be prescribed, or are necessary or convenient to be prescribed, for giving effect to the purposes of this Act.
- (2) Regulations made under this section may prescribe offences, and a penalty for any contravention of those regulations which shall —
 - (a) in the case of a contravention relating to any offence that is also prohibited by the Code of Practice, not exceed \$5 000; and
 - (b) in any other case, not exceed \$2 500.
- (3) For the purpose of any Rule the Council by a resolution may, and in and for the purposes of any direction the CEO may, approve or adopt, with or without modification but subject to subsection (4), a text or any requirement imposed, issued or approved elsewhere.
- (4) Where subsidiary legislation under this Act includes or refers to any text or requirement (including any criteria, standard, specification, formula or other means of conveying detailed information) which is approved or adopted, with or without modification, under subsection (3) that legislation has effect —
 - (a) as if the text or the requirement identified by reference to the person or body from which it originated (being the text or requirement at the date of its approval or adoption or as may otherwise be specified, unless it is

specified that the text or requirement applicable shall be that as from time to time amended) were set out in full; and

- (b) where the text or requirement is to apply as from time to time amended, as if any modification determined by the Council or the CEO at the time the text or requirement was approved or adopted (unless the modification itself is later amended under this Act) prevailed over any subsequent amendment to that text or requirement made by the originating person or body that is inconsistent with the modification.

[Section 60 amended by No. 28 of 2006 s. 270(2).]

Division 3 — General

61. Review of Act

- (1) The Minister shall carry out a review of the operation and effectiveness of this Act as soon as is practicable after the expiry of 5 years from its commencement and in the course of that review the Minister shall consider and have regard to —
 - (a) the effectiveness of the operations of the Council and the committees of the Council;
 - (b) the need for the continuation of the functions conferred, on the Council and on the CEO respectively by this Act; and
 - (c) such matters, other than those referred to in paragraphs (a) and (b), as appear to the Minister to be relevant to the operation and effectiveness of this Act.
- (2) The Minister shall prepare a report based on the review made under subsection (1) and shall, as soon as is practicable after that preparation, cause that report to be laid before each House of Parliament.

[Section 61 amended by No. 28 of 2006 s. 270(1).]

[62, 63. Omitted under the Reprints Act 1984 s. 7(4)(e).]

**Schedule — Provisions relating to the membership and
proceedings of the Council and the annual report on
reproductive technology**

[s. 5 and 8]

[Heading amended by No. 19 of 2010 s. 4.]

1. The Chair of the Council

- (1) The Governor shall, on the recommendation of the Minister, appoint a member as Chairperson to preside over the proceedings of the Council.
- (2) A person may be appointed under subclause (1) on terms that require the fulltime employment of that person in the performance of the duties of the office.
- (3) The Council shall from time to time appoint (for a term fixed by the Council) one of its members to preside as Deputy Chairperson in the absence or incapacity of the Chairperson, but if neither the Chairperson or the Deputy Chairperson is present the members of the Council who are present at a meeting, whether or not a person who is the deputy of the Chairperson or of the Deputy Chairperson is present, shall select a Deputy Chairperson to preside over those proceedings and the person so selected has, whilst so acting, the functions and entitlements of the Chairperson.
- (4) Where a member who is appointed or selected as a Deputy Chairperson is performing the functions of the Chairperson, the deputy of that member may act in the place of the member.

2. Deputies etc.

- (1) On the nomination of the body or person by which or whom the member is nominated, the Minister may appoint a deputy to any member, other than the Executive Officer, who shall, subject to clause 1(3), act in the place of the member on the Council when the person who is the member can not so act.
- (2) The Minister may appoint a deputy to the Executive Officer to act in the place of the Executive Officer when that person is unable to carry out any function required by this Act.

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cl. 3

- (3) While a person is acting in the place of a member on the Council or a committee, under clause 1(4) or this clause, that person is deemed to be a member, and has all the functions and entitlements of that member.
- (4) The Minister may make such arrangements as the Minister considers appropriate for the receipt of nominations for the purposes of an appointment under subclause (1), and any such appointment may be made —
 - (a) for a period; or
 - (b) in relation to particular circumstances,specified in the instrument of appointment.
- (5) Where —
 - (a) a member and the deputy of that member can not, or do not, act in that capacity; or
 - (b) a member can not or does not so act and no deputy has been nominated,the Minister may appoint a person who in the opinion of the Minister is representative of the same interests as that member to act in place of that member, and while so acting the appointee shall be deemed to be the deputy of the member.
- (6) The appointment of a person under this clause to act in the place of a member may be terminated at any time by the Minister.
- (7) No act or omission of a person acting under this clause in place of a member shall be questioned on the ground that the occasion for so acting had not arisen or had ceased.

3. Term of office

- (1) Except as otherwise provided by this Act —
 - (a) a nominated member holds office for such term, not exceeding 3 years, as is specified in the instrument of appointment; and
 - (b) may be reappointed.
- (2) On the occasion of the first appointments to the Council, the term of office of one-half of the nominated members shall not exceed 18 months.

- (3) The Executive Officer shall hold office as a member —
- (a) subject to subclause (4), for such term as may be specified in the instrument of appointment —
 - (i) by reference to the office or employment which that person holds at the time of appointment; or
 - (ii) otherwise;
 - or
 - (b) if no term is so specified, until such time as is determined by the Minister.
- (4) Where a person appointed as the Executive Officer ceases to comply with the requirements of section 8(3)(a), that person thereby ceases to hold that office.
- (5) Where the office of a nominated member becomes vacant otherwise than under clause 5, a nominated member continues in office until a successor comes into office, notwithstanding that the term for which that member was appointed has expired.
- (6) Where an office of nominated member becomes vacant otherwise than by effluxion of time a person appointed to the vacancy shall hold office only for the balance of the term of the person whose vacancy is filled.
- (7) When the office of a member becomes vacant, the Minister shall ensure that a person is appointed to that vacant office in accordance with this Act.

4. Remuneration and leave of members

- (1) A member, and any person appointed to a committee or requested to attend a meeting of the Council or a committee, is entitled to be paid from the funds of the Council —
- (a) unless the person is an officer of the Public Service, such remuneration; and
 - (b) such allowances,
- as may be determined by the Minister after consultation with the Minister for Public Sector Management.

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cl. 5

- (2) The Council may grant leave of absence to a member on such terms and conditions as, subject to any direction given by the Minister, the Council determines.

5. Premature vacation of office

- (1) The office of a nominated member becomes vacant if —
- (a) the member —
 - (i) resigns that office by written notice addressed to the Minister; or
 - (ii) dies; or
 - (b) the member is, according to the *Interpretation Act 1984* section 13D, a bankrupt or a person whose affairs are under insolvency laws; or
 - (c) the member is absent without leave of the Council from 3 consecutive meetings of the Council of which the member was given notice; or
 - (d) the member is removed from office by the Governor on the recommendation of the Minister —
 - (i) for neglect of duty, misbehaviour, or incompetence;
 - (ii) by reason of impairment, within the meaning of Part IVA of the *Equal Opportunity Act 1984*, affecting the performance of the duties of the member;
 - (iii) by reason of the member having acquired, since the date of appointment, a personal or pecuniary interest incompatible with the required perception of the status of a member; or
 - (iv) on the grounds that the member has not retained the confidence of the body or person by which or whom the member was nominated.
- (2) In subclause (1)(d)(i), ***misbehaviour*** shall be construed as including having a direct personal or pecuniary interest (other than an interest to which clause 6(6) applies) in a matter to which this Act relates and which is not disclosed to the Council or a relevant committee.

[Clause 5 amended by No. 18 of 2009 s. 44(3).]

6. Personal or pecuniary interests

- (1) If a matter arising before the Council or a committee (other than a question of general principle) affects the personal or pecuniary interests of a person directly, that person is ineligible to vote on that matter unless —
- (a) subclause (6) applies;
 - (b) a direction given by the Minister under subclause (3) applies; or
 - (c) the Council or that committee, as the case may be, otherwise determines under subclause (3),

and, if ineligible, shall abstain from voting.

- (2) A member, and any person appointed to a committee or requested to attend a meeting of the Council or a committee, who has a direct personal or pecuniary interest, not being an interest to which subclause (6) applies, in a matter being considered or about to be considered by the Council or a committee shall before, or as soon as practicable after, the matter arises for consideration —
- (a) disclose fully, as soon as possible after the relevant facts have come to the knowledge of that person, the nature of the interest at a meeting of the Council or that committee, as the case requires; and
 - (b) subsequently, where the person is present at any meeting of the Council or a committee where the relevant matter is to be considered, declare shortly the nature of the interest and where and when it was disclosed fully under this subclause.
- (3) A disclosure under subclause (2) shall be recorded in the minutes of the meeting of the Council or the committee concerned, as the case requires, and the person having the interest shall not, unless the Minister otherwise directs or the Council or that committee, as the case may be, otherwise determines —
- (a) be present during any deliberation; or
 - (b) take part in any decision,

of the Council or that committee with respect to the matter to which the disclosure relates.

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cl. 6

- (4) For the purpose of the making of a determination by the Council or the committee concerned, as the case requires, under subclause (3) in relation to a person who has made a disclosure under subclause (2), the person who has the interest in the matter to which the disclosure relates shall not —
- (a) be present during any deliberation of the Council or that committee for the purpose of making that determination; or
 - (b) take part in the making of that determination by the Council or that committee.
- (5) A person who contravenes subclause (1), (2), (3) or (4) commits an offence.
Penalty: \$5 000.
- (6) The Minister may, on being satisfied on the application of any person that the nature and extent of any interest of that person has been fully disclosed to the Minister, direct in writing that the interest is an interest to which this clause, other than this subclause and subclauses (7) and (8), shall not apply.
- (7) Where the Minister gives a direction under subclause (6), the person having that interest shall lodge a copy of the direction with the Executive Officer, who shall report the direction, but not the nature or extent of any interest disclosed, to the next meeting of the Council.
- (8) Any question as to whether or not an interest is of the nature and extent disclosed under subclause (6) may be determined by the Minister.
- (9) The requirements of this clause do not apply in a case where the interest of the person consists only of being —
- (a) a member or creditor of a corporation that is interested in a contract or proposed contract related to the matter arising; or
 - (b) a member of a body by which that person was nominated for the purposes of this Act,
- if the interest of that person may properly be regarded as not being both a material personal and also a pecuniary interest of the person.
- (10) For the purposes of this clause, a general notice given to the Council or the committee by a person to the effect that the person is an officer of or associated with a specified corporation, firm or body and is to be regarded as having a pecuniary interest in any contract that may, after

the date of the notice, be made with that corporation, firm or body shall be deemed to be a sufficient disclosure of that interest if —

- (a) the notice states the nature and extent of the interest of the person in the corporation or firm or body; and
- (b) the extent of the interest of that person in the corporation, firm or body is not greater than is stated in the notice.

[Clause 6 amended by No. 78 of 1995 s. 147.]

7. Meetings and proceedings

- (1) The first meeting of the Council shall be convened by the Minister and thereafter meetings shall be held at the times and places determined by the Council but the Chairperson or any 4 members may, on reasonable notice being given as far as is practicable to all members, call a meeting at any time.
- (2) At a meeting of the Council, 6 members eligible to vote constitute a quorum.
- (3) Subject to subsection (2), the Council may act notwithstanding vacancies in its membership.
- (4) The Chairperson, or in the absence of the Chairperson a person appointed or selected as Deputy Chairperson under clause 1(3), shall preside at a meeting of the Council and shall have a deliberative vote, but in the case of an equality of votes shall not, unless subclause (6) applies, have a casting vote.
- (5) Subject to subclause (6), questions arising at a meeting of the Council shall be decided, in open voting, by a majority of the votes of the members present and eligible to vote.
- (6) If the votes cast on a question are equally divided the question shall remain unresolved until a subsequent meeting of the Council, but if the votes cast on the question at that subsequent meeting are again equally divided the question shall be decided on the casting vote of the person presiding.
- (7) For the purposes of determining the existence of a majority or quorum in accordance with section 54 of the *Interpretation Act 1984* a member, or person appointed to a committee, who is precluded under clause 6 from taking part in any deliberation or decision at a meeting

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cl. 8

with respect to a matter shall be deemed to be absent from the meeting while that matter is being deliberated or decided.

- (8) The Council may request a person whom the Council considers may assist it with professional or technical advice on any matter to attend a meeting of the Council or a committee and contribute to the discussion of that matter, but any such person shall not take part in any decision with respect to that matter, or be counted for the purpose of determining the existence of a quorum.
- (9) The Council shall cause accurate minutes to be kept of the proceedings at its meetings, and make them available for inspection by, or by a person on behalf of, the Minister.
- (10) Subject to this Act, the proceedings of the Council shall be conducted as it thinks fit but, if regulations made or directions given by the Minister relate to any such matter, in accordance with those regulations or directions.

8. Unanimous resolution may be passed without meeting

- (1) A resolution of the Council, in writing and signed or assented to by each member by letter, telegram, telex, electronic mail or facsimile transmission, shall be as valid and effectual as if it had been passed at a meeting of the Council.
- (2) The Executive Officer shall report the passing of a resolution under subsection (1) to the next meeting of the Council.

9. Committees

- (1) A committee shall, as soon as is practicable after receiving notification of any matter referred to it by the Council, consider the matter and give to the Council a written report as to the advice or findings of the committee in relation to the matter within such period as the Council directs.
- (2) Subject to this Act, each committee may determine its own procedures.

10. Protection of members etc.

- (1) A person who —

- (a) is a member;
- (b) is appointed to a committee;
- (c) is requested to attend a meeting of the Council or a committee;
- (d) is authorised by a delegation or further delegation under section 11 to perform a function on behalf of the Council; or
- (e) is otherwise a person engaged in the administration or enforcement of this Act,

is not personally liable for any act done or omitted to be done in good faith by the Council, a committee or that person when so acting or attending.

- (2) No proceedings, civil or criminal, shall be taken or lie against any person for any act, matter or thing done or omitted to be done, or required to be done or omitted to be done —
 - (a) by a person purportedly for the purposes of the administration of this Act; or
 - (b) in reliance on or pursuant to any order, direction, or requirement apparently given, issued or made in accordance with the provisions of this Act,

unless it was negligent, malicious or lacked reasonable and probable cause.

11. Annual report on reproductive technology

- (1) The report to be furnished by the Council to the CEO on the use of reproductive technology in the State and the operations of the Council in the preceding year ending 30 June shall be so furnished by such date as, in the opinion of the CEO, will enable the CEO to submit an annual report to the Minister not later than 30 September in each year.
- (2) The report to be furnished by the Council to the CEO, and the annual report to be submitted to the Minister, under subclause (1) —
 - (a) shall set out —
 - (i) any significant developments in the use of, or in the procedures or techniques used in, reproductive technology during the year, whether in the State or elsewhere;

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- (ii) details of research specifically approved by, or being conducted with the prior approval of, the Council during that year;
 - (iii) in statistical terms, the activities of persons licensed under this Act and carried on during that year; and
 - (iv) any discernible social trends that became apparent during that year and are, or may be, attributable to the use of reproductive technology;
- (b) shall contain particulars of —
- (i) any contravention of this Act, or of any terms, condition or direction relating to a licence or exemption; and
 - (ii) any other matter within the responsibilities of the Council or the CEO,
- that is, in the opinion of the Council or of the CEO, of significance to the public interest; and
- (c) shall, if that is practicable, be combined with any annual report that may be required to be submitted in relation to this Act under Part 5 of the *Financial Management Act 2006*.

[Clause 11 amended by No. 28 of 2006 s. 270; No. 77 of 2006 Sch. 1 cl. 88.]

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Notes

¹ This is a compilation of the *Human Reproductive Technology Act 1991* and includes the amendments made by the other written laws referred to in the following table ^{1a}. The table also contains information about any reprint.

Compilation table

Short title	Number and year	Assent	Commencement
<i>Human Reproductive Technology Act 1991</i>	22 of 1991	8 Oct 1991	s. 1 and 2: 8 Oct 1991; Pt. 1 Div. 1 other than s. 1 and 2, Pt. 2, Pt. 6 and Sch.: 6 Mar 1992 (see s. 2 and <i>Gazette</i> 6 Mar 1992 p. 1107); Pt. 1 Div. 2, Pt. 3-5: 8 Apr 1993 (see s. 2)
<i>Acts Amendment (Public Sector Management) Act 1994</i> s. 19	32 of 1994	29 Jun 1994	1 Oct 1994 (see s. 2 and <i>Gazette</i> 30 Sep 1994 p. 4948)
<i>Sentencing (Consequential Provisions) Act 1995</i> s. 147	78 of 1995	16 Jan 1996	4 Nov 1996 (see s. 2 and <i>Gazette</i> 25 Oct 1996 p. 5632)
<i>Human Reproductive Technology Amendment Act 1996</i>	1 of 1996	4 Apr 1996	s. 5: 8 Apr 1993 (see s. 2(2)); Act other than s. 5: 4 Apr 1996 (see s. 2(1))
<i>Statutes (Repeals and Minor Amendments) Act 1997</i> s. 75	57 of 1997	15 Dec 1997	15 Dec 1997 (see s. 2(1))
<i>Corporations (Consequential Amendments) Act 2001</i> Pt. 32	10 of 2001	28 Jun 2001	15 Jul 2001 (see s. 2 and <i>Gazette</i> 29 Jun 2001 p. 3257 and Cwlth <i>Gazette</i> 13 Jul 2001 No. S285)
<i>Acts Amendment (Lesbian and Gay Law Reform) Act 2002</i> Pt. 11	3 of 2002	17 Apr 2002	21 Sep 2002 (see s. 2 and <i>Gazette</i> 20 Sep 2002 p. 4693)
Reprint of the <i>Human Reproductive Technology Act 1991</i> as at 12 Jul 2002 (includes amendments listed above except those in the <i>Acts Amendment (Lesbian and Gay Law Reform) Act 2002</i>)			
<i>Human Reproductive Technology Amendment Act 2004</i>	17 of 2004	16 Jul 2004	s. 1 and 2: 16 Jul 2004; Act other than s. 1 and 2: 1 Dec 2004 (see s. 2 and <i>Gazette</i> 26 Nov 2004 p. 5309)

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Short title	Number and year	Assent	Commencement
<i>Acts Amendment (Prohibition of Human Cloning and Other Practices) Act 2004</i> s. 3-10	18 of 2004	16 Jul 2004	1 Dec 2004 (see s. 2 and <i>Gazette</i> 26 Nov 2004 p. 5309)
<i>Children and Community Services Act 2004</i> Sch. 2 cl. 14	34 of 2004	20 Oct 2004	1 Mar 2006 (see s. 2 and <i>Gazette</i> 14 Feb 2006 p. 695)
<i>State Administrative Tribunal (Conferral of Jurisdiction) Amendment and Repeal Act 2004</i> Pt. 2 Div. 65 ^{2,3}	55 of 2004	24 Nov 2004	1 Jan 2005 (see s. 2 and <i>Gazette</i> 31 Dec 2004 p. 7130)
<i>Criminal Procedure and Appeals (Consequential and Other Provisions) Act 2004</i> s. 80 and 82	84 of 2004	16 Dec 2004	2 May 2005 (see s. 2 and <i>Gazette</i> 31 Dec 2004 p. 7129 (correction in <i>Gazette</i> 7 Jan 2005 p. 53))
Reprint 2: The Human Reproductive Technology Act 1991 as at 11 Nov 2005 (includes amendments listed above except those in the <i>Children and Community Services Act 2004</i>)			
<i>Machinery of Government (Miscellaneous Amendments) Act 2006</i> Pt. 9 Div. 7 ⁴	28 of 2006	26 Jun 2006	1 Jul 2006 (see s. 2 and <i>Gazette</i> 27 Jun 2006 p. 2347)
<i>Financial Legislation Amendment and Repeal Act 2006</i> Sch. 1 cl. 88	77 of 2006	21 Dec 2006	1 Feb 2007 (see s. 2(1) and <i>Gazette</i> 19 Jan 2007 p. 137)
<i>Criminal Law and Evidence Amendment Act 2008</i> s. 63	2 of 2008	12 Mar 2008	27 Apr 2008 (see s. 2 and <i>Gazette</i> 24 Apr 2008 p. 1559)
<i>Medical Practitioners Act 2008</i> Sch. 3 cl. 28	22 of 2008	27 May 2008	1 Dec 2008 (see s. 2 and <i>Gazette</i> 25 Nov 2008 p. 4989)
<i>Surrogacy Act 2008</i> Pt. 4 Div. 5	47 of 2008	10 Dec 2008	1 Mar 2009 (see s. 2(b) and <i>Gazette</i> 27 Feb 2009 p. 512)
<i>Statutes (Repeals and Miscellaneous Amendments) Act 2009</i> s. 76	8 of 2009	21 May 2009	22 May 2009 (see s. 2(b))
Reprint 3: The Human Reproductive Technology Act 1991 as at 17 Jul 2009 (includes amendments listed above)			
<i>Acts Amendment (Bankruptcy) Act 2009</i> s. 44	18 of 2009	16 Sep 2009	17 Sep 2009 (see s. 2(b))

Short title	Number and year	Assent	Commencement
<i>Standardisation of Formatting Act 2010</i> s. 4 and 51	19 of 2010	28 Jun 2010	11 Sep 2010 (see s. 2(b) and <i>Gazette</i> 10 Sep 2010 p. 4341)

^{1a} On the date as at which this compilation was prepared, provisions referred to in the following table had not come into operation and were therefore not included in this compilation. For the text of the provisions see the endnotes referred to in the table.

Provisions that have not come into operation

Short title	Number and year	Assent	Commencement
<i>Health Practitioner Regulation National Law (WA) Act 2010</i> Pt. 5 Div. 27 ⁵	35 of 2010	30 Aug 2010	18 Oct 2010 (see s. 2(b) and <i>Gazette</i> 1 Oct 2010 p. 5075-6)
<i>Public Sector Reform Act 2010</i> s. 89 ⁶	39 of 2010	1 Oct 2010	To be proclaimed (see s. 2(b))

² The *State Administrative Tribunal (Conferral of Jurisdiction) Amendment and Repeal Act 2004* Pt. 5, the *State Administrative Tribunal Act 2004* s. 167 and 169, and the *State Administrative Tribunal Regulations 2004* r. 28 and 42 deal with certain transitional issues some of which may be relevant for this Act.

³ The amendments to s. 29(3) in the *State Administrative Tribunal (Conferral of Jurisdiction) Amendment and Repeal Act 2004* s. 525(1)(c) are not included because it was unclear where it was intended to be made. Section 525(1)(c) reads as follows:

- (c) by deleting “it” after “as and after “provided”” and inserting instead —
“ he or she ”.

⁴ The *Machinery of Government (Miscellaneous Amendments) Act 2006* Pt. 9 Div. 13 reads as follows:

Division 13 — Transitional provisions

289. Commissioner of Health

- (1) A thing done or omitted to be done by, to or in relation to, the Commissioner of Health before commencement under, or for the purposes of, an enactment has the same effect after commencement, to the extent that it has any force or significance after commencement, as if it had been done or omitted by, to or in relation to, the CEO.
- (2) In this section —
CEO has the meaning given by section 3 of the *Health Legislation Administration Act 1984* as in force after commencement;
commencement means the time at which this Division comes into operation;
Commissioner of Health means the Commissioner of Health referred to in section 6(1)(a) of the *Health Legislation Administration Act 1984* as in force before commencement.

⁵ On the date as at which this compilation was prepared, the *Health Practitioner Regulation National Law (WA) Act 2010* Pt. 5 Div. 27 had not come into operation. It reads as follows:

Division 27 — Human Reproductive Technology Act 1991 amended

94. Act amended

This Division amends the *Human Reproductive Technology Act 1991*.

95. Section 3 amended

In section 3(1) delete the definition of *medical practitioner* and insert:

medical practitioner means a person registered under the *Health Practitioner Regulation National Law (Western Australia)* in the medical profession;

⁵ On the date as at which this compilation was prepared, the *Public Sector Reform Act 2010* s. 89 had not come into operation. It reads as follows:

89. Various references to “Minister for Public Sector Management” amended

- (1) This section amends the Acts listed in the Table.
- (2) In the provisions listed in the Table delete “Minister for Public Sector Management” and insert:

Public Sector Commissioner

Table

<i>Human Reproductive Technology Act 1991</i>	Sch. cl. 4(1)
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Defined Terms

Defined Terms

*[This is a list of terms defined and the provisions where they are defined.
The list is not part of the law.]*

Defined Term	Provision(s)
AHEC.....	53T(1)
animal.....	53B(1)
approved counselling	49(2f)
artificial fertilisation procedure.....	3(1)
artificial insemination procedure.....	3(1)
authorised officer	3(1)
biological parent.....	3(1)
CEO	3(1)
Chairperson	3(1)
chimeric embryo	53B(1)
Code.....	3(1)
Code of Practice	3(1)
commencement day	49(2e)(a)
committee.....	3(1)
Commonwealth authority.....	53ZK(3)
Commonwealth Human Embryo Act.....	3(1)
Commonwealth Human Embryo regulations	53T(1)
condition	3(1)
confer	53T(1)
confidential commercial information.....	53T(1)
corresponding law	53T(1)
Council.....	3(1)
counselling services	3(1)
court	53ZK(3)
decision	53ZL
Deputy Chairperson	3(1)
diagnostic investigation.....	53W(4)
directions.....	3(1)
director	3(1)
disclose.....	53T(1)
effective consent	3(1)
eligible person.....	24(2), 53ZL
engage in conduct	53X(2)
excess ART embryo.....	3(1), 53T(1)
Executive Officer	3(1)
exempt use	53W(2)
exemption.....	3(1)
fertilisation	3(1)
guidelines	3(1)

Defined Terms

HREC.....	53T(1)
human cell.....	53L(2)
human egg.....	3(1)
human embryo.....	3(1), 3A(1)
human embryo clone.....	53B(1)
human gamete.....	3(1)
human sperm.....	3(1)
hybrid embryo.....	53B(1)
in vitro fertilisation procedure.....	3(1)
information.....	5(9)
inspector.....	53T(1)
Institutional Ethics Committee.....	3(1)
licence.....	3(1), 53T(1)
licence supervisor.....	3(1)
licensed ART centre.....	53T(1)
licensee.....	3(1)
medical practitioner.....	3(1)
member.....	3(1)
misbehaviour.....	Sch. cl. 5(2)
NHMRC.....	3(1)
NHMRC licence.....	3(1)
NHMRC Licensing Committee.....	53T(1)
nominated member.....	3(1)
observation.....	53W(4)
parliamentary purposes.....	5(9)
participant.....	3(1)
person to whom the licence applies.....	3(1)
practice.....	3(3)(a)
precursor cell.....	53B(1)
premises.....	3(1)
procedure.....	3(1)
prohibited embryo.....	53P(5)
project of research.....	3(1)
proper consent.....	53T(1)
proprietary company.....	3(1)
prosecution notice.....	57(2)
Public Health Official.....	3(1)
reasonable expenses.....	53Q(4)
record.....	3(1), 5(9)
related body corporate.....	3(1)
reproductive technology.....	3(1)
reproductive technology practice.....	3(3)(a)
research.....	3(1)
responsible person.....	53T(1)
Rules.....	3(1)

Defined Terms

specified	57(2)
State	53T(1)
State agency	53ZK(3)
storage	3(4)
storage procedure	3(1)
store.....	3(4)
stored.....	3(4)(b)
subsidiary legislation	3(1)
summary conviction penalty	3(1)
therapeutic use	53S(4)
this Act.....	3(1)
treatment	3(1)
valuable consideration.....	53Q(4)
woman.....	3(1)