



REPRODUCTIVE TECHNOLOGY ACT, 1988

No. 10 of 1988

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ELIZABETHAE II REGINAE

A.D. 1988

No. 10 of 1988

An Act to regulate the use of reproductive technology and research involving experimentation with human reproductive material.

[Assented to 10 March 1988]

The Parliament of South Australia enacts as follows:

**PART I
PRELIMINARY**

- Short title.** 1. This Act may be cited as the "Reproductive Technology Act, 1988".
- Commencement.** 2. (1) This Act will come into operation on a day to be fixed by proclamation.
 (2) The Governor may, in a proclamation fixing a day for this Act to come into operation, suspend the operation of specified provisions of this Act until a subsequent day fixed in the proclamation, or a day to be fixed by subsequent proclamation.
- Interpretation.** 3. In this Act unless the contrary intention appears—
 - "artificial fertilization procedure" means any medical procedure directed at fertilization of a human ovum by artificial means and includes an in vitro fertilization procedure:
 - "artificial insemination" means an artificial fertilization procedure (not being an in vitro fertilization procedure or a surgical procedure) under which human sperm are introduced, by artificial means, into the human female reproductive system:
 - "authorized person" means a person authorized by the Commission to exercise the powers of an authorized person under this Act:
 - "the code of ethical practice" means the code of ethical practice formulated by the Council under Part II:
 - "the Commission" means the South Australian Health Commission:
 - "human reproductive material" means—
 - (a) a human embryo;

- (b) human semen;
- (c) a human ovum:

“in vitro fertilization procedure” means any of the following procedures—

- (a) the removal of a human ovum for the purpose of fertilization within or outside the body;
- (b) the storage of any such ovum prior to fertilization;
- (c) the fertilization by artificial means of any such ovum within or outside the body;
- (d) the culture or storage of a fertilized ovum outside the body;
- (e) the transference of a fertilized or unfertilized ovum into the human body:

“reproductive technology” means the branch of medical science concerned with artificial fertilization.

4. This Act binds the Crown.

Act binds Crown.

PART II

THE SOUTH AUSTRALIAN COUNCIL ON REPRODUCTIVE TECHNOLOGY

DIVISION I—THE COUNCIL

5. (1) The *South Australian Council on Reproductive Technology* is established. Establishment of the Council.

(2) The Council consists of 11 members appointed by the Governor and of these—

- (a) one will be nominated by the Council of the University of Adelaide;
 - (b) one will be nominated by the Council of the Flinders University of South Australia;
 - (c) one will be nominated by the Royal Australian College of Obstetricians and Gynaecologists;
 - (d) one will be nominated by the Royal Australian College of General Practitioners;
 - (e) one will be nominated by the Heads of Churches in South Australia;
 - (f) one will be nominated by the Law Society of South Australia;
- and
- (g) five will be nominated by the Minister.

(3) When nominating a person for membership of the Council a person or body referred to in subsection (2) must recognise that the Council should, as far as practicable, be constituted of equal numbers of men and women.

(4) In selecting nominees for appointment to the Council the Minister will endeavour to ensure—

- (a) that the Council has available to it from its own membership expertise in the various facets of reproductive technology;

(b) that other relevant disciplines and backgrounds are adequately reflected in the Council's membership;

(c) that the Council's membership is sufficiently representative of the general community.

and

(d) that, as far as practicable, the Council is constituted of an equal number of men and women.

(5) The Governor may, on the nomination of the body or person by whom a member was nominated, appoint a deputy to that member and the deputy may, in the absence of that member, act as a member of the Council.

(6) The Council will elect (for a term fixed by the Council) one of its members to preside at meetings of the Council.

Terms of
appointment.

6. (1) A member of the Council will be appointed for a term not exceeding three years and will, on the expiration of a term of appointment, be eligible for reappointment.

(2) The Governor may remove a member of the Council for—

(a) misconduct;

(b) neglect of duty;

(c) incompetence;

or

(d) mental or physical incapacity to carry out official duties satisfactorily.

(3) The office of a member of the Council becomes vacant if the member—

(a) dies;

(b) completes a term of office and is not reappointed;

(c) resigns by written notice to the Minister;

or

(d) is removed from office under subsection (2).

(4) When the office of a member becomes vacant, a person must be appointed in accordance with this Act to the vacant office.

Allowances and
expenses.

7. A member of the Council will be entitled to such fees, allowances and expenses as the Governor may determine.

Procedure at
meetings.

8. (1) A meeting of the Council will be chaired by the member elected to preside or in the absence of that member by a member chosen by the members present from amongst their own number.

(2) Subject to subsection (3), the Council may act notwithstanding vacancies in its membership.

(3) Six members constitute a quorum of the Council.

(4) Each member present at a meeting of the Council is entitled to one vote on a matter arising for decision at the meeting and, in the event of an equality of votes, the member chairing the meeting will be entitled to a second or casting vote.

(5) Subject to this Act, the proceedings of the Council may be conducted as it thinks fit.

9. (1) A member of the Council who has a direct or indirect personal or pecuniary interest in any matter before the Council must disclose the nature of the interest to the Council before, or as soon as practicable after, the matter arises for consideration.

Disclosure of interest.

Penalty: \$2 000.

(2) A disclosure under this section must be recorded in the minutes of the Council.

(3) If a matter arising before the Council (other than a question of general principle) affects a member's personal or pecuniary interests directly or indirectly, the member must abstain from voting on that matter.

Penalty: \$2 000.

DIVISION II—THE COUNCIL'S FUNCTIONS

10. (1) The functions of the Council are as follows:

Functions of the Council.

(a) to formulate, and keep under review, a code of ethical practice to govern—

(i) the use of artificial fertilization procedures;

and

(ii) research involving experimentation with human reproductive material;

(b) (i) to advise the Commission on the conditions to be included in licences authorizing artificial fertilization procedures;

(ii) to formulate appropriate conditions for licences authorizing research involving experimentation with human reproductive material;

(c) to carry out research into the social consequences of reproductive technology;

(d) to promote research into the causes of human infertility (and, in doing so, to attempt to ensure that adequate attention is given to research into the causes of both female and male infertility);

(e) to advise the Minister on any questions arising out of, or in relation to, reproductive technology;

(f) to promote (by the dissemination of information and in other ways) informed public debate on the ethical and social issues that arise from reproductive technology;

(g) to collaborate with other bodies carrying out similar functions in Australia.

(2) The welfare of any child to be born in consequence of an artificial fertilization procedure must be treated as of paramount importance, and accepted as a fundamental principle, in the formulation of the code of ethical practice.

(3) The code of ethical practice must contain provisions to the following effect—

- (a) the practice known as embryo flushing must be prohibited;
- (b) any persons on whose behalf a human embryo is stored outside the human body must have the right to decide how the embryo is to be dealt with or disposed of and a person who has made such a decision must have (while the embryo remains in storage) the right to review the decision at intervals of no more than 12 months;
- (c) a human embryo must not be maintained outside the human body for a period exceeding 10 years;
- (d) the culture of a human embryo outside the human body must be prohibited beyond the stage of development at which implantation would normally occur.

(4) For the purpose of formulating the code of ethical practice, the Council may adopt (with or without modification) codes or standards of practice adopted elsewhere.

(5) The code of ethical practice (and any amendments to it) will be promulgated in the form of regulations.

Officers and employees.

11. (1) The Council may, with the Minister's approval, employ such staff as it needs for the purposes of this Act.

(2) The Council's staff are not members of the Public Service.

(3) The Council may, with the approval of the Chairman of the Commission, on terms and conditions mutually arranged, make use of the services of any of the Commission's staff.

Annual report.

12. (1) The Council must, by 31 March in each year, present a report to the Minister on—

- (a) the use of reproductive technology in the State during the previous year;
- (b) any significant developments in the techniques of reproductive technology over that period;
- (c) any discernible social trends that became apparent over that period attributable to the use of reproductive technology;
- (d) any other matters of importance within the sphere of the Council's responsibilities.

(2) The Minister must, within six sitting days after receipt of a report under this section, cause copies of the report to be laid before both Houses of Parliament.

PART III

LICENSING

DIVISION I—REQUIREMENT FOR LICENCE

Licence required for artificial fertilization procedures.

13. (1) Subject to subsection (7), a person must not carry out an artificial fertilization procedure except in pursuance of a licence granted by the Commission.

Penalty: \$10 000.

(2) The Commission must not grant a licence unless it is satisfied—

(a) that the licence is necessary to fulfil a genuine and substantial social need that cannot be adequately met by existing licensees;

and

(b) that—

(i) the applicant is a fit and proper person to hold the licence;

and

(ii) the applicant has appropriate staff and facilities for carrying out the artificial fertilization procedures for which the licence is sought.

(3) A licence will be subject to—

(a) a condition defining the kinds of artificial fertilization procedures authorized by the licence;

(b) a condition preventing the application of artificial fertilization procedures except for the benefit of married couples in the following circumstances—

(i) the husband or wife (or both) appear to be infertile;

or

(ii) there appears to be a risk that a genetic defect would be transmitted to a child conceived naturally;

(c) a condition requiring the licensee to ensure that the code of ethical practice is observed;

(d) a condition requiring the licensee to keep specified records in relation to—

(i) artificial fertilization procedures conducted in pursuance of the licence;

and

(ii) the source of human reproductive material used in the procedures;

(e) such other conditions as the Commission may, on the advice of the Council determine.

(4) In subsection (3)—

“married couple” includes two people who are not married but who are cohabiting as husband and wife and who—

(a) have cohabited continuously as husband and wife for the immediately preceding five years;

or

(b) have, during the immediately preceding six years, cohabited as husband and wife, for periods aggregating at least five years.

(5) Licence conditions—

(a) (i) if determined at the time of grant of the licence—will be included in the licence itself;

(ii) if determined subsequently—will be imposed by notice in writing given personally or by post to the licensee;

and

(b) may be varied or revoked by notice in writing given personally or by post to the licensee.

(6) If contravention of, or non-compliance with, a condition of a licence occurs, the licensee is guilty of an offence.

Penalty: \$10 000.

(7) A licence is not required under this section in respect of artificial insemination if—

(a) it is carried out by a registered medical practitioner who—

(i) has submitted his or her name for registration by the Commission under this section;

and

(ii) has made an undertaking to the Commission to observe the code of ethical practice;

or

(b) it is carried out gratuitously,

(but this exemption does not extend to any person from whom it has been withdrawn under subsection (8)).

(8) If the Commission suspects on reasonable grounds a breach of the code of ethical practice by a person who is exempt from the requirement to hold a licence by virtue of subsection (7), it may, by notice in writing, withdraw the exemption from that person.

Licence required
for medical
research involving
human
reproductive
material.

14. (1) A person must not carry out research involving experimentation with human reproductive material except in pursuance of a licence granted by the Council.

Penalty: \$10 000.

(2) A licence will be subject to—

(a) a condition defining the kinds of research authorized by the licence;

(b) a condition prohibiting research that may be detrimental to an embryo;

(c) a condition requiring the licensee to ensure observance of the code of ethical practice formulated by the Council in relation to such research;

and

(d) such other conditions as the Council may determine.

(3) Licence conditions—

(a) (i) if determined at the time of grant of the licence—will be included in the licence itself;

(ii) if determined subsequently—will be imposed by notice in writing given personally or by post to the licensee;

and

(b) may be varied or revoked by notice in writing given personally or by post to the licensee.

(4) If contravention of, or non-compliance with, a condition of a licence occurs, the licensee is guilty of an offence.

Penalty: \$10 000.

DIVISION II—SUSPENSION OR CANCELLATION OF LICENCE

15. (1) The Council or the Commission may, if satisfied that contravention of, or non-compliance with, a condition of a licence granted by it has occurred, suspend or cancel the licence. Suspension or cancellation of licence.

(2) Before the Council or the Commission acts under this section it must allow the licensee a reasonable opportunity to make submissions to it in relation to the proposed action.

DIVISION III—APPEAL

16. (1) An appeal lies to the Supreme Court against—

Appeals.

- (a) a refusal by the Commission to grant a licence authorizing artificial fertilization procedures;
- (b) a decision by the Commission to impose a particular licence condition;
- (c) a decision by the Commission to suspend or cancel a licence;
- (d) a decision by the Commission to withdraw an exemption permitting artificial insemination without a licence.

(2) Subject to any contrary order of the Supreme Court, an appeal cannot be commenced after one month from the day on which the appellant receives notice of the decision against which the appeal lies.

(3) On an appeal, the Supreme Court may—

- (a) annul, vary or reverse the decision subject to the appeal;
- and
- (b) make any consequential or ancillary orders.

(4) No appeal lies against a decision by the Council to refuse to grant a licence authorizing research involving experimentation with human reproductive material or against any decision of the Council related to such a licence.

PART IV

MISCELLANEOUS

17. (1) An authorized person may at any reasonable time—

Powers of authorized person.

- (a) enter and inspect any premises—
 - (i) on which artificial fertilization procedures are carried out;
 - or
 - (ii) on which research involving experimentation with human reproductive material is carried out;
- (b) inspect any equipment on the premises;

- (c) put questions to any person on the premises;
- (d) require any person who is apparently in a position to do so, to produce records—
 - (i) relating to artificial fertilization procedures;
 - or
 - (ii) relating to research involving experimentation with human reproductive material;
- and
- (e) examine those records and take extracts from, or make copies of, any of them.

(2) A person who—

- (a) obstructs an authorized person acting in the exercise of a power conferred by this section;
- (b) fails to answer an authorized person's questions to the best of his or her information and belief;
- or
- (c) being in a position to produce records fails to do so when required by an authorized person,

is guilty of an offence.

Penalty: \$2 000.

(3) Confidential information may be disclosed to an authorized person under this section without breach of any principle of professional ethics.

Confidentiality.

18. (1) A person must not disclose the identity of a donor of human reproductive material except—

- (a) in the administration of this Act;
- (b) in order to carry out an artificial fertilization procedure;
- or
- (c) with the consent (given in the prescribed manner) of the donor of the material.

Penalty: \$5 000 or imprisonment for six months.

(2) A person must not divulge any other confidential information obtained (whether by that person or some other person) in the administration of this Act or for the purpose, or in the course, of carrying out an artificial fertilization procedure or research except—

- (a) in the administration of this Act or in order to carry out that procedure or research;
- or
- (b) as may be permitted or required by the code of ethical practice.

Penalty: \$5 000 or imprisonment for six months.

Summary offences.

19. An offence against this Act is a summary offence.

Regulations.

20. (1) The Governor may make such regulations as are contemplated by this Act or as are necessary or expedient for the purposes of this Act.

(2) Without limiting the generality of subsection (1), those regulations may—

- (a) prescribe forms of consent for the purposes of this Act;
- (b) require licensees to furnish periodic returns of information;
- (c) impose penalties (not exceeding \$2 000) for breach of, or non-compliance with, a regulation.

(3) A regulation may incorporate, or operate by reference to, any code or standard (as in force at the date of the regulation, or as in force from time to time) prepared or approved by a body or authority referred to in the regulation.

(4) Regulations under this Act (including a regulation promulgating the code of ethical practice or any amendments to it) will take effect as follows—

- (a) if the regulation has lain before both Houses of Parliament for 14 sitting days and a notice of disallowance has not been given in either House during that period the regulation will take effect at the expiration of that period;
- (b) if notice of disallowance has been given in either House during that period but the regulation has not been disallowed, the regulation will take effect when the motion for disallowance is defeated or lapses or, if such a notice has been given in both Houses, when both motions have been defeated or have lapsed or one motion has been defeated and the other motion has lapsed.

SCHEDULE

Transitional Provision

(1) On the commencement of this Act a licence to carry out in vitro fertilization procedures must be granted—

(a) to the University of Adelaide and the Queen Elizabeth Hospital in relation to the in vitro fertilization programme conducted at the Queen Elizabeth Hospital;

(b) to the Flinders University of South Australia and the Flinders Medical Centre in relation to the in vitro fertilization programme conducted at the Flinders Medical Centre;

(c) to Repromed Pty. Ltd. in relation to the in vitro fertilization programme conducted at the Wakefield Memorial Hospital.

(2) The Commission may, at the time of granting a licence under this clause or subsequently, impose licence conditions.

(3) A condition may be imposed under subclause (2) by giving the licensee written notice of the condition.

In the name and on behalf of Her Majesty, I hereby assent to this Bill.

D. B. DUNSTAN, Governor