

South Australia

Reproductive Technology (Code of Ethical Research Practice) Regulations 1995

under the *Reproductive Technology Act 1988*

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Legislative history

1—Short title

These regulations may be cited as the *Reproductive Technology (Code of Ethical Research Practice) Regulations 1995*.

2—Commencement

These regulations will come into operation in accordance with section 20(4) of the *Reproductive Technology Act 1988*.

3—Code of ethical (research) practice

For the purposes of section 14(2)(c) of the *Reproductive Technology Act 1988*, the code of ethical practice set out in the Schedule is prescribed.

Schedule—Reproductive Technology Code of Ethical Research Practice

Part 1—Preliminary

1—Short title

This code may be cited as the *Reproductive Technology Code of Ethical Research Practice 1995*.

2—Interpretation

In this code, unless the contrary intention appears—

the Act means the *Reproductive Technology Act 1988*;

cloning means any procedure directed at producing two or more genetically identical embryos from the division of one embryo;

the Council means the South Australian Council on Reproductive Technology established by Part 2 of the Act;

counsellor means a social worker, nurse or clinical psychologist who—

- (a) has professional knowledge in the fields of human fertility and infertility and reproductive technology; or
- (b) has had experience working in a reproductive medicine unit where infertility treatment is given pursuant to a licence or exemption under this Act or pursuant to an authority granted under a law of another State, or a Territory, of the Commonwealth;

embryo means a human embryo;

embryo flushing means a surgical procedure by which an ovum in the process of fertilisation, or an embryo, is flushed from the body of a woman before it has implanted in her uterus;

Fertility Society Code of Practice means the *Code of Practice for Units Using In Vitro Fertilisation and Related Reproductive Technologies* prepared by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia, as in force from time to time;

Fertility Society donor screening guidelines means the guidelines for the screening of donors of reproductive material contained in the Fertility Society Code of Practice;

identifying information, in relation to a person, means the person's name or address;

infertility treatment means treatment for human infertility involving the application of an artificial fertilisation procedure;

licensee means a person who holds a licence under section 14(1) of the Act;

medical practitioner means—

- (a) a person who is registered on the general register under the *Medical Practitioners Act 1983*; or
- (b) a person registered as a medical practitioner under the law of another State, or a Territory, of the Commonwealth;

nurse means a person registered under the *Nurses Act 1984*;

ovum means a human ovum;

psychologist means—

- (a) a person registered as a psychologist under the *Psychological Practices Act 1973*; or
- (b) a person registered as a psychologist under the law of another State, or a Territory, of the Commonwealth;

reproductive material means human reproductive material;

reproductive medicine unit means a hospital, clinic or other premises, or any particular part of such a place, at which infertility treatment is given;

social worker means a person who holds a tertiary qualification in social work;

sperm means human sperm;

storage, in relation to reproductive material, means storage outside the human body;

treatment includes—

- (a) all medical or surgical advice, attendances, procedures, operations and other services carried out by a medical practitioner in the course of medical or surgical practice; and
- (b) the prescription or supply of drugs.

Part 2—Prohibited practices

3—Prohibition on embryo flushing

A licensee must not carry out, or cause, suffer or permit to be carried out, the procedure of embryo flushing.

4—Prohibition on culturing or maintaining embryo outside body

A licensee must not—

- (a) continue, or cause, suffer or permit to be continued, the culture of an embryo outside the human body after the embryo has reached a developmental age of 14 days after fertilisation; or
- (b) maintain an embryo, or cause, suffer or permit an embryo to be maintained, outside the human body for more than 10 years after fertilisation.

5—Prohibition on research on embryos more than 14 days old

A licensee must not, in any research, use or cause, suffer or permit to be used, an embryo of a developmental age of more than 14 days after fertilisation.

6—Prohibition on cloning

A licensee must not carry out, or cause, suffer or permit to be carried out, the procedure of cloning.

7—Prohibition on placing part of an embryo in human body

A licensee must not place any cells extracted from an embryo into the body of any person or cause, suffer or permit such cells to be so placed.

8—Prohibition on altering genetic structure of reproductive material

A licensee must not alter, or cause, suffer or permit to be altered, the genetic structure of a cell while the cell forms part of an embryo or an ovum in the process of fertilisation.

9—Prohibition on replacing nucleus of embryo cells

A licensee must not replace, or cause, suffer or permit the replacement of, the nucleus of a cell of an embryo, or of an ovum in the process of fertilisation, with any other nucleus.

10—Prohibition on placing reproductive material in animals

A licensee must not place reproductive material, or cause, suffer or permit reproductive material to be placed, in the body of an animal.

11—Prohibition on mixing of reproductive material from different sources

A licensee must not, in any research, do, or cause, suffer or permit to be done, any of the following things:

- (a) the mixing of ova with sperm produced by more than one man; or
- (b) the mixing of sperm with ova produced by more than one woman; or
- (c) the mixing of embryos other than those resulting from fertilisation of ova produced by the one woman by sperm produced by the one man.

12—Prohibition on mixing of human and animal reproductive material

A licensee must not, in any research, mix, or cause, suffer or permit the mixing of, human reproductive material with animal reproductive material.

13—Prohibition on giving value for gamete donation

- (1) A licensee must not give or offer valuable consideration, or cause, suffer or permit valuable consideration to be given or offered, to any person for donation of reproductive material of that person or of any other person.
- (2) In subclause (1)—

valuable consideration includes a discount or priority in the provision of a service but does not include the disbursement of any reasonable expense incurred by a person in connection with a donation of his or her reproductive material.

Part 3—Eligibility for gamete donation

14—Eligibility for donation of reproductive material

- (1) A licensee must not accept the donation of reproductive material from any person unless—
 - (a) the prospective donor has been screened in accordance with the Fertility Society donor screening guidelines; and
 - (b) the prospective donor has signed a lifestyle declaration in the form set out in the Fertility Society Code of Practice and furnished it to the licensee; and
 - (c) the prospective donor has received adequate information from a medical practitioner or counsellor regarding the law of this State relating to the parentage of children born in consequence of the use of donor reproductive material; and

- (d) the prospective donor has been informed by a medical practitioner or counsellor that if it comes to the knowledge of the licensee that a child born in consequence of the use of the donor's reproductive material has been diagnosed as suffering from a hereditary illness or disease, the licensee will give the donor a written notice setting out the matters referred to in clause 44(2)(a) to (c) of the *Reproductive Technology Code of Ethical Clinical Practice 1995* and advising of the availability of counselling.
- (2) A licensee must provide a prospective donor of reproductive material who signs a lifestyle declaration with a copy of the declaration.

Part 4—Consent

Division 1—Consent to collection of donor ova

15—Consent to collection of donor ova

A licensee must not enter into any arrangement with a woman for the donation of her ova unless she has consented in accordance with this Part to the carrying out of any medical or surgical procedure (including the use of drugs) that will be associated with the removal of the ova from her body.

Division 2—Consent to use of reproductive material

16—Consent to use of gametes and embryos

A licensee must not use reproductive material, or cause, suffer or permit reproductive material to be used, for any purpose unless the person or persons who produced the material has or have consented in accordance with this Part to the use of the material for that purpose.

Division 3—Consent to disclosure of confidential information

17—Consent to disclosure of confidential information

For the purposes of section 18(1)(c) of the Act and clause 26 of this code, the provisions of clause 18 apply in relation to the giving of consent by a person to the disclosure of information concerning himself or herself.

Division 4—General provisions

18—Form of consent etc

- (1) For the purposes of this code, a consent—
 - (a) must be given in writing in a manner and form that complies with the *Reproductive Technology (Consent Forms) Standard 1995* prepared by the Council, as in force from time to time; and
 - (b) will not be regarded as effective unless the person giving consent has, before signing the consent form, received an information statement that complies with the *Reproductive Technology (Information Statements) Standard 1995* prepared by the Council, as in force from time to time; and

- (c) may be given subject to conditions; and
 - (d) may be varied at any time by the signatories by notice in writing given to the licensee; and
 - (e) may be revoked at any time by a signatory by notice in writing given to the licensee.
- (2) A licensee must not, without lawful excuse, contravene or fail to comply with any condition of a consent given under this Part.

19—Licensee to provide copy of consent form

A licensee must provide a person who gives consent under this Part with a copy of any consent form signed by the person.

20—Licensee to dispose of stored donor gametes and embryos in certain cases

A licensee must dispose of reproductive material kept in storage if consent to the storage or use of the material is revoked by the donor in accordance with this Part.

21—Effect of this Part on other laws

The provisions of this Part are in addition to the requirements of any other laws relating to obtaining informed consent to the carrying out of medical or surgical procedures.

Part 5—Records

Division 1—Records relating to donors of reproductive material

22—Record to be kept

- (1) A licensee who accepts the donation of reproductive material must establish a record in relation to the donor.
- (2) The record must contain the following information:
 - (a) the date of birth, country of birth, racial origin, nationality, religion, educational history, occupation, marital status, number of children and leisure interests of the donor;
 - (b) the donor's sex, height, weight, eye colour, hair colour and skin colour;
 - (c) full particulars of the medical history of the donor and of his or her parents;
 - (d) such particulars as the donor provides of any known hereditary illness or disease of the donor's grandparents, great grandparents, brothers, sisters and children;
 - (e) the donor's assessment of his or her personality;
 - (f) the reasons given by the donor for donating reproductive material;
 - (g) full particulars of any payment to the donor for the disbursement of expenses incurred by the donor in connection with his or her donation of reproductive material;
 - (h) full particulars of any consent given by the donor under Part 4;

- (i) in relation to the reproductive material—
 - (i) the date on which it was collected;
 - (ii) the time and place at which it was collected;
 - (iii) in the case of the donation of ova, the name of the person or persons who performed any procedures associated with the collection of the ova;
 - (j) such other information as the donor requests to be included in the record.
- (3) A licensee must ensure that identifying information relating to a donor of reproductive material is kept separate from all other information concerning the donor.

23—Access to record

- (1) A licensee must, on application in writing by a donor of reproductive material in relation to whom a record is kept by the licensee under this Division, provide the donor with a copy of the record.
- (2) Subject to subclause (3), a licensee must, on application by a person of or over the age of 16 years who was born in consequence of the use of donor reproductive material, give to the person a copy of all information (other than identifying information) relating to the donor or donors kept by the licensee under this code.
- (3) Where the licensee has reason to believe that, if all or some of that information were disclosed to the applicant, there may, in the circumstances of the particular case, be a reasonable likelihood of the donor's identity thereby being readily ascertainable, the licensee must not disclose that information.

Division 2—Other records

24—Records to be kept relating to reproductive material

A licensee must establish and maintain detailed records relating to the collection, storage, use and disposal of reproductive material by the licensee.

Division 3—General provisions

25—Confidentiality

- (1) A licensee must ensure that such steps are taken as are necessary to ensure that any confidential information kept by the licensee under this code is disclosed only as is authorised or required by the Act and this code.
- (2) Where a licensee has reasonable grounds for suspecting that confidential information kept by the licensee under this code has been disclosed in contravention of the Act or this code, the licensee must as soon as practicable—
 - (a) cause an investigation of the matter to be carried out; and
 - (b) cause a written report of the results of the investigation to be prepared and submitted to the Council.

- (3) If, in the course or in consequence of the investigation, the licensee is satisfied that there are reasonable grounds to suspect that a person has committed an offence against the Act, the licensee must immediately report the matter to the Commissioner of Police.

26—Access to personal information

- (1) Subject to subclause (2), where—
- (a) application is made to a licensee for access to information concerning the personal affairs of a person in relation to whom the licensee keeps a record under this code; and
 - (b) the person to whom the information relates has given his or her consent in accordance with Part 4 to disclosure of the information,
- the licensee must give the applicant a copy of that information.
- (2) A licensee must not disclose the identity of a donor of reproductive material to a person who was born in consequence of the use of the donor's reproductive material unless the person is of or over the age of 16 years.

27—Documents to be preserved

A licensee must preserve a copy of the following documents for at least 50 years from the date on which they were received by the licensee:

- (a) any document furnished to the licensee under Part 3; and
- (b) any consent given to the licensee under Part 4.

28—Period for which records must be preserved

A licensee must preserve a record kept by the licensee under this Part for 50 years from the date on which the last entry was made in the record.

29—Maintenance of records

A licensee must take reasonable steps to ensure that all records kept by the licensee under this code are at all times complete and accurate.

30—Amendment of personal records

A licensee must, on application by a donor of reproductive material in relation to whom the licensee keeps a record under this code, make such amendments to the record as are requested by the applicant unless the licensee has reason to believe that the requested amendments would result in the record being incomplete, inaccurate or misleading.

Part 6—Miscellaneous

31—Availability of Act and regulations for inspection

A licensee must ensure that a copy of the Act, any regulations made under the Act (including this code) and any standard or code of practice adopted by or referred to in such regulations are kept available for inspection by any interested person.

32—Annual report to Council

A licensee must, not later than 28 February in each year, furnish the Council with a report that contains the following information:

- (a) in relation to donations of reproductive material made during the previous calendar year—
 - (i) the total number of donors of reproductive material;
 - (ii) the number of persons who donated reproductive material for the first time;
 - (iii) the number of sperm donors;
 - (iv) the number of ova donors;
 - (v) the number of married couples who donated embryos;
 - (vi) the number of embryos donated for use in research;
- (b) in relation to embryos kept in storage by the licensee in the previous calendar year—
 - (i) the number of embryos frozen;
 - (ii) the number of embryos thawed;
 - (iii) the number of embryos used by the licensee in research;
 - (iv) the number of embryos transferred to another licensee;
 - (v) the number of embryos transferred out of the State;
 - (vi) the number of embryos disposed of by the licensee;
 - (vii) the number of embryos in storage at the end of the year;
- (c) such other information as the Council may require by notice in writing given to the licensee.

Legislative history

Notes

- For further information relating to the Act and subordinate legislation made under the Act see the Index of South Australian Statutes.

Revocation of regulations

The *Reproductive Technology (Code of Ethical Research Practice) Regulations 1995* were revoked by r 3 of the *Reproductive Technology (Clinical Practices) (Code of Ethical Research Practice) Revocation Regulations 2003* on 2.4.2004.

Principal regulations

Year	No	Reference	Commencement
1995	188	<i>Gazette 5.10.1995 p908</i>	11.7.1996: r 2